

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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor, family planning nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. What Ovranette is and what it is used for

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

- **painful menstruation** (dysmenorrhea) or **pre-menstrual tension**
- **endometriosis**
- **heavy or irregular bleeding** from the womb (uterus).

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. What you need to know before you take Ovranette

Warnings and precautions

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 check/confirm that you are not pregnant then ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast, abdomen or pelvic examination but only if these examinations are necessary for you, or if you have any special concerns.

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 your 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 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 Ovranelle 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 a **disease affecting your heart valves** or 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)
- **problems with speech** (such as slurred speech or difficulty talking)
- 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 very 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 or ovary**
- If you have **vaginal bleeding** that has not been explained by your doctor
- 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**) or any other parts of the body
- If you have **very high or uncontrolled blood pressure**
- 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 an **irregular heartbeat** (atrial fibrillation) or a **heart valve disorder**
- If you have **migraine with visual disturbances**
- If you have **diabetes** which has affected your circulation
- If you are 35 years old or over and **smoke** 15 or more cigarettes per day
- If you have the disease **systemic lupus erythematosus (SLE)**
- If you have ever had liver tumours or **severe liver disease and been told by your doctor that your liver function tests are not yet back to normal**
- If you are **allergic** (hypersensitive) to the active substances, levonorgestrel and ethinylestradiol or any of the other ingredients of this medicine (listed in section 6).

→ **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** for which you take medicines
 - **diabetes**

- If you have ever had **liver problems**, or have had **gallstones** in the past
 - If you have high levels of cholesterol or lipids (fats) in the blood (hyperlipidaemia)
 - If you have had **migraines**
 - If you have had **any illness that worsened during pregnancy or previous use of the Pill.**
- **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.**

See your doctor as soon as possible as you may need to stop using Ovranelte if

- You develop migraine for the first time or suffer worsening of existing migraine or headaches
- You experience any sudden unexplained changes in your vision
- You have symptoms such as unusual pains in or swelling of the legs, stabbing pains on breathing, persistent cough or coughing blood, pain or tightness in the chest
- Your blood pressure rises significantly
- You develop jaundice (yellowing of skin and/or white of eyes)

2.5 Other medicines and Ovranelte

Tell your doctor, pharmacist or dentist if you are taking, have recently taken or might take any other medicines. 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 and may cause unexpected bleeding and irregular periods, for example:

- **some medicines used to treat epilepsy**
- **some medicines used to treat tuberculosis**
- **some medicines used to treat HIV or AIDS**
- **some medicines used to treat fungal infections**
- **some medicines used to treat sleep disorders**
- **some medicines used to treat inflammatory conditions such as gout**
- **some antibiotics used to treat bacterial infections**
- **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 during and for 7 to 28 days after treatment with the other medicines. 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:

- **certain medicines used to prevent rejection after an organ transplant**
 - **certain drugs for asthma**
 - **certain medicines used to treat epilepsy**
- **Remind your doctor that you are taking the Pill if you take any of the above medicines.**

Laboratory tests

If you are scheduled for any laboratory tests, tell your doctor you are taking the Pill. Certain blood tests may be affected by the Pill.

2.6 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 Ovranette if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Ovranette.

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

2.8 Driving and using machines

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

2.9 Ovranette contains lactose and sucrose

Ovranette contains the sugars, lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using Ovranette.

3. How to take Ovranette

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

3.1 How to take it

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

Take Ovranette every day for 21 days

Ovranette 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 Ovranette after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

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

3.2 Starting Ovranette

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

Either take your first Ovranette 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

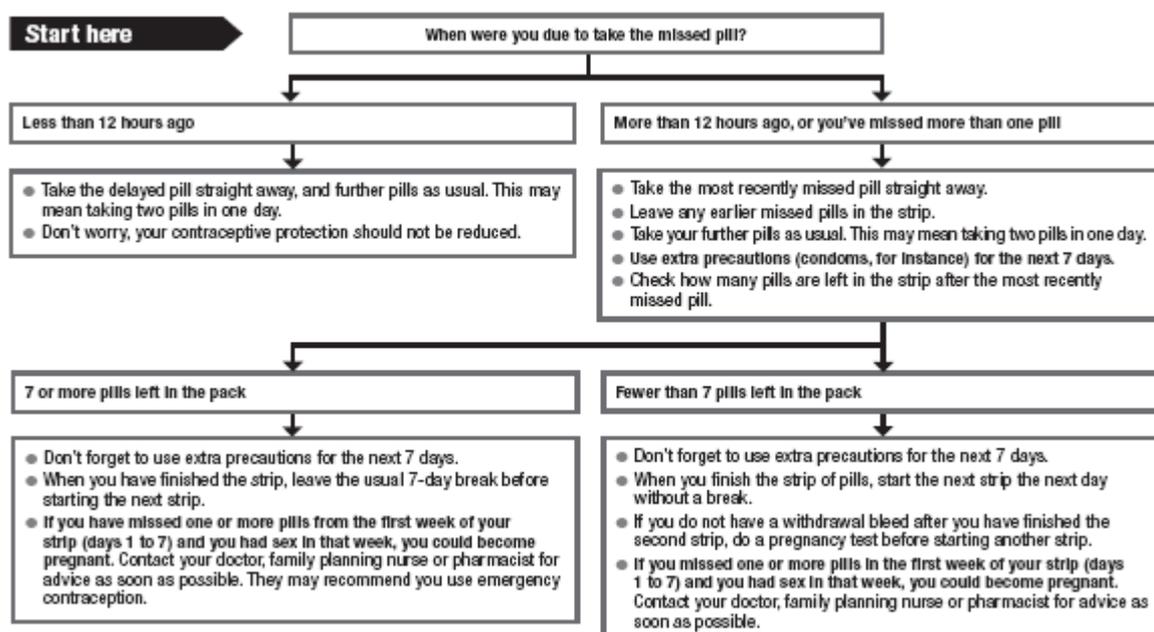
You can start using Ovranelte after 21 days if you are **not** breast-feeding and had a vaginal delivery with no complications and you are fully mobile.

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 If you forget to take Ovranelte

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 within 4 hours after taking your Ovranelte, your body may not get its usual dose of hormones from that pill. Take another pill as soon as you are able to and continue to take your next pills at your usual time. If you are still sick or have diarrhoea for more than 24 hours after taking Ovranelte, follow the instructions in section 3.3, If you forget to take Ovranelte.

→ **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 If you take more Ovranelte than you should

It is unlikely that taking more than one pill will do you any harm, but you may feel sick or vomit; have breast tenderness or abdominal pain; feel dizzy, drowsy or tired; or you may have some vaginal bleeding. You should talk to your doctor as soon as possible if you have any of these symptoms.

3.7 Taking Ovranelte for something other than contraception

Your doctor may have prescribed Ovranelle 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.

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

4. Possible side effects

Like all medicines, this medicine 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 Ovranelle.

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 Ovranelle:

- **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 Ovranette.

4.2 Other possible side effects

Very common (affect more than 1 in 10 women)

- Headaches including migraines (but if it is severe, or the headache is unusual or long lasting, see a doctor as soon as possible)
- Breakthrough bleeding or spotting

Common (affect less than 1 in 10 women)

- Infections of the vagina including thrush
- Feeling sick (nausea) or being sick (vomiting)
- Stomach pain or cramps
- Changes in weight
- Change in mood including depression or low mood
- Dizziness
- Nervousness
- Change in sex drive
- Acne
- Sore, painful or tender breasts
- Changes in the secretion from the breast, enlargement of breasts

Uncommon (affect less than 1 in 100 women)

- Diarrhoea
- Changes in appetite
- Change in menstrual flow
- Rash
- Brown patches on your face or body (chloasma)
- Hives (urticaria)
- Fluid retention resulting in swollen ankles, hands or feet
- Increase in blood pressure
- Changes in the fat levels in your blood (e.g. high triglyceride levels)

Rare (affect less than 1 in 1000 women)

- Change in glucose tolerance
- Contact lenses may feel uncomfortable
- Painful red lumps on skin (erythema nodosum)
- Pink-red blotches on skin (erythema multiforme)
- Period pain (dysmenorrhea), lack/absence of periods (amenorrhea)
- Vaginal discharge

Very rare (affect less than 1 in 10,000 women)

- Inflammation of the pancreas (pancreatitis)
- New gallbladder disease and worsening of existing gallbladder disease
- Worsening of chorea (a nerve disease causing sudden movements of the body)
- Worsening of systemic lupus erythematosus
- Problems at the back of your eye which may cause partial or complete loss of vision (retinal vein thrombosis)
- Worsening of porphyria (a rare disease of the blood pigments)
- Liver tumour

Other adverse events include:

- Worsening of varicose veins
- Crohn's disease, ulcerative colitis (Inflammatory bowel disease)

- Bloating
- Herpes gestationis (skin rash with fluid-filled blisters during pregnancy)

→ **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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ovranelte

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

Store Ovranelte at or below room temperature.

Do not use this medicine after the expiry date which is stated on the blister strip and the carton. The expiry date refers to the last day of the 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 Ovranelte contains

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

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

What Ovranelte looks like and contents of the pack

Each carton of Ovranelte contains three strips of 21 tablets. Ovranelte tablets are packed in aluminium foil/pvc blister strips. Each strip of Ovranelte contains 21 white tablets.

Each blister strip is packed inside an aluminium foil pouch together with a silica gel desiccant sachet. The silica gel desiccant should be thrown away on opening the pouch.

Ovranette is available in pack sizes of 1, 3 and 50 blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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[Pfizer Logo]

Company Contact Address: For further information on your medicine, please contact Medical Information at the following address: Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS; Tel 01304 616161.

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