Package leaflet:
Information for the patient

Ovranette®
150 micrograms/ 30 micrograms coated tablets

levonorgestrel and ethinylestradiol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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 side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ovranette is and what it is used for

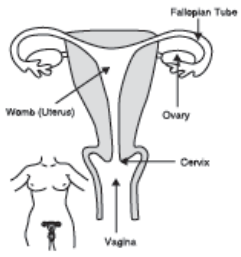
The name of your medicine is Ovranette.

Ovranette is an oral contraceptive.

How the female reproductive system works

Once a month, an egg (or ovum) is released from one of the ovaries and passes along the Fallopian tube to the womb. Fertilisation, (the joining together of the male's sperm with the female's egg) usually takes place while the egg is still in the Fallopian tube. The fertilised egg embeds itself in the wall of the womb, which has been specially prepared to receive it, and it grows into a baby.

If fertilisation does not take place, then the egg leaves the body in the next menstrual period.



What do your tablets do?

Ovranette is a combined oral contraceptive (COC), one of a group of drugs often referred to as the Pill. It contains two types of hormone: an estrogen, ethinylestradiol and a progestogen, levonorgestrel. These hormones stop the ovary from releasing an egg each month (ovulation). They also thicken the fluid (mucus) at the neck of the womb (cervix), making it more difficult for the sperm to reach the egg, and alter the lining of the womb to make it less likely to accept a fertilised egg.

Medical research and vast experience have shown that, if taken correctly, the Pill is an effective reversible form of contraception.

Sexually transmitted diseases

Ovranette will not protect you against HIV infection (AIDS) or other sexually transmitted diseases. If you think you are at risk you should use a condom in addition to the Pill.

2. What you need to know before you take Ovranette

Do not take Ovranette:
- If you are allergic to levonorgestrel or ethinylestradiol or any of the other ingredients of this medicine (listed in section 6)
- If you have had a heart attack or stroke
- If you have or have had heart disease
- If you have blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism) or eyes
- If you have blood clots in the deep veins of your legs
- If you have any condition, or a family history of a condition, which may put you at an increased risk of blood clots
- If you have known or suspected breast cancer
- If you have cancer of the lining of the womb, cervix or vagina
- If you have a liver tumour (non-cancerous or cancerous)
- If you have liver disease and your liver is not yet back to normal
- If you have chest pains (angina pectoris)
- If you have migraine with focal symptoms, such as aura
- If you have uncontrolled high blood pressure
- If you have diabetes which has affected your blood vessels
- If you have unexplained vaginal bleeding (until a diagnosis is reached by your doctor)
- If you have known or suspected pregnancy
- If you are breast-feeding
- If you have inflammation of the pancreas (pancreatitis) associated with very high level of fat in the blood (cholesterol or triglycerides)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ovranette.

Tell your doctor if you or a member of your family have ever had:
- Breast nodules, fibrocystic disease of the breast, or an abnormal breast X-ray or mammogram
- Diabetes
- High cholesterol or triglycerides
- High blood pressure
- Migraine, severe headaches or epilepsy
- Depression
- Gallbladder, heart or kidney disease

If you are worried about whether the Pill is suitable for you, or if you have suffered from or think you may have suffered from, any of the conditions mentioned above, see your doctor to ask for his/her advice.

Warning for Patients
- While you are receiving this medication, you should see your doctor regularly for examination. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman.
- If you have any unusual symptoms such as unexplained pains in the chest, tummy or legs you must consult your doctor immediately.
- This product 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 taking this medicinal product.

Information for smokers

Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with the extent of smoking and is marked in women over 35 years of age. Women who use oral contraceptives are advised not to smoke.

The Pill and Thrombosis (blood clots)

Studies suggest that women who take the Pill have an increased risk of developing a blood clot which can block a vein or artery (thrombosis). This can have severe effects, including the risk of a heart attack or stroke. Full recovery from these disorders may not always happen and in rare cases they can be fatal. There have been reports of blood clots affecting the liver, intestines and kidneys. These reports, however, are extremely rare and may not be associated with COCs.

The increased risk of developing a blood clot in a vein (venous thrombosis) when taking the Pill is lower than the risk during pregnancy, which is estimated to be about 60 cases in 100,000 pregnancies. This increased risk is highest during the first year a woman ever uses a combined oral contraceptive. For healthy women who are not on the Pill or pregnant, the risk is estimated to be about 5 to 10 cases in 100,000 women in one year.

Some studies suggest that for oral contraceptives containing less than 50 micrograms of ethinylestradiol the estimated risk ranges from about 20 to 40 cases in 100,000 women in one year, but this risk estimate varies according to the progestogen.

Women who have blood or heart disease, high blood pressure, lipid disorders, high cholesterol, diabetes, smoke, are overweight, have migraines, or are older, are at an increased risk of arterial thrombosis.

Women who are overweight, or are older, or are immobile or inactive due to an operation or accident, have recently had a baby or had an abortion in the second three months of pregnancy, or have a family history of venous thrombosis are at risk of developing venous thrombosis.

Stroke

Women with high blood pressure or who smoke have a greater risk of stroke. This risk is highest in women older than 35 years who smoke and have high blood pressure. Combined oral contraceptive users with migraine (particularly migraine with aura) may also be at increased risk of stroke.

If any of these conditions apply to you, or you are worried about your risk of developing a blood clot, you should discuss the matter fully with your doctor.

Women over 35 years

The Pill is not recommended for women older than 35 years who smoke because the risk of developing thrombosis is greater in these women. The Pill may not remain suitable for older women. If you are older than 35 years you should discuss with your doctor whether you should continue taking the Pill or consider another method of contraception. It is very important that you have regular check-ups, including having your blood pressure taken, so that your doctor can make sure you can continue to take the Pill.

The Pill and Cancer

Every woman is at risk of breast cancer whether or not she takes the Pill. Breast cancer is rare under the age of 40 years, but the risk increases as a woman gets older.

Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill this reduces the risk, so that 10 years after stopping the Pill the risk of finding breast cancer is the same as for women who have never taken the Pill. Breast cancer seems less likely to have spread when it was found in women who take the Pill than in those women who do not take the Pill.

It is not certain whether the Pill causes the increased risk of breast cancer. It may be that women taking the Pill are examined more often so that breast cancer is noticed earlier. The risk of finding breast cancer is not affected by how long a woman takes the Pill but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older. Cancer of the liver has rarely been reported in long-term users of the Pill. Non-malignant liver tumours have also been linked with women taking the Pill. Discontinuation of the Pill may be necessary with sudden or long-term disturbances of the liver, do not take the Pill until liver function has returned to normal.

Some studies suggest that oral contraceptives may increase your risk of cancer of the cervix (cervical cancer) – although this may be due to differences in sexual behaviour, rather than the Pill. All women should have regular smear tests.
Chronic infection with the Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer. You should consider these possible risks alongside the benefits of taking the Pill.

Ocular Lesions

There have been case reports of retinal thrombosis (closure of the central retinal artery causing sudden, usually nearly complete, loss of vision) with the use of oral contraceptives. Oral contraceptives should be discontinued if there is unexplained partial or complete loss of vision; rapid swelling of an eyeball; double vision or any sudden changes to your eyesight.

Gallbladder Disease

An increased relative risk of gallbladder disease in users of oral contraceptives and estrogens has been reported in some studies.

Bleeding Irregularities

With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 tablet taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

If you have missed tablets and then do not get a withdrawal bleeding in the first normal tablet-free interval, the possibility of pregnancy must be considered.

If you have missed taking one (or more) pills, and have had unprotected sexual intercourse; you may be pregnant. Ask your doctor or pharmacist about emergency contraception.

Some women who are no longer taking this product may experience post-pill amenorrhea (absence of menstrual period) or oligomenorrhea (infrequent or very light menstrual period), especially when such a condition was pre-existent.

Other Conditions

Some conditions that you already suffer from may be made worse by taking the Pill. Tell your doctor if you think any of the following problems get any worse while you are taking the Pill:
- severe depression
- varicose veins
- high blood pressure
- diabetes
- the disorder of metabolism known as porphyria
- liver problems
- systemic lupus erythematosus (SLE – a disease of the connective tissue)
- heart disease
- kidney disease
- brown patches on the face and body like those that occur in pregnancy (chloasma)
- fibroids of the womb (non-cancerous (benign) tumors that grow from the muscle layers of the womb)
- problems wearing contact lenses
- migraine
- gallstones
- disturbance of vision
- Sydenham's Chorea (a disease characterized by rapid, uncoordinated jerking movements affecting primarily the face, feet and hands)
- pemphigoid gestationis (a blistering skin disease that occurs during pregnancy)
- otosclerosis- related hearing loss
- lipid disorders (high or low levels of fat in your blood)
- calcium deficiency with muscle cramps (tetany)
- inflammation of the veins (phlebitis)
- swelling of face, eyes, mouth or difficulty breathing

Tell your doctor as soon as possible if you suffer from any of the above conditions for the first time while taking the Pill.

<u>Make sure your doctor knows if you have any other disease.</u>

Physical Examination

Your doctor will have given you a check-up before prescribing Ovranette and this should be repeated regularly. Blood pressure should be measured, and the check-up should include examination of your womb and surrounding organs, breasts, pelvis and abdomen. Your doctor should also note your family history.

A PAP smear should be performed if the patient has been sexually active or if it is otherwise indicated.

Ovranette should be stopped four weeks before planned operations, or during periods when you are unable to move (for example after accidents). You should not take Ovranette for two weeks after surgery or during bed rest. This is because the risk of getting blood clots is increased by many surgical operations and by periods of inactivity. It may also be increased after injuries, such as fractures.

Other medicines and Ovranette

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Several medicines may interfere with the way the Pill works. You may need to use a nonhormonal method of contraception during and at least 7 days after any cycle in which you take drugs that can make COCs less effective. If you are continuing to take these drugs beyond the end of the tablets in the COC pack, the next COC pack should be started without the usual tablet-free interval. Always mention that you are on the combined pill if you are prescribed any medicines.
Some medicines may prevent your Pill from working, and may cause breakthrough bleeding
(bleeding in between periods) and irregular periods. These include:
- medicines used to treat epilepsy such as phenytoin, primidone, carbamazepine, oxycarbazepine, topiramate, felbamate
- some drugs used to treat tuberculosis (rifabutin)
- phenylbutazone, dexamethasone (an anti-inflammatory medicine)
- modafinil (for excessive daytime sleepiness)
- some drugs used to treat HIV/AIDS (some protease inhibitors such as ritonavir and nevirapine)
- some sedatives and tranquillisers (called 'barbiturates')
- griseofulvin (a medicine used to treat fungal infections)
- drugs that speed up the passage of food through your body reduce gastrointestinal transit time
- certain antibiotics (e.g. rifampicin)
- the herbal remedy commonly known as St John's wort (Hypericum perforatum)

You may have to use another method of contraception as well, such as a condom, while you are taking these medicines - and for a further seven days afterwards. In some cases you may need to continue to use additional barrier contraception for several weeks after you have stopped taking the medicine. Your doctor can tell you if this is necessary and for how long.

In addition, follow the advice in the sub section 'If you forget to take Ovranette' in section three of this leaflet.

The herbal remedy, St John's wort: Breakthrough bleeding and unintended pregnancies have been reported in women taking the Pill and St John's wort, may stop oral contraceptives from working properly and should not be taken at the same time as this medicine. If you are already taking a St John's wort preparation, stop taking St John's wort and tell your doctor at your next visit. If the Pill and St. John's wort are used concomitantly, a non-hormonal backup method of birth control is recommended e.g. a condom.

Some medicines may decrease the activity of your liver enzymes. This may cause the blood levels of the ingredients in your Pill to rise. Examples of these medicines include atorvastatin, indinavir, fluconazole and troleandomycin.

Drugs that affect absorption of your Pill in your intestines (e.g. ascorbic acid (vitamin C) and paracetamol) may also have this affect.

Your Pill may affect the way that other drugs work, or increase the risk of potential side effects. These include some drugs that are broken down by your liver (e.g. ciclosporin and theophylline) and the drugs flunarizine and lamotrigine.

Before you have any blood tests
Tell your doctor that you are taking the Pill, because oral contraceptives interfere with some tests.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you become pregnant stop taking your tablets immediately and consult your doctor. Use another method of contraception, such as a condom, until the pregnancy is confirmed.

Small amounts of contraceptive steroids and/or metabolites have been identified in the milk of nursing mothers, and a few adverse effects on the child have been reported, including jaundice and breast enlargement.

The use of the Pill is generally not recommended until the nursing mother has completely weaned her child.

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

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

3. How to take Ovranette

TAKING YOUR TABLETS
Always take Ovranette exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

About the pack
The memo pack has been designed to help you to remember when to take your tablets. The pack is marked with the day of the week on which each pill should be taken. If you are ever in any doubt about whether you have taken your pill, a glance at the appropriate day on the memo pack will tell you.

Starting the first pack
When no hormonal contraceptive has been used in the past month:
Take the first pill on the first day of your period. This is day one of your cycle, the day when bleeding starts. You will be protected at once. If you start on any other day of your period, you should use another method of contraception as well, such as the condom, for the first seven pill-taking days, but this is only for the first pack.

You can take your pill at any time, but you should take it about the same time each day. You may find it convenient to take it either last thing at night or first thing in the morning. Take a pill every day in the order shown until you finish all 21 pills in the pack.

Once you have taken all 21 pills, stop for seven days. You will probably bleed during some of these seven days.

You do not need to use any other form of contraception during the seven-day break provided you have taken the 21 pills properly and you start the next pack on time.

The next pack
After seven pill-free days, start your next pack. Do this whether or not you are still bleeding. You will always start a new pack on the same day of the week.

Starting after childbirth or pregnancy
After a birth, abortion or miscarriage, your doctor should advise you about taking the Pill. After a miscarriage or abortion in the first three months of pregnancy you can start using Ovranette immediately.

If you have had a baby with a normal delivery without any later complications, and are fully mobile and are not breast-feeding or you have had an abortion in months four, five or six of pregnancy, you can start taking Ovranette 28 days after delivery or abortion. Additional contraception such as a condom, must be used for the first seven days of pill-taking. If you have had unprotected sex after day 21 you should not start Ovranette until your period starts.

If you are breast feeding, the combined Pill is not recommended because it can reduce your flow of milk. If you have any questions about starting Ovranette after childbirth or pregnancy, ask your doctor or pharmacist.

If you are changing to Ovranette after taking another Pill
If you are changing to Ovranette after taking another Pill, follow your doctor's instructions.

When changing from another 21-day combined Pill, start taking Ovranette the next day after the end of the previous course. If you are changing from a 28-day combined pill, start taking Ovranette the day after you take the last active pill in the previous course.

In either of these cases a withdrawal bleed (period) should not be expected until the end of the first course of Ovranette. No additional contraception is required.

Switching from a progestin-only method of birth control (e.g. progestin only Pill, implant, intrauterine device (IUD), or an injection)
If you are changing from a progestogen only pill (POP), you can stop taking the POP any day and start taking Ovranette on the next day at the same time. An additional form of contraception, such as the condom, should be used for the first seven days of pill-taking.

If you are changing from an injectable or implant contraceptive you can start using Ovranette when your next injection is due or on the day your implant is removed. An additional form of contraception, such as the condom, should be used for the first seven days of pill-taking.

Any pills left in packs after changing your Pill should be returned to your pharmacist or doctor.

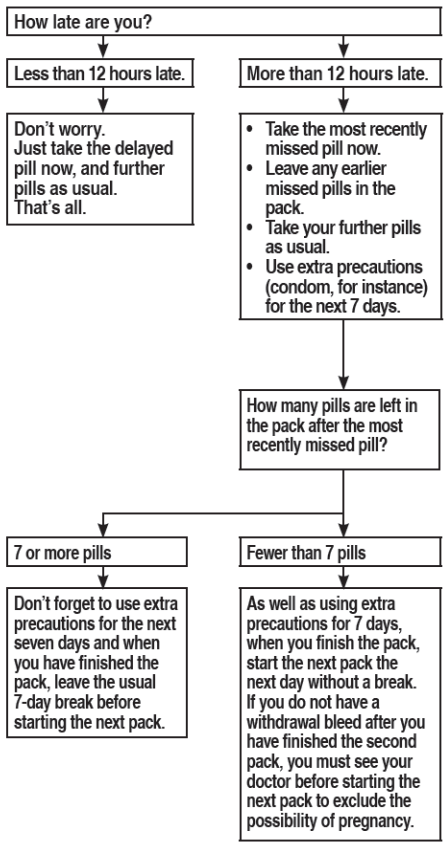
If you miss a period
If you have taken all your pills correctly it is unlikely you are pregnant. However, you should make sure that you are not pregnant before you start your next pack.

If you take more Ovranette than you should
Taking too many tablets might cause nausea (feeling sick), vomiting (being sick), breast tenderness, dizziness, tummy pain, and drowsiness/fatigue. Withdrawal bleeding may occur in some females. In case of overdose, contact your doctor or pharmacist.

If you forget to take Ovranette
If you are **less than 12 hours late** in taking your pill, take it as soon as you remember, and carry on taking your Pills as normal.

If you are **more than 12 hours late** in taking one or more pills, take the last missed pill as soon as you remember, even if it means taking two pills in one day, continue to take further pills as usual and use extra contraception (condom, for instance) for the next seven days. If these 7 days run beyond the end of the pack, start the next pack immediately, without a gap. In this case a withdrawal bleed (period) should not occur until the end of the second pack. If you do not have a withdrawal bleed (period) then, consult your doctor before starting the next pack.

This advice is summarised by following the diagram:



If you have been sick or had diarrhoea
If you have been sick or had diarrhoea the Pill may not work. If the sickness or diarrhoea happens within 4 hours after taking the Pill follow the instructions under "If you forget to take Ovranette for "If you are less than 12 hours late in taking your Pill"." The extra tablet should be taken from a back-up pack. If the sickness or diarrhoea happens more than 4 hours after taking the pill, continue to take it, but you may not be protected from the first day of vomiting or diarrhoea. Use another method, such as a condom, for any sexual intercourse during the sickness and diarrhoea and until you start your next pack.

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

4. Possible side effects

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

If you get any of the side effects gets serious, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

If you become pregnant stop taking your tablets immediately and consult your doctor. Use another method of contraception, such as a condom, until the pregnancy is confirmed.

Occasionally some side-effects could be more serious. TELL YOUR DOCTOR STRAIGHT AWAY IF YOU GET ANY OF THESE SYMPTOMS AFTER TAKING YOUR TABLETS:

- Swelling of the face, lips or throat which makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Ovranette.
- Severe sudden onset of rash
- Severe headache or migraine
- Difficulties in seeing or speaking
- Pain or swelling in the legs
- Fainting
- Pain in the chest or stomach
- Shortness of breath
- Numbness in an arm or leg
- Coughing with blood
- Breast lumps

Your doctor will probably stop Ovranette if:

- You become jaundiced
- Your blood pressure is raised
- You have any condition which can worsen with the Pill and shows signs of getting worse (see section 2)

If you have bleeding while you are taking the Tablets
You may at first have some breakthrough bleeding, or spotting, whilst you are taking your tablets, but your periods should settle down after a few months. However, if the bleeding is heavy, continuous or keeps returning, see your doctor.

Ovranette may cause some minor side effects. Tell your doctor if the following symptoms bother you:

Very common: may affect more than 1 in 10 people

- Headache, migraines
- Breakthrough bleeding/spotting

Common: may affect up to 1 in 10 people

- Abdominal (tummy) pain
- Feeling or being sick
- Changes in body weight
- Changes in interest in sex (libido)
- Mood changes, depressive moods, nervousness
- Dizziness
- Breast pain or tenderness, breast enlargement, breast secretion
- Acne
- Irregular bleeding or missed bleeds
- Fluid retention or swelling
- Vaginal infections such as thrush

Uncommon: may affect up to 1 in 100 people

- Changes in appetite
- Abdominal cramps, bloating
- Diarrhoea
- Rash, brown patches on the face and body like those that occur in pregnancy (chloasma), itching
- Hair thinning or unusual hairiness
- Increase in blood pressure
- Changes in serum lipid levels, including hypertriglyceridemia

Rare: may affect up to 1 in 1,000 people

- Anaphylactic/anaphylactoid reactions (swelling of the face, lips or throat which makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Ovranette)
- Angioedema
- Glucose intolerance
- Problems with contact lenses
- Discharge from your breasts
- Changes in vaginal discharge
- Cholestatic jaundice
- Erythema nodosum, erythema multiform
- Decrease in serum folate levels

Very rare: may affect up to 1 in 10,000 people

- Gallbladder disease (including gallstones)
- Pancreatitis (inflammation of the pancreas)
- A blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail)
- Herpes gestationis
- Exacerbation of systemic lupus erythematosus – SLE (an inflammatory disease which can affect many parts of the body, including the skin, joints and internal organs), porphyria and Sydenham's Chorea (a movement disease)
- Optic neuritis inflammation of the optic nerve (may lead to partial or complete loss of vision)
- Aggravation of varicose veins
- Retinal vascular thrombosis (blood clot of the eye)
- Ischaemic colitis (inflammation and injury of the large intestine result from inadequate blood supply)
- Hepatic adenomas (benign liver tumors)
- Hepatocellular carcinomas (cancer of the liver)
- Erythema multiforme (fever and rash of the face, arms and legs)

Not known: frequency cannot be estimated from available data

- Hepatocellular injury (e.g. hepatitis, hepatic function abnormal)
- Inflammatory bowel disease (Crohn's Disease, ulcerative colitis), including worsening of these conditions

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ovranette

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 blister pack and carton after 'EXP'.

The expiry date refers to the last day of that month.

Do not store your tablets above 25°C.

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 Ovranette contains
The active substances are levonorgestrel and ethinylestradiol. Each tablet contains 150 micrograms of levonorgestrel and 30 micrograms of ethinylestradiol.

The other ingredients are: lactose monohydrate, sucrose (see section 2 Ovranette contains lactose and sucrose), maize starch, povidone 25, magnesium stearate, talc, polyethylene glycol 6000, calcium carbonate, white wax and carnauba wax.

What Ovranette looks like and contents of the pack
Each Ovranette carton contains one blister strip of 21 white, sugar coated tablets. Each blister strip is packed inside a foil pouch together with a silica gel desiccant sachet. Do not take the silica gel desiccant. Throw away the desiccant sachet when you open the foil pouch.

Manufacturer
Haupt Pharma Münster GmbH, Schleebrüggenkamp 15, D-48159 Münster, Germany

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Parallel Product Authorisation Number
PPA 465/431/1

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Date leaflet prepared by PCO Manufacturing: August 2017