

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ovranette® 150/30 micrograms Coated Tablets

levonorgestrel and ethinylestradiol

Five important things to know about the Pill.

- The Pill is a reliable contraceptive and may reduce your risk of cancer of the ovary and womb if used in the long term.
- The Pill will not protect you against sexually transmitted diseases.
- This medicine can increase your risk of problems such as blood clots and breast cancer.
- Some women should not take the Pill because of current medical problems or illnesses. Please read this leaflet to make sure Ovranette is right for you.
- To prevent pregnancy it is important to take Ovranette as instructed and start each pack on time. Please make sure that you understand what to do if you miss a pill or if you think you are pregnant.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, family planning nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor, family planning nurse or pharmacist.

In this leaflet:

1. What Ovranette does
2. Make sure Ovranette is OK for you
3. Taking Ovranette
- 3.3 A missed pill
4. Possible side effects
5. How to store Ovranette
6. What is in Ovranette and who makes it

1. What Ovranette Does

Ovranette is a combined oral contraceptive pill ('the Pill'). **You take it to stop you getting pregnant.**

Your doctor may also prescribe Ovranette for some other conditions such as **pre-menstrual tension**, or for **heavy, painful or irregular bleeding**.

This contraceptive contains two types of female sex hormones, estrogen and progestogen. These hormones prevent an egg being released from your ovaries so you can't get pregnant. Also, Ovranette makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb.

Ovranette is a 21-day pill – you take one each day for 21 days, followed by 7 days when you take no pills.

The benefits of taking the Pill include:

- it is one of the most reliable reversible methods of contraception if used correctly
- it doesn't interrupt sex
- it usually makes your periods regular, lighter and less painful
- it may help with pre-menstrual symptoms.

Ovranette will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Ovranette needs to be taken as directed to prevent pregnancy.

2. Make sure Ovranette is OK for you

It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn't suitable for everyone.

→ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking the Pill

- Your doctor will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination.

While you're on the Pill

- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
- You should go for **regular cervical smear** tests.
- **Check you breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again.

2.1 The Pill and blood clots

The Pill may slightly increase your risk of having a blood clot (called a thrombosis), especially in the first year of taking it.

A clot in a leg vein – a deep vein thrombosis (or DVT) – is not always serious. However, if it moves up the veins to the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called a 'pulmonary embolism' and is very rare.

Your chances of having a blood clot are only increased slightly by taking the Pill.

- Of 100,000 women who are **not on the Pill** and not pregnant, about **5** will have a blood clot in a year.
- Of 100,000 women **taking a Pill** such as Ovranette, about **15** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year.

You are more at risk of having a blood clot in your veins:

- as you get **older**
- if you are **seriously overweight**
- if you or any of your close family have had **blood clots**
- if you have any **blood clotting problem** that needs treatment with a medicine such as warfarin
- if you have certain rare medical conditions such as **systemic lupus erythematosus (SLE)**
- if you're **off your feet for a long time** because of major surgery, injury or illness
- if you have had one or more **miscarriages**
- if you have **recently had a baby**.

→ **Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Ovranette may not be suitable for you.

Signs of a blood clot include:

- **painful swelling in your leg**
- **sudden chest pain**
- **difficulty breathing.**

→ **See a doctor as soon as possible. Do not take any more Ovranelle** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

You are more at risk of having a heart attack or stroke:

- as you get **older**
- if you have **high blood pressure**
- if you **smoke**
- if you have an **irregular heartbeat** (atrial fibrillation)
- if you have certain rare medical conditions such as **systemic lupus erythematosus (SLE)**
- if you or someone in your close family has had a **heart attack** or **stroke** at a young age
- if you have **migraines**
- if you have **diabetes.**

→ **Tell your doctor** if any of these risk factors apply to you. Taking the Pill may add to this risk so Ovranelle may not be suitable for you.

Signs of a heart attack or stroke include:

- sudden **sharp pains in your chest** which may reach your left arm
- sudden **weakness** or **numbness** in one side or part of your body
- if you have a **migraine** for the first time or any migraine that is worse than normal
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- dizziness, fainting, collapse or seizures.

→ **See a doctor as soon as possible. Do not take any more Ovranelle** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

2.2 The Pill and cancer

The Pill reduces your risk of cancer of the ovary and womb if used in the long term. However, it also seems to slightly increase your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than the Pill. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you're on the Pill, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users is small. For example:

- Of 10,000 women who have **never taken the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight.

→ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

→ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice)**. You may need to stop taking Ovranette.

2.3 Ovranette should not be taken by some women

→ **Tell your doctor** or family planning nurse if you have any medical problems or illnesses.

Do not take Ovranette if any of the following apply to you. Taking Ovranette would put your health at risk.

- If you are **pregnant**, think you might be pregnant or breast-feeding
- If you have cancer affected by sex hormones – such as some **cancers of the breast, womb lining or ovary**
- If you have **vaginal bleeding** that has not been explained by your doctor
- If you have **excessive thickening of the womb lining**
- If you or anyone in your close family has ever had a problem with their blood circulation. This includes a **blood clot** (thrombosis) in the legs (deep vein thrombosis), lungs (pulmonary embolism), heart (**heart attack**), brain (**stroke**), hypertension (high blood pressure) or any other parts of the body
- If you have any condition which makes you **more at risk of a blood clot** (thrombosis – see section 2.1, The Pill and blood clots)
- If you have **high fat levels in your blood** (high **cholesterol** or **triglyceride** levels)
- If you have ever had a **severe liver disease**
- If you have had any of the following **problems while pregnant** or while **using steroids**:
 - itching of the whole body (pruritus)
 - jaundice which was not caused by infection
 - a blister-like rash, called pemphigoid gestationis
 - a hearing problem called otosclerosis
- If you have the disease **systemic lupus erythematosus (SLE)**
- If you are **allergic** (hypersensitive) to any of the ingredients in Ovranette (see section 6, What is in Ovranette).

→ **If you suffer from any of these**, or get them for the first time while taking Ovranette, contact your doctor as soon as possible. You should not take Ovranette.

2.4 Ovranette can make some illnesses worse

Some of the conditions listed below can be made worse by taking the Pill. Or they may mean it is less suitable for you. You may still be able to take Ovranette but you need to take special care and have check-ups more often.

- If you have problems with your heart, circulation or blood clotting, such as **heart disease, high blood pressure** or **sickle cell disease** (a type of anaemia)
- If you have **diabetes**
- If you have any **gynaecological problems**, such as **fibroids** or **endometriosis**
- If you have ever had **kidney** or **liver problems**, or have had **gallstones** in the past
- If you have had severe **depression**
- If you have had **epilepsy** or **migraines**
- If you have **brown patches on your face or body** (chloasma)
- If you have **varicose veins**
- If you have **multiple sclerosis**

- If you have a metabolism disorder known as **porphyria**
- If you have **calcium deficiency with muscle cramps** (tetany)
- If you have **asthma**
- If you have problems wearing **contact lenses**.

→ **Tell your doctor or family planning nurse if any of these apply to you. Also tell them if you get any of these for the first time while taking the Pill, or if any get worse or come back, because you may need to stop taking Ovranelte.**

2.5 Taking other medicines

If you ever need to take another medicine at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you're taking Ovranelte. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop Ovranelte from working properly – for example:

- **some medicines used to treat epilepsy**
- **some medicines used to treat tuberculosis**
- **some medicines used to treat HIV or AIDS**
- **certain antibiotics**
- **certain sedatives** (called 'barbiturates')
- **St. John's wort** (a herbal remedy).

If you do need to take one of these medicines, Ovranelte may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Ovranelte can also affect how well other medicines work. For example, if you have diabetes, you may need to take more insulin or other anti-diabetic drugs while you take Ovranelte. Your doctor will tell you if this is necessary. You should also tell your doctor if you have been prescribed the medicine called metyrapone, which is used to treat Cushing's syndrome (overactive adrenal gland). Ovranelte may also interfere with the way this drug works.

2.6 Taking Ovranelte with food and drink

There are no special instructions about food and drink while on Ovranelte.

2.7 Pregnancy and breast-feeding

Do not use Ovranelte if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Ovranelte.

If you are breast-feeding, your doctor or family planning nurse may advise you not to take Ovranelte. Talk to them about alternative contraception. Breast-feeding will not stop you getting pregnant.

2.8 Driving and using machines

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

2.9 Ovranelte contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Ovranelte.

3. Taking Ovranelte

3.1 How to take it

To prevent pregnancy, always take Ovranelte as described below. Check with your doctor or family planning nurse if you are not sure.

Take Ovranelte every day for 21 days

Ovranelte comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

You don't need to use extra contraception during these seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time.

Then start your next strip

Start taking your next strip of Ovranelte after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

As long as you take Ovranelte correctly, you will always start each new strip on the same day of the week.

3.2 Starting Ovranelte

As a new user or starting the Pill again after a break

Either take your first Ovranelte pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Or start taking Ovranelte on any other day of your period. You must also use extra contraception, such as condoms, until you have taken the first seven pills correctly.

Changing to Ovranelte from another contraceptive Pill

- **If you are currently on a 21-day Pill:** start Ovranelte the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Ovranelte.
- **If you are currently on a 28-day Pill:** start taking Ovranelte the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Ovranelte.
- **If you are taking a progestogen-only Pill (POP or “mini Pill”):** start Ovranelte on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Ovranelte after a miscarriage or abortion

If you have had a miscarriage or an abortion **during the first three months** of pregnancy, your doctor may tell you to start taking Ovranelte straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

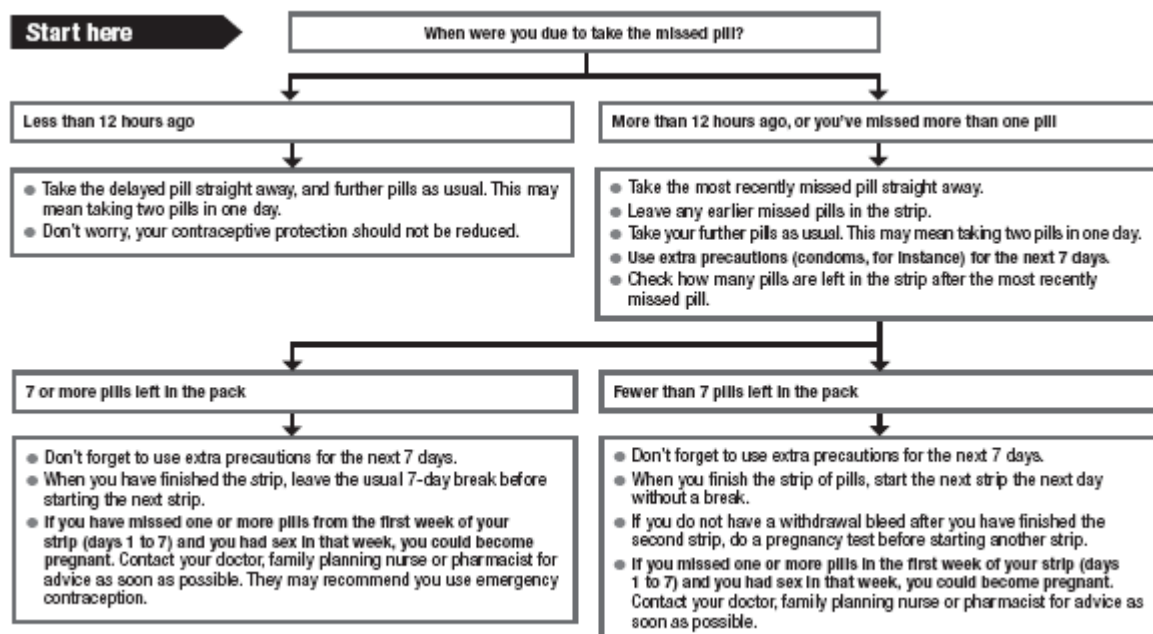
You can start using Ovranette after 21 days if you are **not** breast-feeding and had a vaginal delivery with no complications and you are fully mobile.

If the pill is started later than 21 days after delivery, then alternative contraception, such as condoms, should be used until oral contraception is started and for the first 7 days of pill taking. If unprotected intercourse has taken place after 21 days of delivery, then oral contraception should not be started until the first period after childbirth.

Your doctor or family planning clinic can provide further advice about contraception.

3.3 A missed pill

If you miss a pill, follow these instructions:



If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant. Contact your doctor or family planning clinic, or do a pregnancy test yourself.

If you start a new strip of pills late, or make your 'week off' longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor, family planning nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

3.4 If you are sick or have diarrhoea

If you are sick (vomit) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. Continue to take your next pills at your usual time. **Use extra contraception, such as condoms, while you are ill and for the next seven days after you are better.** Follow the instructions for if you are more than 12 hours late – see section 3.3, A missed pill.

→ **Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

3.5 Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines) you should do a pregnancy test before you start your next pack. You can buy these from the chemist or get a free test at your family planning clinic or doctors surgery. If you are pregnant, stop taking Ovranelte and see your doctor.

3.6 Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you should talk to your doctor as soon as possible.

3.7 Taking Ovranelte for something other than contraception

Your doctor may have prescribed Ovranelte for something other than contraception and at a different daily dose. The usual doses are:

- **Painful menstruation (dysmenhorrea) or premenstrual tension:** The same dose is used as for oral contraception (see 3.1, How to take it). You take a pill every day for 21 days, then have a seven day break (when you take no pills) before starting your next pack.
- **Endometriosis:** You take **two pills** every day **continuously** without any breaks.
- **Bleeding of the womb (uterus):** You take **two pills** every day for 21 days, then have a 7 day break. For the first month or two, your doctor may ask you to take 4 or 5 pills a day. However, if the bleeding from your womb is more serious, your doctor may ask you to take 4 pills immediately, then 4-8 pills daily until the bleeding is controlled.

4. Possible side effects

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

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Ovranelte.

4.1 Serious side effects – see a doctor straight away

Signs of a blood clot in a vein include:

- **painful swelling in your leg**
- **sudden chest pain**
- **difficulty breathing.**

Signs of heart attack or stroke include:

- a **migraine** for the first time, or a migraine that is worse than normal
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- problems with speech (such as slurred speech or difficulty talking)
- sudden **weakness** or **numbness** in one side or part of your body
- sudden **sharp pains in your chest** which may reach your left arm
- dizziness, fainting or seizures
- sharp pains in your stomach.

Signs of a severe allergic reaction to Ovranelte:

- **swelling of the face, lips, mouth, tongue or throat.**

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**

- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex.**

Signs of severe liver problems include:

- severe **pain** in your **upper abdomen**
- **yellow skin or eyes** (jaundice).

→ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Ovranelte.

4.2 Other possible side effects

- **changes to blood pressure** such as swollen ankles, hands or feet (but if your blood pressure increases severely or suddenly, or you faint, see a doctor as soon as possible)
- **headache** (but if it is severe, or the headache is unusual or long lasting, see a doctor as soon as possible)
- **weight gain**
- **weight loss**
- **sore or larger breasts**
- **bleeding and spotting between your periods** for the first few months (though this usually stops when your body adjusts to Ovranelte) – see section 4.3, Bleeding between periods should not last long.
- **depression, or low mood**
- **lower sex drive**
- **stomach problems**, such as nausea; vomiting
- **skin reactions** such as brown patches on the face and body (chloasma). Avoiding too much sunlight may reduce this.

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Ovranelte. Also tell them if any existing conditions get worse while you are taking Ovranelte.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Ovranelte, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Ovranelte as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

→ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Ovranelte for a while
- carries on even after you've stopped taking Ovranelte.

5. How to store Ovranelte

Keep all medicines out of the reach and sight of children.

Store Ovranelle al or below room temperature.

Do not use Ovranelle after the expiry date shown on the strip.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6. What is in Ovranelle and who makes it

What is in Ovranelle

Each box of Ovranelle contains three strips of 21 tablets.

Each strip of Ovranelle contains 21 white tablets.

Each tablet contains: 150 micrograms of the progestogen levonorgestrel, and 30 micrograms of the estrogen ethinylestradiol.

Ovranelle also contains the inactive ingredients: lactose, maize starch, povidone, magnesium stearate, talc, sucrose, polyethylene glycol, calcium carbonate, white wax and wax carnauba.

The company that holds the product licence for Ovranelle is:

**Pfizer Limited
Ramsgate Road
Sandwich, Kent CT13 9NJ
United Kingdom**

Ovranelle is made by:

**Pfizer Ireland Pharmaceuticals
Little Connell
Newbridge
Co. Kildare
Republic of Ireland**

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[Pfizer Logo]

This leaflet can be made available in large print, audio or Braille on request. Contact 0800 198 5000 to request this, quoting the following number: 00057/1283.
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