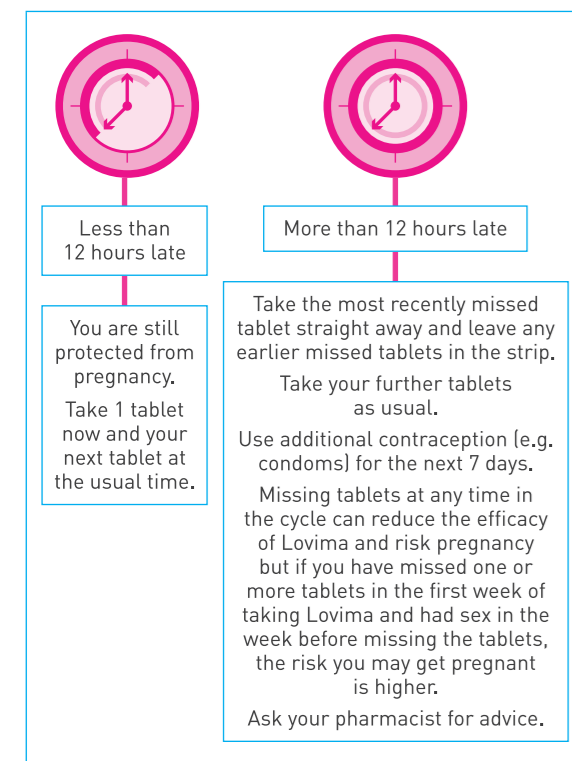


# Lovima<sup>®</sup> 75 microgram film-coated tablets desogestrel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Lovima is a progestogen-only daily contraceptive pill (also known as mini-pill or POP) for women of child bearing age who want to prevent pregnancy.
- It is important to take one tablet at about the same time each day without a break between packs.
- If you forget to take a tablet at the correct time follow the below advice. See section 3 'If you forget to take Lovima'.



- Some medicines may reduce the efficacy of Lovima. Tell your pharmacist if you are taking or may start taking any other medicines. See section 2 'Other medicines and Lovima'.
- Irregular bleeding is the most commonly reported side effect with desogestrel. See section 4 'Possible side effects'.
- If you get any side effects, talk to your pharmacist, doctor or family planning nurse. This includes any possible side effects not listed in this leaflet. See section 4 'Possible side effects'.

## What is in this leaflet

1. What Lovima is and what it is used for
2. What you need to know before you take Lovima
3. How to take Lovima
4. Possible side effects
5. How to store Lovima
6. Contents of the pack and other information

## 1. What Lovima is and what it is used for

Lovima is a daily hormonal contraceptive used to prevent pregnancy in women and adolescents of child bearing age.

There are 2 main kinds of hormonal contraceptive.

- The combined pill (COC), which contains 2 types of female sex hormone – an oestrogen and a progestogen.
- The progestogen-only pill, POP or mini-pill, which doesn't contain an oestrogen.

Lovima is a progestogen-only pill (POP) or a mini-pill.

It contains a small amount of one type of female sex hormone, the progestogen desogestrel.

- Most POPs or mini-pills work primarily by preventing the sperm cells from entering the womb but do not always prevent the egg cell from ripening, which is the main way that combined pills work.
- Desogestrel is different from other mini-pills in that it works primarily by inhibition of ovulation (preventing the egg cell from ripening).

- In contrast to the combined pill, Lovima can be used by women who do not tolerate oestrogens and by women who are breastfeeding.
- A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Lovima. On the other hand, you may not have any bleeding at all. For further information see section 4 'Vaginal bleeding'.

## 2. What you need to know before you take Lovima

Lovima like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

### ⊗ Do not take Lovima

- If you are **pregnant** or think you **may be pregnant**. If you are unsure talk to your pharmacist.
- If you have a **thrombosis**. Thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". Signs of a thrombosis include: severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially if you cough up blood.
- If you have or have had **jaundice** (yellowing of the skin) or severe liver disease and you have been told that your liver is still not working normally.
- If you have or if you are suspected of having **cancer** that grows under the influence of sex-steroids, such as certain types of breast, uterine or ovarian cancer.
- If you have any **unexplained vaginal bleeding**.
- If you are **allergic** to **desogestrel, peanut, soya** or any of the other ingredients of this medicine (listed in section 6).

If any of these conditions apply to you, you should consult your doctor before using Lovima.

### ⚠ Warnings and precautions

Talk to your pharmacist, doctor or family planning nurse **before using** Lovima:

- if you have ever had **breast cancer**
- if you have **liver cancer** or **other liver problems**
- if you have ever had a **thrombosis**
- if you have **diabetes**
- if you suffer from **epilepsy** (see section 2 'Other medicines and Lovima')
- if you suffer from **tuberculosis** (see section 2 'Other medicines and Lovima')
- if you have **high blood pressure**
- if you have or have had **chloasma** (yellowish-brown pigmentation patches on the skin, particularly of the face); if so avoid too much exposure to the sun or ultraviolet radiation.

These are important conditions that your doctor may need to monitor carefully.

### Breast cancer

It is **important to regularly check your breasts** and you should contact your doctor as soon as possible if you feel any lump in your breasts.

Breast cancer has been found slightly more often in women who take the combined oestrogen/progestogen pill (COC) 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 the COC pill. Breast cancer is rare under 40 years of age but the risk increases as the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if a woman continues to take the COC pill when she is older. How long she takes the COC pill is less important.

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
- the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed
- the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.

The risk of breast cancer in users of progestogen-only pills like Lovima is believed to be similar to that in women who use the COC pill, but the evidence is less conclusive. Breast cancers found in women who take the COC pill seem less likely to have spread than breast cancers found in women who do not take the COC pill. It is not certain whether the COC pill causes the increased risk of breast cancer. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

### Thrombosis

See your doctor **immediately** if you notice possible signs of a thrombosis (see also 'Regular check ups'). Signs of a thrombosis include e.g. severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially if you cough up blood.

Thrombosis is the formation of a blood clot, which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". A pulmonary embolism can cause chest pain, breathlessness, collapse or even death.

Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant.

The risk is higher in users of the combined oestrogen/progesterone pill (COC) than in non-users. However, the risk with progestogen-only pills, like Lovima has not been established.

### Ectopic pregnancy

Although desogestrel consistently inhibits ovulation and is an effective contraceptive, pregnancies and in some cases ectopic pregnancies (pregnancies where the fertilised egg attaches itself outside the womb) have been reported. Contact your doctor **immediately** if you have a sudden or severe **pain in the lower abdomen** or **stomach** area with or without vaginal bleeding, even if you don't think you are pregnant.

### Psychiatric disorders

Some women using hormonal contraceptives including desogestrel have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### High blood pressure

If you develop high blood pressure while taking Lovima seek medical advice as soon as possible. You may need to stop using Lovima.

### Diabetes

The active ingredient (desogestrel) in Lovima may have an effect on the control of diabetes. If you are diabetic consult your doctor before starting treatment with Lovima.

### Bone strength

Treatment with desogestrel leads to decreased oestrogen levels in the blood to levels similar to those which occur naturally during the menstrual cycle. There is no evidence to show that this reduction has any effect on bone strength.

### Children and adolescents

No clinical data on efficacy and safety are available in adolescents below 18 years.

### Other medicines and Lovima

Tell your pharmacist, doctor or family planning nurse if you are taking, have recently taken or might take any other medicines or herbal products. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take Lovima.

**Some medicines can make Lovima less effective at preventing pregnancy.**

If you are using one of these medicines or herbal products for **short-term** treatment, you can continue using Lovima but **you must also use additional contraception** (for example, condoms) every time you have sex during treatment and for 28 days after stopping the last dose of the other medicine or herbal product.

If you are using any of these medicines or herbal products either **chronically** or for **long-term** treatment you should **consult your doctor for advice**, as an alternative method of contraception may be more appropriate for you.

Medicines classed as enzyme-inducers which can make Lovima less effective include those used for the treatment of:

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, topiramate, felbamate, and phenobarbital)
- tuberculosis (e.g. rifampicin and rifabutin)
- HIV infections (e.g. ritonavir and nelfinavir), or other infectious diseases (e.g. griseofulvin)
- depressive moods (the herbal remedy St John's wort).

Medicinal charcoal used to treat drug poisoning or overdose may reduce the absorption of Lovima and can make it less effective at preventing pregnancy.

Some other medicines may also reduce the efficacy of Lovima. Tell your pharmacist about all medicines you are taking so that the pharmacist can advise you what to do.

Lovima may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine used to prevent organ rejection following transplant) or a decrease in effect (e.g. lamotrigine for epilepsy).

### Taking emergency contraception containing ulipristal acetate

Using Lovima and emergency contraception containing ulipristal acetate together can alter the effect of both these medicines, resulting in reduced contraceptive effect and increased risk of pregnancy.

If you have used emergency contraception containing ulipristal acetate during your cycle, you must wait 5 days after taking ulipristal acetate before taking Lovima. You **must also use additional contraception** (for example, condoms) every time you have sex during the 5 days while you wait to start or resume taking Lovima and for the first 7 days of taking Lovima (ie. for a **total of 12 days**).

### Pregnancy and breastfeeding

#### ⊗ Pregnancy

Do not use Lovima if you are pregnant, or think you may be pregnant. Take a pregnancy test or talk to your pharmacist, doctor or family planning nurse if your period is late after missing any tablets in the last month, or if you think you may be pregnant.

**Stop taking Lovima and see your doctor** if you become pregnant.

#### Breastfeeding

Lovima may be used while you are breastfeeding. Desogestrel (the active substance in Lovima) does not appear to influence the production or the quality of breast milk. However, there have been infrequent reports of a decrease in breast milk production while using desogestrel. A small amount of desogestrel passes over into the milk.

If you are breastfeeding, let your pharmacist know.

The health of children breast-fed for 7 months while their mothers were using desogestrel has been studied up until they were 2.5 years of age. No effects on the growth and development of the children were observed.

### Driving and using machines

This medicine has no known effect on the ability to drive or use machines.

### Lovima contains soybean oil and lactose

If you are allergic to peanut or soya, do not use this medicinal product.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### Regular check ups

When you are using Lovima, your pharmacist will check that it is still suitable for you every time you need a new supply. How often you need these checks and what the pharmacist needs to know will depend on your personal medical details.

**!** Contact your doctor immediately if:

- you notice possible **signs of a blood clot** (e.g. severe pain or swelling in either of your legs, unexplained pains in the chest, breathlessness, an unusual cough, especially if you cough up blood)

- you have a sudden, **severe stomach ache** or **jaundice** (you may notice yellowing of the skin, the whites of the eyes, or dark urine, possibly a sign of liver problems)

- you have a sudden or severe **pain in the lower abdomen** or **stomach** area (possibly a sign of a pregnancy outside the womb).

**!** Contact your doctor as soon as possible if:

- you feel a **lump in your breast** (possibly a sign of breast cancer)

- you are unable to get out of bed or a chair for more than a few days, for example, due to surgery or illness as this may increase the risk of a blood clot while using Lovima

- you have unusual, **heavy vaginal bleeding**

- you suspect that you are **pregnant**.

### 3. How to take Lovima

#### When and how to take the tablets

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure.

Each blister strip of Lovima contains 28 tablets – 4 weeks supply. One tablet should be taken **each day at the same time without a break between packs**.

The days of the week are printed on the blister strip. Arrows are also printed on the blister strip indicating the order in which to take the pills. Each day corresponds to one tablet.

Every time you start a new pack of Lovima, take a tablet from the top row. Don't start with just any tablet. For example if you start on a Wednesday, you must take the tablet from the top row marked with 'WED' (Wednesday).

**How you first start taking Lovima will depend on whether you have previously used other contraception or if you have recently been pregnant. You may also need to use additional contraception for the first 7 days.**

**Read the following information carefully to see which applies to you.**

If you are not sure what to do, talk to your pharmacist.

**If you are starting or resuming Lovima following emergency contraception**

Ask your pharmacist for advice on how to start taking or resume taking Lovima following emergency contraception. If you have taken emergency contraception, it is advisable to wait until day 1 of your next menstrual cycle before taking Lovima.

- Emergency contraception containing **levonorgestrel** can be used with Lovima. If you want to start taking or continue taking Lovima after using emergency contraception containing levonorgestrel, you can start or continue taking Lovima the same day. You **need to use additional barrier contraception** (condom) for the next 7 days.

- Using Lovima and emergency contraception containing **ulipristal acetate** together can alter the effect of both medicines, resulting in reduced contraceptive effect and increased risk of pregnancy. If you have used emergency contraception containing ulipristal acetate during your cycle, you must wait 5 days after taking ulipristal acetate before taking Lovima. You **need to use additional barrier contraception** (condom) for 5 days after taking ulipristal acetate while you wait to start or resume taking Lovima and then for the first 7 days after starting Lovima. (ie. for a **total of 12 days**).

**If you are not using hormonal contraception at present or have not used it in the past month**

- Wait for your period to begin and start taking Lovima on the first day of your period. You do not need additional contraception.
- You can also start on day 2–5 of your period. You need to use additional barrier contraception (condom) for 7 days.

**If you are changing from a combined pill (COC)**

- Start taking Lovima on the day after the last active tablet from your present Pill pack. Some COC packs have inactive pills so if you are not sure what is the last active tablet, check with the pharmacist. You do not need additional contraception.

- If there is a break between when you took your last COC pill and when you start taking Lovima (i.e. you do not start taking Lovima the day immediately after taking the last active tablet), you need to use additional barrier contraception (condom) for 7 days.

**If you are changing from a vaginal ring or transdermal patch**

- Start taking Lovima on the day your vaginal ring or patch is removed. You do not need additional contraception.

- If there is a break between removal of your ring or patch before you start taking Lovima (i.e. you do not take it on the same day), you need to use additional (barrier) contraception (condom) for 7 days.

**If you are changing from another progestogen-only pill (mini-pill) including another desogestrel mini-pill which your doctor may have prescribed for you**

- Start taking Lovima without a break. You do not need additional contraception.

**If you are changing from an injection or implant or hormonal IUS**

- Start taking Lovima when your next injection is due or on the day your implant or IUS is removed. You do not need additional contraception.

**If you have recently given birth and your period has not started again**

- You can start Lovima before your period starts.

- If you start taking Lovima more than 21 days after giving birth, you need to use additional contraception (condom) for 7 days. If you have had sex check that you are not pregnant before taking Lovima.

- If your period has started again, refer to section 'If you are not using hormonal contraception at present or have not used it in the past month'.

Information on breastfeeding can be found in section 2.

**If you have recently had a miscarriage or abortion**

- Start taking Lovima immediately or within 5 days after a miscarriage or abortion. You do not need additional contraception.

#### Continuing to use Lovima

Once you have started taking Lovima continue to take one tablet **every day at about the same time** until the pack is empty. Always follow the direction indicated by the arrows on the pack.

Swallow the tablet whole, with water.

When one blister strip is empty, you must start with a new strip of Lovima on the next day – that is without interruption and without waiting for a bleed.

You may have some vaginal bleeding during the use of Lovima, but you must continue to take your tablets as normal.

#### **!** If you forget to take Lovima

If you are **less than 12 hours** late:

- Take the missed tablet as soon as you remember and take the next tablet at the usual time. Lovima will still protect you from pregnancy.

If you are **more than 12 hours** late:

- If you are more than 12 hours late in taking any tablet, you may not be completely protected against pregnancy. The more consecutive tablets you have missed, the higher the risk that you might fall pregnant.

- Take a tablet as soon as you remember and take the next one at the usual time. This may mean taking two in one day. This is not harmful. (If you have forgotten more than one tablet, you don't need to take the earlier missed ones). Continue to take your tablets as usual but you must also use additional barrier contraception (condom) for the next 7 days.

- If you are more than 12 hours late taking your tablet and have sex consult your pharmacist for advice.

- Missing tablets at any time in the cycle can reduce the efficacy of Lovima and risk pregnancy but if you have missed one or more tablets in the first week of taking Lovima and had sex in the week before missing the tablets, the risk that you may get pregnant is higher. Ask your pharmacist for advice and if you need to use emergency contraception.

#### If you vomit or have severe diarrhoea

If you vomit within 3 – 4 hours of taking Lovima, then the tablet should be considered 'missed' and the advice under 'If you forget to take Lovima' should be followed.

If you have severe or persistent vomiting or diarrhoea, Lovima may not have been completely absorbed and the contraceptive effect may be reduced. You should use an additional method of contraception (for example, condoms) for the duration of your illness and for the first 7 days of normal tablet-taking.

If you are not sure what to do talk to your pharmacist.

#### If you take more Lovima than you should

There have been no reports of serious harmful effects from taking too many Lovima tablets at one time. Symptoms that may occur are nausea, vomiting and in young girls, slight vaginal bleeding. For more information, ask your pharmacist for advice.

#### If you stop taking Lovima

You can stop taking Lovima whenever you want. From the day you stop, you are no longer protected against pregnancy.

If you have any further questions on the use of this medicine, ask your pharmacist, doctor or family planning nurse.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor or pharmacist if you notice any unwanted effect, especially if severe or persistent.**

Serious side effects associated with the use of Lovima are described in section 2 'What you need to know before you take Lovima'. Please read this section for additional information on 'Thrombosis' and 'Ectopic pregnancy' and consult your doctor **immediately** where appropriate.

**You should seek medical advice immediately** if you experience symptoms of angioedema (rapid swelling of area under skin or mucous membranes usually caused by an allergic reaction). Symptoms of angioedema include swollen face, tongue or throat, difficulty in swallowing, or hives and difficulty in breathing.

**Vaginal bleeding** may occur at irregular intervals while using this medicine. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period. You may need to use tampons or sanitary towels. You may also not have any bleeding at all. After a few months of treatment bleeding tends to become less frequent or stop altogether. Irregular bleeding is not a sign that Lovima is not working. In general, you do not need to take any action; just continue to take Lovima. **If bleeding is frequent, heavy or prolonged, or if you are worried by any changes in bleeding, you should talk to your doctor.**

#### How often are other possible side effects seen?

**Common** (may affect up to 1 in 10 women): mood changes, depressed mood (see section 2 Psychiatric disorders), decreased sexual drive (libido), headache, nausea, acne, breast pain, irregular or no periods, weight increase.

**Uncommon** (may affect up to 1 in 100 women): infection of the vagina, difficulties in wearing contact lenses, vomiting, hair loss, painful periods, ovarian cyst, tiredness.

**Rare** (may affect up to 1 in 1,000 women): skin conditions such as rash, hives, erythema nodosum (painful rounded blue-red skin lumps usually on the shin and ankles, or sometimes thighs or forearms). Breast secretion or leakage may occur.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or family planning nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. How to store Lovima

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP:'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What Lovima contains

The active substance is desogestrel (75 microgram).

The other ingredients are: lactose monohydrate, maize starch, povidone K30 (E1201), d- $\alpha$ -tocopherol (E307), soybean oil, silica, colloidal hydrated (E551), silica, colloidal anhydrous (E551), stearic acid (E570), hypromellose 2910 (E464), polyethylene glycol, titanium dioxide (E171) (see also 'Lovima contains soybean oil and lactose' in section 2).

#### What Lovima looks like and contents of the pack

Each blister strip of Lovima contains 28 white round film-coated tablets.

Each carton contains 1, 3 or 6 blister strips.

#### Marketing Authorisation Holder

Maxwellia Ltd., Alderley Park, Alderley Edge, SK10 4TG, UK.

#### Manufacturer

Laboratorios León Farma, S.A., Pol. Ind. Navatejera, C/ La Vallina s/n, 24008 – Navatejera, León, Spain.

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#### Contraceptive choices

Other contraceptive options are available from GPs, pharmacies, family planning services and other healthcare providers. These include long acting reversible contraceptives (e.g. intra-uterine device (IUD) or implant), other oral hormonal contraceptives (e.g. COC); topical hormonal contraceptives (e.g. transdermal patch); barrier-type contraceptives (e.g. condoms). For further information about sexual health and other forms of contraception please visit [www.sexwise.fpa.org.uk](http://www.sexwise.fpa.org.uk)

Remember to attend your cervical screening test and regularly check your breasts. For more information visit the NHS website.