NEW
PHARMACY (P) PRODUCT

Lovima®

Pharmacist training guide

Daily Contraception for women

and pharmacy supply of Lovima® 75 microgram film-coated tablets (**desogestrel**)

Introduction

Overall aim of this training guide

To support you in conducting effective, patient-specific, clinical consultations on contraception, and enable you to appropriately supply Lovima® 75 microgram film-coated tablets (desogestrel) now available without prescription from pharmacies to women who are eligible.

Lovima 75 microgram film-coated tablets

Lovima 75 microgram film-coated tablets (desogestrel) are a daily oral contraceptive pill now available without prescription from pharmacies. The tablets contain desogestrel, which is the most prescribed progestogen-only contraceptive tablet [1] and has been shown to be 99% effective at preventing pregnancy when used optimally [2, 3].

Desogestrel 75 microgram film-coated tablets, under the brand name Lovima, have been reclassified as a Pharmacy Only (P) medicine for use as a daily oral hormonal contraceptive in women of child-bearing age to be supplied under the supervision of a pharmacist.

Revising the menstrual cycle and contraceptive options

LEARNING OBJECTIVES: To refresh your understanding of the menstrual cycle and contraceptive options, so you can confidently help women visiting your pharmacy to make informed choices about their fertility control.

Contraceptive options

There are multiple contraceptive options available, through general practitioners (GPs), pharmacies, family planning services and other healthcare providers.

The choice of contraceptive type may be influenced by a variety of factors, and it is important that the patient is free to make an informed choice of the method that is most appropriate for their individual circumstances [5].

When a woman presents to the pharmacy requesting contraceptive advice, she must be informed of all contraceptive options available to her in order to establish which method is most suitable.

Options include:

- **Long-acting reversible contraceptives (LARCs)** (e.g. intra-uterine device [IUD], intra-uterine system [IUS] injection or implant)

- **Oral hormonal contraceptives** (e.g. a progesterone only pill or a combined oral contraceptive pill)

- **Topical hormonal contraceptives** (e.g. vaginal ring or contraceptive patch)

- **Barrier-type contraceptives** (e.g. condoms, caps or diaphragms).

For further details on the mode of action, effectiveness, advantages and disadvantages of each of these options, please see Appendix 1. Where relevant, you should also consult the Summary of Product Characteristics (SmPC) for each product, which provides detailed information on appropriate use.

Patient-focused information on each of these options can be found on the Family Planning Association website, and you may wish to recommend this website to women considering contraceptive options (**https://www.sexwise.fpa.org.uk/contraception**).

When considering contraceptive options, it is important to note that barrier forms of contraception are the only form that can prevent sexually transmitted infections (STIs), including human immunodeficiency virus (HIV).

COUNSELLING TIP: When discussing contraception with patients, highlight that condoms are the only form of contraception that can prevent STIs and HIV.

Contraception can only be effective if it is used correctly and consistently. LARCs are one of the most effective forms of contraception in terms of prevention of unintended pregnancy, as women do not need to remember to use them, whereas barrier methods are less effective [5].

Oral hormonal contraceptives such as Lovima® 75 microgram film-coated tablets also have the potential to be highly effective, and when used optimally can be 99% effective in preventing unplanned pregnancies [3, 5].

COUNSELLING TIPS:

- LARCs are considered the most effective contraceptive because they do not need a woman to remember to use them, but they need to be administered or fitted by a doctor or trained nurse.
- When conducting consultations with women considering contraceptive options, ensure the patient is aware of the availability of LARCs.

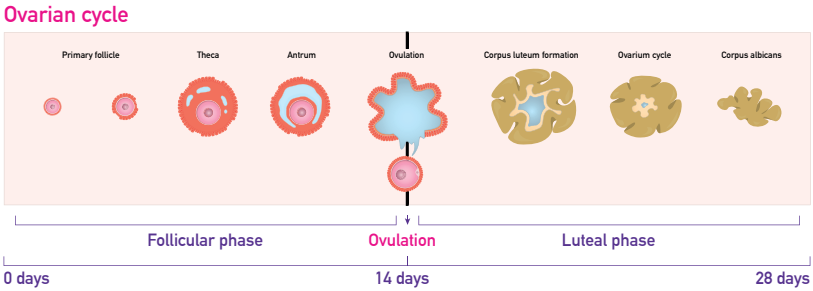
Overview of the menstrual cycle

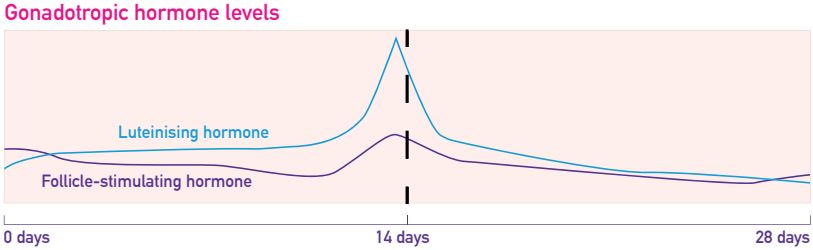
To understand how hormonal contraception works, it's important to understand the menstrual cycle and the role of the female hormones, including oestrogen and progesterone [4].

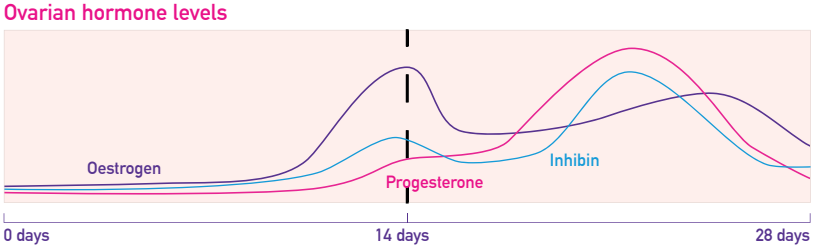
The figures below show the different phases of the normal menstrual cycle, including changes in hormone levels, changes in the ovarian follicle (the ovarian cycle) and changes in the endometrium (uterine cycle). Menstruation itself is considered as the period during which a layer of the endometrium is shed (menses), accompanied by a discharge of blood; it typically lasts 3–7 days. Day 1 of the menstrual cycle is the first day of menstruation.

The menstrual cycle is controlled by the complex interaction of several hormones.

1. At the start of the cycle, follicle-stimulating hormone (FSH) and luteinising hormone (LH) are produced from the anterior pituitary gland.
2. These hormones act on the ovaries, promoting the development of a small number of follicles and stimulating the release of the hormone oestrogen.
3. Oestrogen stimulates regeneration of the endometrium, thickening the lining of the womb.
4. At about Day 14 oestrogen levels peak, causing a rise in LH levels, which promotes a mature follicle to release an egg from the ovary (ovulation).
5. As soon as ovulation has occurred, the follicle starts producing the hormone progesterone.
6. Progesterone causes: i) further build-up of the lining of the womb in preparation for the implantation of a fertilised egg; and ii) changes in the cervical mucus, making it less hospitable to sperm. In addition, progesterone has a negative feedback effect, decreasing the release of LH.
7. As the empty follicle shrinks, if the egg is not fertilised, levels of oestrogen and progesterone decrease.
8. Without the high levels of hormones to help maintain it, the thick womb lining that has been built up starts to break down. This is the beginning of the next menstrual cycle.







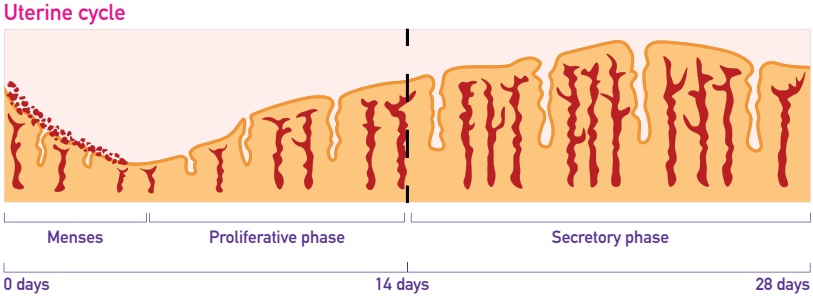


Fig 1 | Normal menstrual cycle

Lovima® 75 microgram film-coated tablets (desogestrel)

LEARNING OBJECTIVES: This section outlines the key information you need regarding desogestrel, including guidance on who may be suitable for Lovima 75 microgram film-coated tablets and when to refer to a doctor.

Refer to the SmPC for more details on Lovima 75 microgram film-coated tablets.

What are Lovima 75 microgram film-coated tablets (desogestrel)?

Lovima 75 microgram film-coated tablets are a daily oral contraceptive now available without prescription from a pharmacy for purchase as a P medicine to prevent pregnancy in women.

Lovima is a type of progesterone-only pill (POP) that contains the progestogen desogestrel. Desogestrel has been available as a Prescription-Only Medicine (POM) since 1998 (initially as Cerazette®; other brands are now available, such as Cerelle® and Feanolla™) [7]. It has now been reclassified and approved for sale as Lovima, a P medicine to be supplied by a pharmacist as a daily oral hormonal contraceptive for women of child-bearing age.

How does desogestrel work?

Relative hormone levels during ovulation

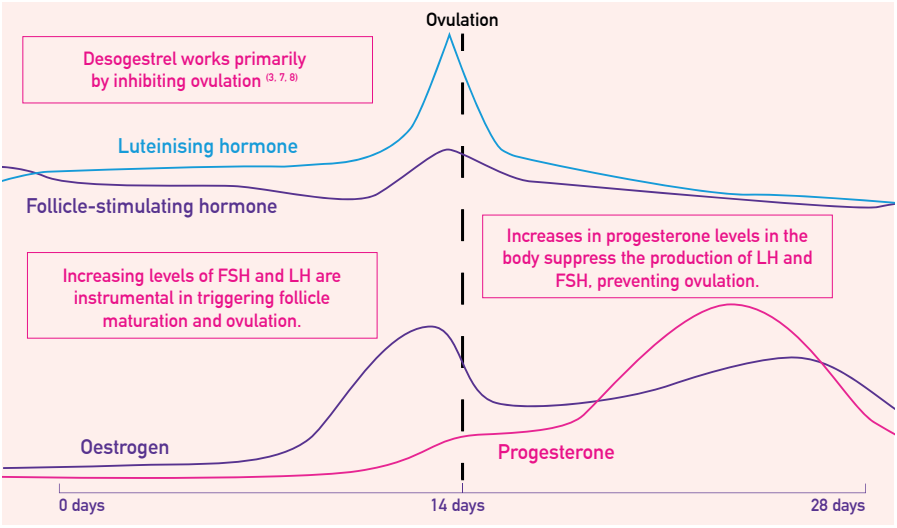


Fig 2 | Relative hormone levels during ovulation

Lovima® 75 microgram film-coated tablets contain the progestogen desogestrel, which has been shown to inhibit ovulation in up to 97% of cycles [2, 3].

Although desogestrel's primary contraceptive effect is inhibition of ovulation, secondary effects include increasing the viscosity of cervical mucus making it difficult for the sperm to reach the egg if ovulation has occurred [3, 8].

By contrast, traditional POPs such as levonorgestrel are thought to prevent pregnancy primarily by thickening the mucus in the cervix to stop sperm reaching the egg [9], and complete inhibition of ovulation is achieved in only about 60% of the cycles with, for example, levonorgestrel [8].

Owing to its ability to prevent ovulation, desogestrel can be taken up to 36 hours after the last pill (less than 12 hours late) without loss of contraceptive efficacy compared with 3 hours late for traditional POPs [2, 8].

Who can take Lovima®?

Lovima 75 microgram film-coated tablets are indicated for oral contraception for women who [2]:

- are of child-bearing age
- are not pregnant and in whom pregnancy can be ruled out with reasonable certainty (see 'Who can't take Lovima' overleaf).

COUNSELLING TIP: When discussing contraception and Lovima with young women, consider your training on safeguarding and competency (see Age and Safeguarding section).

Who can't take Lovima® and what circumstances require special consideration?

The Lovima carton is designed to act as a tool (an 'active pack') to give you the prompts you need to aid the consultation process. The carton provides a list of:

- contraindications ('DO NOT TAKE' section)
- situations in which further advice or referral to a doctor may be required
- recommendations to discuss use of other medicines

The active pack lists the contraindications under the '**DO NOT TAKE**' section

Lovima® 75 microgram film-coated tablets
Each tablet contains 75 microgram desogestrel. Lovima is a progestogen-only contraceptive pill (POP) used to prevent pregnancy in women of child bearing age.

Read the package leaflet before use.
For oral use. Contains lactose and soybean oil.
See leaflet for further information.
Keep out of the sight and reach of children.

How to use: It is important to take one tablet at the same time each day until the pack is empty. Then start a new pack on the next day without a break.

If you have taken Lovima before, tell your pharmacist if:
- you are taking or have been prescribed any new medicines
- there have been any changes in your health
- there have been any changes in your bleeding patterns.

DO NOT TAKE if you:
- are pregnant or may be pregnant. If you are unsure talk to your pharmacist
- have a thrombosis (blood clot)
- have or have had jaundice or severe liver disease
- have or are suspected of having a sex-steroid sensitive cancer (e.g. breast cancer)
- have any unexplained vaginal bleeding
- are allergic to **peanuts** or **soya**
- are allergic to desogestrel, lactose, or any of the ingredients in Lovima.

Tell your pharmacist before taking if you:
- are taking any **other medicines** or **herbal products** or have taken **emergency contraception** within the last 5 days
- have ever had breast cancer
- have liver cancer or other liver disorders
- have diabetes or high blood pressure
- have ever had a thrombosis (blood clot).

The warnings are listed under '**Tell your pharmacist**' section

The following sections describe the contraindications and warnings in more detail, when you should refer the patient to a doctor, and how to manage potential interactions with other drugs. More detailed information can be found in the Lovima SmPC.

In addition, a Lovima pharmacy consultation checklist is provided to act as a reminder and support the consultation process.

COUNSELLING TIP: Lovima may not be suitable for everybody or may not be the preferred method of contraception. It is important that you make women aware of the options available to them, and refer them to a GP or a family planning clinic if they are interested in choosing a prescription-only contraceptive.

When is Lovima® not suitable?

Lovima 75 microgram film-coated tablets are contraindicated for a woman if the answer to **any** of the questions listed below is YES. In such cases, Lovima should **not** be supplied and the woman should be referred to her doctor.

If the answer to **all** the questions below is NO, then Lovima is not contraindicated, and you should check the 'When to refer' and 'Drug interactions' sections to confirm whether the woman needs to visit her doctor before supplying Lovima [2].

SIX KEY QUESTIONS

1. Could she be pregnant?
2. Does she have a thrombosis (blood clot)?
3. Has she ever had liver disease?
4. Does she have or suspect she has an active cancer that grows under the influence of sex steroids, such as certain types of breast, uterine or ovarian cancer?
5. Does she have any undiagnosed vaginal bleeding?
6. Is she allergic to any of the ingredients, including peanut or soya?

QUESTION: Could she be pregnant?

Context

Lovima® 75 microgram film-coated tablets are contraindicated in pregnant women [2, 10]. Pregnancy can be ruled out with reasonable certainty if the woman has no symptoms or signs of pregnancy and if she meets one or more of the following conditions::

- She has not had sexual intercourse since her last period, or since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease
- She has used a reliable alternative method of contraception correctly and consistently (note that barrier methods are considered reliable, providing that they have been used consistently and correctly for every episode of intercourse)
- She is within the first 5 days of the start of a normal (natural) menstrual period
- She is less than 21 days after giving birth (non-breastfeeding women)
- She is fully breastfeeding, not having periods and less than 6 months after giving birth
- She is within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease
- She has had a high-sensitivity urine pregnancy test (able to detect human chorionic gonadotrophin [hCG] levels around 20 mIU/ml) performed at least 3 weeks after the last episode of unprotected sexual intercourse, and it was negative.

It is important to note that sometimes women may experience light bleeding or spotting during the early stages of pregnancy around the time when a period would have been due, which may be confused with having a period [10]. However, if all the above steps are followed to assess pregnancy, and the woman starts taking Lovima in accordance with the recommended posology (see Chapter 4), it is very unlikely that she will be pregnant at the time of starting treatment or will subsequently become pregnant.

Counselling tips

If pregnancy cannot be ruled out with reasonable certainty, you should not recommend Lovima and instead you should recommend alternative methods of contraception until it can be confirmed that the woman is not pregnant.
A pregnancy test is not always the most effective way to confirm whether a woman is pregnant or not. For an accurate reading, the last episode of unprotected sex must have been at least 3 weeks before completing the test, or it may give a false-negative result.

If the answer is 'No' to this question proceed to the next question.

QUESTION: Does she have a thrombosis (blood clot)?

Context

Lovima® 75 microgram film-coated tablets are contraindicated in women with an active or suspected venous thromboembolism (VTE). Women should consult a doctor immediately in the event of a thrombosis [2]. See 'Possible side effects' in Chapter 4 for further information.

If the answer is 'No' to this question proceed to the next question.

QUESTION: Has she ever had liver disease?

Context

Lovima 75 microgram film-coated tablets are contraindicated in women who currently have liver disease, or who have a history of liver disease where liver function has not returned to normal [2].

Counselling tips

Advise women with liver disease or a history of liver disease to discuss their contraceptive options with their doctor before starting Lovima.

If the answer is 'No' to this question proceed to the next question.

QUESTION: Does she have or suspect she has an active cancer that grows under the influence of sex steroids, such as certain types of breast, uterine or ovarian cancer?

Context

Lovima 75 microgram film-coated tablets are contraindicated in patients who have known or suspected sex-steroid-sensitive malignancies [2]. See 'Possible side effects' section in Chapter 4 for further information.

Counselling tips

Advise women with a previous history of breast cancer to discuss the use of hormonal contraceptives with their doctor before starting treatment.

If the answer is 'No' to this question proceed to the next question.

QUESTION: Does she have any undiagnosed vaginal bleeding?

Context

Lovima® 75 microgram film-coated tablets are contraindicated in women who have undiagnosed vaginal bleeding [2]. Undiagnosed vaginal bleeding includes bleeding between periods (spotting), infrequent periods (oligomenorrhoea) or complete absence of periods (amenorrhoea). Such undiagnosed bleeding may be due to STIs, pelvic inflammatory disease, malignancy, or pregnancy, in particular ectopic pregnancy (see Chapter 4 'Bleeding changes').

Counselling tips

Advise women who have unexplained vaginal bleeding to consult their doctor for further investigation.

If the answer is 'No' to this question proceed to the next question.

QUESTION: Is she allergic to any of the ingredients, including peanut or soya?

Context

Lovima 75 microgram film-coated tablets are contraindicated in women who are hypersensitive to the active substance (desogestrel), to peanut, lactose or soya, or to any of the excipients, as listed below [2]:

Tablet core | Lactose monohydrate, Maise starch, Povidone K30 (E1201), d-α-Tocopherol (E307), Soybean oil, Silica, colloidal hydrated (E551), Silica, colloidal anhydrous (E551), Stearic acid (E570)
Film coating | Hypromellose 2910 (E464), Polyethylene glycol, Titanium dioxide (E171)

Counselling tips

Recommend to women who have a known allergy to desogestrel or any of the ingredients of Lovima 75 microgram film-coated tablets to consider alternative contraceptives or brands of desogestrel.

If the answer to all of the questions is 'No' Lovima is not contraindicated. Check 'when to refer' and 'drug interactions' sections before supply.

When should you refer the woman to a doctor?

The benefits of taking Lovima® should be weighed against the possible risks for women who have certain medical conditions, as listed below. Discuss these medical conditions with the woman before she decides to start taking Lovima. In the event of aggravation, exacerbation or first appearance of any of these conditions, the woman should contact her doctor [2].

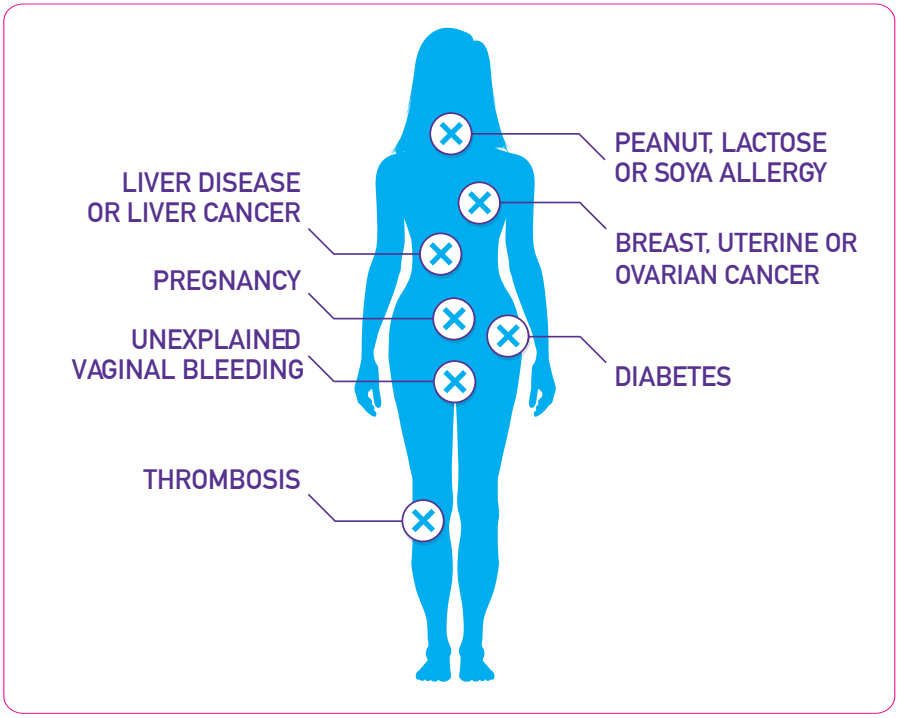


Fig 3 | Medical conditions with possible risks when taking Lovima

Women with multiple co-morbidities should be referred to a doctor to assess the most suitable method of contraception for them.

Condition	Context	Action
History of breast, uterine or ovarian cancer	As noted in the previous section, Lovima® is contraindicated in patients who have known or suspected sex-steroid-sensitive malignancies, such as breast, uterine or ovarian cancer [2]. Patients with a past history of breast cancer require additional counselling on contraceptive options before starting Lovima because the risk of desogestrel is likely to outweigh the benefits [11]. See 'Breast cancer risk' section in chapter 4 for further information.	**Do not supply** Lovima to patients with a history of breast uterine or ovarian cancer. Refer her to her doctor.
Liver disease and liver cancer	As noted in the previous section, liver disease or a history of liver disease where liver function has not returned to normal are contraindications to the use of Lovima. As the metabolism of steroid hormones can be impaired in those with severe liver disease, use in these patients is contra-indicated [2]. This includes liver cancer. A biological effect of progestogens on liver cancer cannot be excluded, and therefore an individual benefit/risk assessment should be made in women with liver cancer or liver disease [2]. As such, patients who have or have had liver cancer or liver disease should be advised to discuss contraceptive options with their doctor before starting Lovima [11].	**Do not supply** Lovima to patients with liver cancer or current or a previous history of liver disease. Refer her to her doctor.
Diabetes	Diabetes is not a contraindication for Lovima. Although progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in patients with diabetes (Type 1 or Type 2) using POPs [2]. However, patients with diabetes should be carefully observed during the first months of use.	**Do not supply** Lovima to patients with diabetes considering Lovima and refer them to their doctor.
A history of thrombosis	As noted in the previous section, only an active VTE is a contraindication for Lovima. Women with a history of VTE are not contraindicated for Lovima but should be made aware of the possibility of recurrence. They may wish to discuss alternative contraception with their doctor or a family planning nurse.	Lovima can be supplied but additional counselling is required for those with a history of VTE. See 'Cardiovascular risk' section in Chapter 4 for further information.

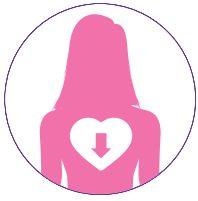
Condition	Context	Action
Hypertension (high blood pressure)	Hypertension is not a contraindication for Lovima. Checking and monitoring blood pressure is not a requirement for supply. However, obtaining a baseline blood pressure reading might be considered good practice as part of general health surveillance. Women found to have hypertension at any time should be referred to their doctor to discuss their antihypertensive treatment options. However, several drugs used to treat hypertension can increase the clearance of contraceptive hormones, leading to increased risk of contraceptive failure [2].	See the 'Drug interactions' section for further information and guidance on how to advise such patients.

Considerations with hormonal contraceptives

Diabetes

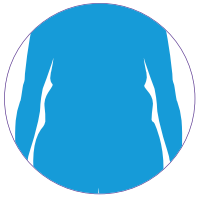
Although some progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in patients with diabetes using POPs. However, patients with diabetes should be carefully observed during the first months of use. For this reason, it is recommended that women talk to their doctor or nurse before using Lovima® if they have Type 1 or Type 2 diabetes [2].

Blood pressure



There is no requirement to check blood pressure before or during treatment with Lovima. Unlike some combined oral contraceptive (COC) pills, hypertension (high blood pressure) is not a contraindication for POPs. The available evidence does not support an association between POPs and an increase in blood pressure [3]. However, several antihypertensive drugs can interact with contraceptive hormones (see Drug Interactions section).

Weight



Unlike for some types of emergency contraception, increased dosages for women who are overweight or obese are not recommended for Lovima or other POPs [2, 12]. The currently available evidence indicates that the efficacy of POPs is not influenced by body weight or body mass index. In addition, there is no evidence suggesting a relationship between the POP and weight gain, although it is a commonly reported side effect (see Chapter 4 'Possible side effects').

Breastfeeding

Breastfeeding is not a contraindication for Lovima. Lovima does not appear to influence the production or the quality (protein, lactose or fat concentrations) of breast milk. However, there have been infrequent reports of a decrease in breast milk production while using desogestrel. A small amount of etonogestrel is excreted in the breast milk and may be ingested by the child [2]. Based on the available data, desogestrel may be used during lactation.The development and growth of a nursing infant whose mother uses desogestrel should however, be carefully monitored [2]. This monitoring is expected to occur automatically through routine child health surveillance checks that are already in place in the UK for all children.

Migraines

Although data are limited, the currently available evidence does not suggest an increased risk of migraine with the use of POPs [3]. There is no contraindication, warning or precaution required relating to use of Lovima in patients who suffer from migraines [2]. This is in contrast to COCs – the Faculty of Sexual and Reproductive Healthcare (FSRH) recommends that use of COCs is either strongly cautioned or avoided for women who have migraines with aura or new-onset migraine without aura [13].

Drug interactions

Effect of other medicinal products on desogestrel

ALL medications a woman is taking, whether prescribed, OTC, or herbal. should be checked for potential interactions with Lovima®.

Interactions can occur between desogestrel and drugs that induce liver enzymes, which can then lead to increased clearance of sex hormones such as desogestrel [2]. Drugs that have this effect may also include some herbal medications, such as St John's wort. As a result, blood levels of desogestrel may be reduced, potentially leading to breakthrough bleeding and/or an increased risk of contraceptive failure [2].

The prescribing information (SmPC, British National Formulary [BNF] or Stockley's Drug Interactions) of any concomitant medications should always be consulted to identify potential interactions with Lovima. If clinically relevant interactions are identified, the woman should be referred to her doctor for further contraceptive advice.

Hepatic enzyme-inducing drugs may increase the clearance of contraceptive hormones such as Lovima. Some examples include:

Drug class	Therapy area	Examples
Anti-convulsants	Epilepsy	**Hydantoins** (e.g. phenytoin) **Barbiturates** (e.g. phenobarbital) **Primidone, carbamazepine, oxcarbazepine, felbamate, topiramate**

Drug class	Therapy area	Examples
Antibiotics and antivirals	Tuberculosis	**Rifampicin, rifabutin**
	HIV infections, hepatitis C infections or other infectious diseases	**Ritonavir,* nelfinavir,* nevirapine,* boceprevir,* telaprevir,* efavirenz, griseofulvin**
Endothelin receptor antagonists	Pulmonary arterial hypertension	**Bosentan**
Herbal remedies	Depressive mood	**St John's wort (Hypericum perforatum)**

* These agents have variable effects on clearance of contraceptive hormones and may increase or decrease plasma concentrations of progestins.

Women taking any of the above medications should not be supplied Lovima tablets and should be referred to their doctor.

Concomitant administration of strong or moderate CYP3A4 inhibitors may **decrease** the clearance of contraceptive hormones such as Lovima and may increase the risk of an adverse event (see Chapter 4). Some examples are included in the table below:

Drug class	Therapy area	Examples
Antibiotics	Bacterial infection	**Clarithromycin, erythromycin**
Calcium channel blockers	Hypertension	**Diltiazem**
Antifungals	Fungal infections	**Ketoconazole, itraconazole, fluconazole**

* Note: these lists above are not exhaustive, and all concomitant medicines should be checked for interactions with Lovima.

COUNSELLING TIP: Women taking CYP3A4 inhibitors long-term should be advised to consult their GP to discuss their contraceptive options.

Effect of desogestrel on other medicinal products

Desogestrel can also affect the concentration and efficacy of other medicines. **ALL** medicines a woman is currently taking or planning to take should be checked for interactions with Lovima.

Use after emergency hormonal contraception (EHC)

With the availability of a POP without a prescription from a pharmacy, a pharmacist is able to provide immediate advice and pharmacy access to contraception for women requesting EHC and improve the probability of women using effective contraception in the long term.

Ulipristal acetate

It is important to note that the effectiveness of ulipristal acetate (for emergency contraception) could be reduced if Lovima is taken in the 5 days following the ulipristal dose. Therefore, the start of Lovima should be delayed for 5 days (120 hours) after emergency contraception with ulipristal acetate. Women should be advised to use additional contraception (barrier or abstinence) during these 5 days and then for an additional 7 days after starting Lovima, until contraception becomes effective. Ulipristal may also reduce the effectiveness of Lovima and, therefore, concomitant use is not recommended.

Levonorgestrel

After use of levonorgestrel (for emergency contraception), Lovima® can be started immediately, but additional contraceptive measures (abstinence or use of barrier contraceptive measures) should be taken for the first 7 days of use.

Supplying Lovima® in the pharmacy

LEARNING OBJECTIVES: This section helps you deliver effective consultations with women starting treatment with Lovima 75 microgram film-coated tablets and advise them on how to take Lovima correctly.

Supply scenarios

You will encounter many different scenarios concerning women visiting the pharmacy to ask about contraception and specifically Lovima. In all scenarios, you will need to check that the woman is (still) suitable for supply and that this is the right contraceptive option for her. Information on when to supply and how to take Lovima in different scenarios is provided in Chapter 5. Depending on the women's scenario, there may be additional areas to consider. You should investigate these areas to ensure you provide the women with the most appropriate advice.

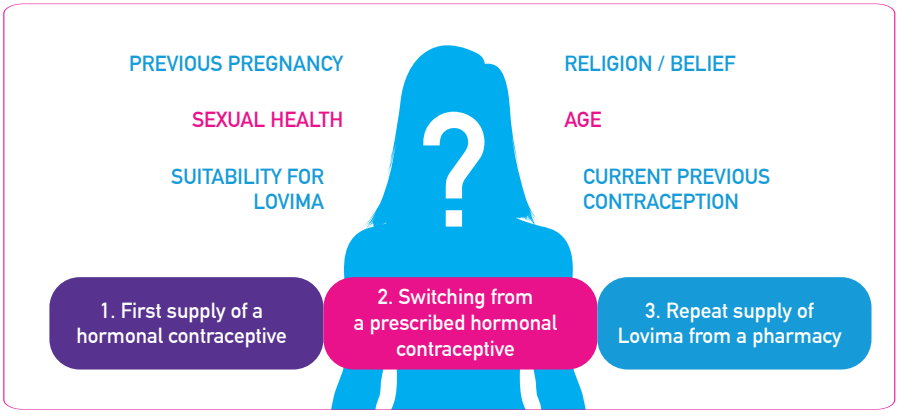


Fig 4 | Factors to consider when supplying Lovima

1. Lovima® 75 microgram film-coated tablets as the first supply of a hormonal contraceptive

There are various scenarios where Lovima may be considered to be the first supply of a hormonal contraceptive. The recommendations for how to take Lovima differ between these scenarios, and it is important that you provide the appropriate advice (see 'How to take' section). It is important to establish what contraception the woman is currently using (e.g. abstinence or a barrier method) and confirm that she is not pregnant (see Chapter 3). Consideration should be given to any safeguarding and consent issues with vulnerable women visiting the pharmacy (see section on 'Age and safeguarding considerations').

2. Switching from another prescribed hormonal contraceptive to Lovima

The type of hormonal contraceptive the patient was previously receiving impacts how they should take Lovima, and it is important that you provide the appropriate advice to the patient (see 'How to take' section). You should check that she has been using the prescribed method correctly and therefore rule out any risk of pregnancy. It may be that a woman has lost or forgotten her prescribed contraceptive, and you should check whether you are able to provide an emergency supply of her current prescribed contraceptive rather than switch her to Lovima.

3. Repeat supply of Lovima 75 microgram film-coated tablets from a pharmacy

Some women asking for a supply of Lovima may have been using it previously and this is a repeat supply. At each request for a repeat supply, conduct a thorough follow-up consultation to ensure the woman is still suitable for Lovima, exclude pregnancy and ensure there have been no changes to the patient's health that impact the appropriateness of continued treatment.

Advise the woman that if she thinks she may be pregnant at any time when taking Lovima, she should confirm she is pregnant before stopping Lovima. The risk of harm to the foetus with Lovima is low[2]. Stopping Lovima on the basis of a suspected pregnancy would leave the woman without contraception and potentially lead to an unplanned pregnancy.

Ask if there have been any changes to her:

MEDICATION:
at each resupply, check any changes to medications being taken concomitantly with Lovima for potential interactions.

MENSTRUAL CYCLE:
taking desogestrel can cause changes in menstruation, but any changes that cause concern, and in particular very frequent or irregular bleeding, should be discussed with her GP. Another contraceptive method could be considered and you should advise the woman accordingly (see 'Bleeding changes' section).

BLOOD PRESSURE
increases (e.g. discovered on routine checks): if sustained hypertension develops during Lovima treatment, or a significant increase in blood pressure does not respond to antihypertensive therapy, the woman should be referred to her doctor.

Take the opportunity during the check-ups at resupply to check if any of the conditions listed in the 'Possible side effects' section have occurred while taking Lovima, and particularly conditions that require immediate medical attention, such as VTE, liver problems and ectopic pregnancy (see section on 'Possible side effects').

The woman can find information in the PIL about health changes to which she needs to alert her doctor or pharmacist.

COUNSELLING TIPS: Consider the woman's scenario when determining the quantity of Lovima® to supply. It is recommended that:

- For a first supply of Lovima from a pharmacy, up to 3 months' supply (84 tablets) can be provided. This ensures that those starting treatment with Lovima do not receive Lovima for prolonged periods without a follow-up consultation.
- For a repeat supply, up to 12 months (4 x 84 tablets) could be considered in women over 18 years.
- Supply to women under 18 years should be limited to 3 months to ensure a regular opportunity to assess safeguarding, compliance and counselling on sexual health.

COUNSELLING TIPS: STIs and sexual health consultation. The consultation should be used as an opportunity to discuss general sexual health as well as contraceptive options, including LARCs so the patient can make an informed choice. Women should be advised that Lovima 75 microgram film-coated tablets do not protect against HIV infection and other sexually transmitted diseases (STDs), and that they should use a barrier method in addition to their contraception if they have any concerns regarding STIs/STDs. Condoms could also be offered with the supply of Lovima if they are available and a risk is identified.

COMMON MISCONCEPTION: 'I don't need contraception because I am on HRT'. Hormone replacement therapy (HRT) is not a method of contraception, and premenopausal or menopausal women should still use an effective method of contraception in conjunction with HRT until fertility can be assumed to have ceased (from the age of 55 years). The dose of progestogen in HRT can be too low for it to be effective as a contraceptive. Desogestrel may be a suitable method of contraception for women using HRT; however, the recommended method for these women is an IUS [18].

Age and safeguarding considerations

Safeguarding / child protection

As a key part of the duties of a pharmacy professional, appropriate safeguarding of children will be important, working with other organisations and authorities where needed [14]. Evidence of sexual activity/relationships that are inappropriate for a child's age or competence may be an indicator of child abuse [14].

Children who are under the age of 13 years are considered too young to legally consent to any sexual activity [14, 15]. The GPhC guidelines on Medical Ethics and Practice state that such instances should be reported to Social Services, unless the circumstances are considered to be exceptional and can be backed with documented reasons for not sharing information [16].

The age of consent in the UK is 16 years, although sexual activity in children under the age of 16 may be consensual, and typically does not lead to prosecution unless involving abuse or exploitation [14, 15]. Guidelines from the FSRH on contraception in young people suggest that 'Practitioners may wish to inform a young person of the law in relation to sexual activity' [15].

Pharmacists can provide contraception and sexual health advice to children under the age of 16, with appropriate assessment and documentation of consent (see 'Consent' section) [14, 15]. In such cases, the duty of patient confidentiality should apply, with consent sought for any decision to share patient information, unless judged that sharing is in the best interests of the child (e.g. to prevent abuse) [14]. FSRH guidelines recommend that young patients are made aware of confidentiality policies and the circumstances in which confidentiality may need to be broken [15]. The FSRH also provides guidance on eligibility criteria for different types of contraceptives based on age [15]. It is important to note that the SmPC for Lovima® 75 microgram film-coated tablets states that although the product is indicated for women of child-bearing age, the safety and efficacy of Lovima in adolescents below the age of 18 years has not been established [2].

Various national and local guidelines and frameworks are available regarding appropriate safeguarding of vulnerable patients, including young people – further information about these frameworks can be found in the FSRH guidelines (available from **https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/**) [15]. In particular, FSRH recommend that:

Appropriate training on the possibility of exploitation or coercion should be provided to all staff involved in contraceptive services for young people.

Staff should know how to act on child protection issues, in line with local policies / procedures.

Staff should know who to contact for advice.

Consent

Obtaining consent is a fundamental component of providing safe, effective patient-centred care [13, 16]. In the setting of provision of healthcare services or treatment, children under the age of 16 years must demonstrate their competence to consent [13, 16]. According to GPhC and RPS guidelines [13, 16]:

'A child can give consent if the pharmacy professional is satisfied that the treatment is in their best interests, and that they have the maturity and ability to fully understand the information given and what they are consenting to. In this case pharmacy professionals do not also need consent from a person with parental responsibility'.

In England, Wales and Northern Ireland, the FSRH recommends use of the Fraser Guidelines/criteria (available from **https://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-8-gillick-competency-fraser-guidelines**) when considering whether a young person under the age of 16 years is able to consent to provision of contraception: [15, 17]

Fraser Guidelines / Criteria [15,17]

Able to understand professional's advice / the nature and implications of treatment?	Cannot be persuaded to inform parents or allow a healthcare professional to do so?	Likely to begin /continue sexual intercourse with or without contraceptive treatment?	Physical or mental health likely to suffer unless contraceptive treatment received?	In the patient's best interests to receive contraceptive advice or treatment?
☑	☑	☑	☑	☑

In Scotland, the Fraser Guidelines have no legal authority, and instead competency is primarily addressed by ensuring that the child meets the criterion of understanding the nature and consequence of treatment [15]. FSRH guidelines recommend assessment and documentation of competence to consent to treatment at each visit for those aged under 16 years [15].

Contraception for women aged > 40 years

Separate guidance, such as that issued by the FSRH, is needed for women over the age of 40 years as they have a higher risk of cardiovascular disease, obesity, and breast and most gynaecological cancers, compared with younger women [18]. The increased risk may affect choice of contraceptive method. Pharmacists should also make women aware that [18]:

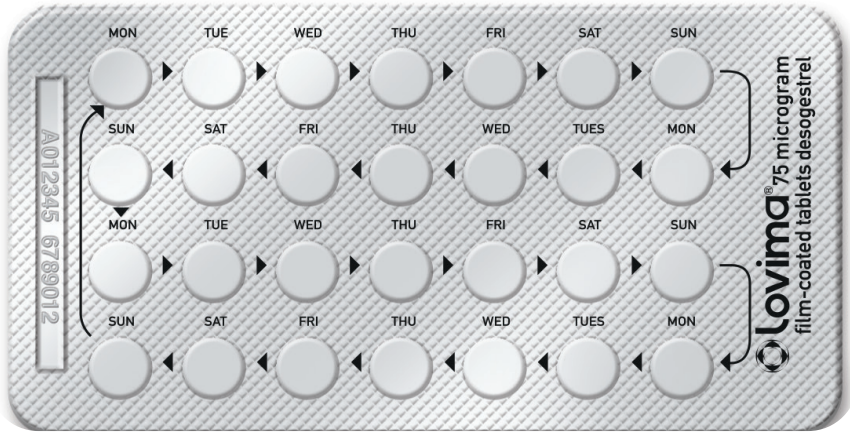
- Contraception does not affect the onset or duration of menopausal symptoms but may mask the signs and symptoms of menopause.
- POPs are not associated with increased risks of VTE, stroke or heart attack, and have not been shown to affect bone mineral density.
- POPs can be used until the age of 55 years, when natural loss of fertility can be assumed.

How to take Lovima®

Once a woman is considered suitable for supply of Lovima (see previous chapter) the following counselling advice should be given. **Tablets must be taken daily at the same time each day** to maintain the 24-hour interval between two tablets. This should be at a convenient time when the woman is least likely to forget.

The woman should be instructed to continue to take one tablet every day until the pack is empty. When a strip is empty, she should start with a new strip of Lovima the next day, without interruption and without waiting for a bleed. Point out that the days of the week and arrows printed on the blister strip are designed to help the woman remember whether or not she has taken her pill.

How to start Lovima



Women considering taking Lovima will start differently, dependent on whether they have given birth, had a miscarriage or abortion or have previously used contraception. Below are the different scenarios you may encounter and information on how to advise women appropriately.

1. Starting Lovima® after no hormonal contraception

First supply of Lovima in those without prior use of contraception (including emergency).

	When to start taking Lovima 75 microgram film-coated tablets	Need additional contraception?
Not using hormonal contraception at present and have not used it in the past month	Wait for a period to begin. Start taking Lovima on the first day of the period (day 1 is the first day of menstrual bleeding).	Do not need additional contraception, except while waiting for period to start.
	Or can also be started on days 2–5 of a period.	Need to use additional barrier contraception (condom) for first 7 days of tablet-taking.

Supply of Lovima after a birth, miscarriage or abortion.
Remember to first exclude pregnancy if the women's periods have not returned after birth, miscarriage or abortion.

	When to start taking Lovima 75 microgram film-coated tablets	Need additional contraception?
Following childbirth and period has not started again	Lovima can be started immediately following childbirth. If it is more than 21 days after delivery, pregnancy must first be excluded. Once this is confirmed, Lovima can be initiated before periods have started. Lovima can be started immediately following childbirth.	No additional contraception needed up to day 21 after childbirth if periods have not started again. If more than 21 days after delivery, need to use additional barrier method of contraception (e.g. condom) for first 7 days of tablet-taking.
Following childbirth and period has started again	Start taking Lovima on the first day of the period (day 1 is the first day of menstrual bleeding).	No additional contraception needed, except when waiting for period to start.
Recently had a miscarriage or abortion	Lovima can be started immediately or within 5 days after a miscarriage or abortion.	No additional contraception needed.

2. Starting Lovima® after other contraception

Supply of Lovima after emergency contraception supply.

	When to start taking Lovima 75 microgram film-coated tablets	Need additional contraception?
Have taken levonorgestrel	Start or continue taking Lovima immediately.	Use additional barrier contraception (condom) for 7 days.
Have taken ulipristal	Delay taking Lovima until 5 days (120 hours) after taking ulipristal. This is because Lovima can stop ulipristal working, and vice versa.	Use additional barrier contraception (condom) for 5 days (120 hours) after taking ulipristal and then for a further 7 days after starting Lovima. That is 12 days in total.

Further information on drug interactions can be found in chapter 3.

Switching from a combined oral contraceptive (COC), vaginal ring or transdermal patch.

	When to start taking Lovima 75 microgram film-coated tablets	Need additional contraception?
Changing from a COC, vaginal ring or transdermal patch	Start taking Lovima on the day after the last active tablet from the present pill pack or on the day of removal of the vaginal ring or transdermal patch.	Do not need additional contraception. If there is a break between the last active COC and taking Lovima (i.e. the usual tablet-free, patch-free, ring-free or placebo tablet interval of the previous COC), need to use additional barrier contraception (e.g. condom) for the first 7 days of Lovima tablet-taking.

Switching from a progestogen-only method of contraception.

	When to start taking Lovima® 75 microgram film-coated tablets	Need additional contraception?
Changing from another POP pill	Start taking Lovima without a break, on any day of changing from another progesterone only pill.	Do not need additional contraception.
Changing from an implant, hormonal IUS or an injectable	Start taking Lovima on the day of removal or when the next injection would be due.	Do not need additional contraception.

3. Repeat supply of Lovima 75 microgram film-coated tablets from a pharmacy

	When to start taking Lovima 75 microgram film-coated tablets	Need additional contraception?
Repeat supply when already taking Lovima	Start taking Lovima without a break.	Do not need additional contraception.

QUICK STARTING CONTRACEPTION [6, 19]

'Quick starting' is the term used to describe immediate initiation of a contraceptive method at the time a woman requests it (i.e. at any time during the cycle). 'Quick starting' Lovima is **off-label** use. Although it cannot be recommended by a pharmacist, it is important to be aware of quick start contraception as it is a common practice in family planning settings and may be appropriate for some women or situations.

QUICK STARTING CONTRACEPTION CONTINUED

The benefits of quick starting to provide immediate initiation of contraception include reducing the time period where a woman is at risk of unplanned pregnancy, which is a particular benefit for those with irregular cycles or who have taken emergency contraception and reducing barriers to returning for a further contraceptive appointment (e.g. time, transport costs) [6].

There are disadvantages, however. The safety and efficacy of starting after day 5 of the menstrual cycle has not been established. Additional contraception methods should be used for the first 7 days of tablet-taking [6]. There is a small chance that the woman is already pregnant and there is little evidence on the risk of ectopic pregnancy when contraceptive hormones are initiated around the time of conception [6]. There is also a theoretical risk of unintentional foetal exposure to hormones, such as desogestrel, however, pharmacovigilance data do not indicate an increased foetal risk [2,6]. If pregnancy cannot be ruled out prior to quick starting, it is recommended that a pregnancy test is undertaken at least three weeks after the last episode of unprotected sex [6], including any episodes within the 7 days it takes for desogestrel efficacy to build up.

Further information can be found in the FSRH guideline on quick starting contraception: **https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/**. The MHRA offers advice on the off-label use of medicines: **https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities**.

BRIDGING CONTRACEPTION

There may be times when a woman's first-choice contraception is not available or not appropriate when she presents to you [6]. For example, she may wish to use a LARC, but may need contraception before she is able to see a doctor to obtain her LARC. In this instance, Lovima could be used as a bridging option until she can begin her preferred contraception [6].

COUNSELLING TIP: It is important to encourage women to advise their GP or other healthcare professionals when they have been supplied with Lovima® in the pharmacy.

What happens if a woman forgets/misses a pill?

If a woman forgets to take her Lovima tablet on time, there is a risk that the contraceptive effect may be reduced and she may not be protected from pregnancy [20]. Pharmacists should advise all women of the actions to take if they have missed a pill:

Woman has forgotten to take Lovima

Less than 12 hours late
(< 36 hours since last pill taken)

The missed tablet should be taken as soon as it is remembered and the next tablet should be taken at the usual time - this may mean taking 2 tablets in one day.

She will still be protected from pregnancy with continued use of Lovima.

More than 12 hours late
(>36 hours since last pill taken)

If the patient is more than 12 hours late **she may not be completely protected against pregnancy** - the more consecutive tablets missed, the higher the risk of pregnancy.

If unprotected sexual intercourse occurred after the missed pill and within 7 days of restarting the POP there is a risk of pregnancy. Emergency contraception should be considered.

If unprotected intercourse has not occurred since the missed pill, the missed tablet should be taken as soon as it is remembered and the next tablet should be taken at the usual time - this may mean taking 2 tablets in one day. If more than one tablet has been missed the earlier missed doses need not be taken.

Tablets should be continued as usual but a barrier method of contraception should be used for the next 7 days.

Missing tablets at anytime in the cycle can reduce the efficacy of Lovima and risk pregnancy, but missing a tablet in the first week after initiation is especially vulnerable.

What should the woman do if she has a gastrointestinal upset after taking Lovima?

Advise women during the initial consultation that if they experience vomiting within 3–4 hours after taking the tablet, Lovima may not have been absorbed sufficiently to provide contraceptive protection and they should follow the advice as if the tablet has been missed.

If she has severe or persistent vomiting or diarrhoea she should also use an additional method of contraception for the first 7 days of normal tablet taking.

Information on what to do if a woman vomits or has diarrhoea is available in the patient information leaflet.

The same guidance applies if medical charcoal is used within 3–4 hours after taking Lovima [20].

COUNSELLING TIP: Advise women that if they think they may be pregnant at any time when taking Lovima®, they should confirm pregnancy before stopping Lovima.

Possible side effects and other conditions with Lovima

Known side effects of desogestrel (reported)

The graphic below lists the possible side effects reported with regular use of desogestrel tablets such as Lovima®, by system organ class and frequency [2, 20].

COMMON

(≥ 1/100 to <1/10)

Menstruation irregularity
Depressed mood
Libido decreased
Headache
Nausea
Acne
Breast pain
Amenorrhoea
Weight increase

UNCOMMON

(≥ 1/1,000 to <1/100)

Vaginal infection
Contact lens intolerance
Vomiting
Alopoecia
Dysmenorrhoea
Ovarian cyst
Fatigue

RARE

(≥ 1/10,000 to <1/1,000)

Rash
Uticaria
Erythema nodosum

Several of the most commonly reported side effects are also reported with other POPs, including mood changes, altered bleeding patterns, decreased libido and weight changes [3].

Side effects associated with oral contraceptives

Take the opportunity during the initial consultation and during check-ups at resupply to check if any of the conditions listed below have occurred while taking Lovima.

It helps to talk about these medical conditions using terms the woman will understand and using signs and symptoms that she can more easily recognise [2, 20].

Although there is little evidence of an increased risk of these conditions listed below with Lovima or other POPs, it is important to recognise the symptoms.

Signs and symptoms	Possible condition	Action for patient
▪ **Swollen face, tongue or throat** ▪ **Difficulty in swallowing** ▪ **Hives** ▪ **Difficulty in breathing**	Angioedema	**STOP** taking Lovima® and seek **immediate** medical attention
▪ **Severe pain or swelling in either of the legs** ▪ **Unexplained pains in the chest** ▪ **Breathlessness** ▪ **An unusual cough, especially if blood is coughed up**	Thrombosis and blood clots (see 'Common concerns with long-term use of oral contraception' section below for further information)	Seek **immediate** medical attention
▪ **Sudden severe stomach-ache** ▪ **Jaundice with yellowing of the skin or the whites of the eyes, or dark urine**	Liver disease (see Chapter 3 for further information)	Seek **immediate** medical attention
▪ **Sudden or severe pain in the lower abdomen or stomach area, with or without amenorrhoea and with or without vaginal bleeding**	Ectopic pregnancy. Note: The protection against ectopic pregnancies with traditional POPs is not as good as with COCs, as traditional POPs do not inhibit ovulation. The risk is considered to be lower with desogestrel compared with traditional POPs as ovulation is inhibited consistently when used effectively.	Seek **immediate** medical attention
▪ **Lump in the breast** ▪ **Nipple discharge** ▪ **Other uninvestigated breast symptoms**	Breast cancer (see below for further information)	Seek medical attention

Bleeding changes

The most commonly reported side effect is menstrual bleeding irregularity [2]. Some kind of bleeding irregularity has been reported in up to 50% of women using desogestrel 75 microgram tablets. As Lovima® results in close to 100% ovulation inhibition in contrast to other POPs, irregular bleeding is more common than with other POPs. In 20–30% of the women, bleeding may become more frequent, whereas in another 20%, bleeding may become less frequent or totally absent. Vaginal bleeding may also be of longer duration.

After a couple of months of treatment, bleeds tend to become less frequent. Some women may find the change in bleeding frequency or duration, or the absence of bleeding an advantage. Women can be reassured that it is normal for their periods to become less frequent or stop altogether after a few months of treatment [2]. The FSRH recommends that, as a guide, women considering desogestrel tablets such as Lovima can be advised that after 12 months of use, over a 3-month period approximately [3]:

- 5 in 10 women can expect to have infrequent bleeding or no periods
- 4 in 10 women can expect to have regular spotting/bleeding episodes (3–5 episodes)
- 1 in 10 women can expect frequent spotting/bleeding episodes (>6 episodes)
- 2 in 10 women will experience a prolonged spotting/bleeding episode (lasting >14 days).

COUNSELLING TIPS [2]:

- Inform women of the potential impact on their bleeding pattern.
- Irregular bleeding is not a sign that Lovima is not working.
- In general, the woman does not need to take any action and can continue to take Lovima.
- However, if she is worried about changes in her menstruation or if bleeding becomes very frequent, irregular or heavy, she should be instructed to consult her doctor.
- Information, counselling and a bleeding diary can improve the patient's acceptance of changes in bleeding pattern.

Changes in mood

Depressed mood and depression have been reported as possible side effects of hormonal contraceptives [2, 3]. Depression can be serious, and is a well-known risk factor for suicidal behaviour and suicide. 1 in 10 women have reported depressed mood when using hormonal contraceptives, including desogestrel. However, there is no evidence of a causal link between use of POPs and mood changes or depression [3].

COUNSELLING TIP: Advise women that if they experience mood changes or depressive symptoms, they should contact their doctor for medical advice as soon as possible [2].

Common concerns with long-term use of oral hormonal contraception

'Does long-term use of the pill increase cardiovascular risk?'

The evidence available to date does not support an association between POPs and the risk of cardiovascular disease and there is no evidence that they increase blood pressure [3]. The benefits of using a POP are regarded as outweighing any theoretical or potential risks even when used by women with vascular disease [3].

COUNSELLING TIP: Advise the women that there is no evidence that POPs increase blood pressure and the product can be used even by women with heart disease (aside from a blood clot). [2, 3]

'Does long-term use of the pill increase the risk of blood clots?'

The evidence available to date does not support an association between POPs and the risk of VTE [3]. An association between the use of COCs and an increase in the incidence of VTE has been shown [9]. The clinical relevance of this finding for oral contraceptives such as desogestrel, which lack an oestrogenic component, is unknown [7]. However, it is still recommended that Lovima® 75 microgram film-coated tablets should be discontinued in the event of a thrombosis, and that women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence [2].

There are conflicting data for the risk of arterial embolic events (ATEs), such as myocardial infarction and ischaemic/cerebral stroke, among those using third-generation COCs including those containing desogestrel [21]. It is suggested that the risk of stroke or myocardial infarction (MI) is comparable to second-generation COCs, where there is a very small, relative risk of ischaemic stroke in healthy women, particularly among older age groups [21,22,23].

More broadly, guidelines from the FSRH note that POPs have not been associated with an increased risk of stroke [3]. However, as the risk of ATEs is increased among women who smoke, have diabetes, hypercholesterolaemia or hypertension [21, 23] pharmacists can play an active role in advising women on how to modify these risk factors.

COUNSELLING TIPS:

- Counsel the woman on the need to seek IMMEDIATE medical advice in the event of a suspected thrombosis.
- Advise that she should return to the pharmacy or visit her GP if she is due to be immobilised or is to have surgery (ideally she should contact her doctor at least 4 weeks in advance).

'Does long-term use of the pill increase the risk of breast cancer?'

The risk of breast cancer increases in general with increasing age, and is also associated with a variety of factors including obesity and alcohol drinking [24]. According to Cancer Research UK, less than 1% of breast cancer cases in the UK are caused by oral contraceptive use [21, 24].

The risk in users of POPs, such as desogestrel, is thought to be of similar magnitude to that associated with COCs [20]. Breast cancer has been found slightly more often in women who take the COC pill than in women of the same age who do not take the COC pill. If women stop taking the COC pill, this reduces the risk, so that 10 years after stopping the COC pill, the risk is the same as for women who have never taken it. It is important to understand that breast cancer is rare in those under the age of 40, but that the risk increases as the woman gets older. As such, the extra number of breast cancers diagnosed is higher if a woman continues to take the COC pill when she is older. The increased risk is not linked to the duration of use but to the age of the woman. In every 10,000 women who take the COC pill for up to 5 years but stop taking it:

- by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group;
- by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed;
- by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed. [2]

Compared with the risk of getting breast cancer ever in life, the increased risk associated with COCs is low [2]. The cases of breast cancer diagnosed in COC users tend to be less advanced than in those who have not used COCs. The increased risk in COC users may be due to an earlier diagnosis, biological effects of the pill or a combination of both.

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First supply | Case study | Aisha

Presentation

Aisha is 17 years old and asks to speak to you privately because she finds it difficult to get to the GP and she has concerns about confidentiality. Her mum is best friends with one of the GP's receptionists. Aisha has started having sex with her boyfriend. They have been very careful to use condoms and have not had any unprotected sex. Aisha wants to start using a more reliable method of contraception without having to go to her GP or contraception clinic. You discuss the available options with Aisha, including highlighting that only barrier methods can protect from STIs and HIV infection. Aisha decides that she would like to use Lovima®.

On further questioning, you ascertain that Aisha is fit and healthy with no history of thrombosis, liver disease or cancer. However, she does have a strong family history of breast cancer in that her mother and grandmother have both been diagnosed with this. She is not on any medication. Her periods are normally very regular, although she has been getting some spotting and irregular bleeding between her periods and after sex during the past 3 months. Aisha has read up on contraception and wants to have the progestogen-only pill ready to start with her next period, which is due in a few days.

Select the correct course(s) of action from the following:

A | Not supply Lovima® | Aisha is too young for you to supply the desogestrel pill.

B | Supply Lovima | Aisha has been using contraception correctly with no mistakes and so it is reasonable to assume that she is not pregnant.

C | Not supply Lovima | Aisha is getting irregular bleeding and this should be investigated prior to starting the desogestrel pill.

D | Not supply Lovima | a strong family history of breast cancer is a contraindication to the desogestrel pill.

Previous contraceptive use
Case study | Nina

Post-emergency contraception

Presentation

Nina, a 42-year-old businesswoman, has entered a new relationship and has come to the pharmacy to request emergency contraception and to discuss longer-term contraception. You have assessed that she is suitable for emergency contraception and supply ulipristal acetate. She had surgery for an ectopic pregnancy when she was 31 years old. She has suffered from extremely painful periods all her life, was diagnosed with endometriosis and has had surgery to help with this problem. She also has hypothyroidism and continues to take levothyroxine 100 microgram once daily.

You discuss the available options with Nina, including highlighting that only barrier methods can protect from STIs and HIV infection. Nina wants a reliable method of contraception that is easily accessible and under her control, and she decides that she would like to use Lovima®. Her periods are regular with no abnormal bleeding. She has no personal or family history of blood clots, breast cancer or liver disease.

Select the correct course(s) of action from the following:

A | Not supply Lovima® | Contraindicated by a history of ectopic pregnancy, and by endometriosis.

B | Not supply Lovima | Cannot be used after emergency contraception.

C | Not supply Lovima | There is a potential drug interaction with levothyroxine.

D | Supply Lovima | No contraindications are present.

First supply
Case study | Aisha
Answers

Correct course of action: C. Not supply

Aisha is getting irregular bleeding and this should be investigated prior to starting the desogestrel pill.

Girls aged 17 years are eligible for Lovima® (pharmacists can provide contraception and sexual health advice to children under the age of 18, with appropriate assessment and documentation of consent [see 'Consent' section]). However, in Aisha's case you should not supply Lovima, as the symptom of unexplained vaginal bleeding (such as the spotting and irregular bleeding reported by her) is a contraindication for Lovima. Instead, you should advise Aisha to see her GP before supply of Lovima can be considered [20]. At this age and with the history of having a new sexual partner there is a possibility that she has chlamydia or another STI/STD. This could affect her fertility it not treated.

It is reasonable to assume Aisha is not pregnant because she reports she has been using a reliable method of contraception consistently. The presence of breast cancer is a contraindication for desogestrel tablets, and those with a personal history of breast cancer or any symptoms of breast disease should be advised to discuss use of hormone contraceptives with their doctor before starting treatment; however, a family history of breast cancer, as in Aisha's case, is not a contraindication, and there are no specific warnings or precautions that need to be considered before supply of Lovima in patients with such a family history. In view of her strong family history of breast cancer, it would be good practice to advise Aisha to be 'breast aware' and to suggest she discusses with her GP whether she needs further risk assessment or an alternative contraceptive.

Post-pregnancy
Case study | Nina
Answers

Correct course of action: D. Supply

No contraindications are present.

Nina has no contraindications for Lovima® or other medical conditions that require referral prior to supply. However, the effectiveness of ulipristal acetate (for emergency contraception) could be reduced if Lovima is taken in the 5 days following the dose. You should recommend that Nina starts taking Lovima 5 days after taking the emergency contraceptive, and that she should use additional contraception (barrier or abstinence) during these 5 days and then for an additional 7 days after starting Lovima, while contraception becomes effective. If the patient were given levonorgestrel as emergency contraception instead, then Lovima could be started immediately, with the advice to use a barrier method of contraception for the first 7 days.

A history of ectopic pregnancy is not a contraindication for Lovima. The protection against ectopic pregnancies with traditional POPs is not as good as with COCs, as traditional POPs do not inhibit ovulation. The risk is considered to be lower with desogestrel tablets such as Lovima compared with traditional POPs, as ovulation is inhibited consistently when used effectively.

A past history of endometriosis is not a contraindication to Lovima, and there is some limited evidence that desogestrel tablets may offer some benefits in women with painful periods (dysmenorrhoea) and endometriosis [3].

Desogestrel could potentially affect the results of certain laboratory tests, including that of thyroid function, but concurrent use of levothyroxine is not a contraindication to use [2].

Learn your way

Learn about contraception for women and the supply of Lovima® 75 microgram film-coated tablets (desogestrel). Click on this QR code to download print resources.

Lovima® 75 microgram film-coated tablets (desogestrel) - PL 42807/0002

Indications: Oral contraception for women of childbearing age including adolescents. **Posology:** One tablet every day continuously; 24 hours between tablets. First tablet taken on the first day of menstrual bleeding. **Contraindications:** Active venous thromboembolic disorder. Presence or history of severe hepatic disease. Known or suspected sex-steroid sensitive malignancies. Undiagnosed vaginal bleeding. Hypersensitivity to any ingredients. Peanut or soya allergy. **Precautions:** Pregnancy should be excluded, contains lactose; not for patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption. Caution in patients with: a history of breast cancer, diabetes, liver cancer or chloasma or depressed mood arising during use. Efficacy may be reduced with missed tablets, gastro-intestinal disturbances, or concomitant medications. Stop if sustained hypertension not controlled. **Side effects:** Very common (≥1/100 to <1/10) breast pain; depressed mood; mood altered; libido decreased; menstrual cycle irregularities: nausea; acne; weight increased, headache. Uncommon (≥1/1,000 to <1/100) vaginal infections, contact lens intolerance, vomiting, alopecia, dysmenorrhoea, ovarian cyst, fatigue. Rare (≥1/10.000 to <1/1,000) rash, urticaria, erythema nodosum. **MA holder:** Maxwellia Ltd, Alderley Park, Alderley Edge, SK10 4TG **Classification:** P **Price (ex.VAT):** 28 tablets £15.23 or 84 tablets £31.42. **Date:** November 2020.

Lovima®

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