

HARMONET 75 microgram/20 microgram Coated Tablets **Gestodene and Ethinylestradiol**

PATIENT INFORMATION LEAFLET (Republic of Ireland)

Please read this carefully before you start to take your tablets. Keep this leaflet you may need to read it again. This leaflet provides only a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

What's in your tablets?

The name of your medicine is Harmonet Tablets.

Harmonet is supplied in a carton containing one blister pack of tablets.

The blister strip may be packaged inside an aluminium 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.

Each blister pack of tablets contains 21 white tablets, each containing 75 micrograms of gestodene and 20 micrograms of ethinylestradiol.

Your tablets also contain: lactose, maize starch, povidone, magnesium stearate, sucrose, polyethylene glycol 6000, calcium carbonate, talc and wax E.

Harmonet is an oral contraceptive.

The Product Authorisation is held by:

Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24
Ireland

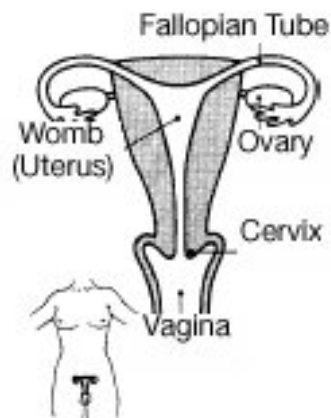
The Manufacturer is:

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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 is shed in the next menstrual period.



What do your tablets do?

Harmonet is a combined oral contraceptive, one of a group of drugs often referred to as the Pill. It contains two types of hormone: an estrogen, ethinylestradiol, and a progestogen, gestodene. 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.

BEFORE YOU TAKE YOUR TABLETS

Reasons for not taking Harmonet

You should **not** take Harmonet if you have any of the following conditions:

- Heart attack or stroke
- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism) or eyes
- Blood clots in the deep veins of your legs
- Any condition, or a family history of a condition, which may put you at an increased risk of blood clots
- Known or suspected breast cancer
- Cancer of the lining of the womb, cervix or vagina
- Liver tumour (non-cancerous or cancerous)
- Liver disease and your liver is not yet back to normal
- Chest pains (angina pectoris)
- Migraine with focal symptoms, such as aura
- Uncontrolled high blood pressure
- Severe diabetes which has affected your blood vessels
- Unexplained vaginal bleeding (until a diagnosis is reached by your doctor)
- Known or suspected pregnancy or you are breast feeding
- Allergy to any of the ingredients of Harmonet
- An inflammation of the pancreas (pancreatitis)

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 your suitability to take the Pill or you have suffered from or think you may have suffered from, any of the disorders mentioned above, see your doctor and ask 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, abdomen 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.

What you should know before you take Harmonet

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 should be 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 heart attack or stroke. Full recovery from these disorders may not always occur and in rare cases they can be fatal.

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 women in one year. 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 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 cases in 100,000 women in one year for levonorgestrel containing contraceptives (known as “second generation” pills) to 40 cases in 100,000 women in one year for desogestrel/gestodene containing contraceptives (known as “third generation” pills).

Harmonet is a third generation pill containing gestodene with 20 micrograms of ethinylestradiol. No information is available comparing the risk of VTE for Harmonet with that for pills containing 30 micrograms or more of ethinylestradiol

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

Women who are overweight, or are older, 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.

Women with a 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.

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, who should discuss with their doctor whether they 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 found in women who take the Pill than in 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 taking it. 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 Pill usage. 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 research has shown an increased risk of cancer of the neck of the womb (cervix) in long-term Pill takers, but it is unclear how much this increase is due to the Pill.

Chronic infection with the Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer.

These possible risks should be considered together with the benefits of the Pill.

Other conditions

Some conditions 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); heart disease; kidney disease; brown patches on the face and body like those that occur in pregnancy (chloasma); fibroids of the womb; problems wearing contact lenses; migraine; disturbance of vision; Sydenham's Chorea; pemphigoid gestationis; otosclerosis- related hearing loss; lipid disorders; 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.

Make sure your doctor knows if you have any other disease.

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.

Physical Examination

Your doctor will have given you a check-up before prescribing Harmonet 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.

Harmonet 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 Harmonet for two weeks after surgery or during bed rest. This is because the risk of developing blood clots is increased by many surgical operations and by periods of inactivity. It may also be increased after injuries, such as fractures.

If you are taking other medicines

Several medicines may interfere with the way the Pill works. Medicines that increase the activity of your liver enzymes may prevent your Pill from working, and may cause breakthrough bleeding and irregular periods. These include some drugs used to treat epilepsy tuberculosis, and HIV/AIDS, some sedatives and tranquillisers and the drugs griseofulvin and modafinil. Other medicines that do not affect your liver enzymes may also have this effect. These include drugs that speed up the passage of food through your body and certain antibiotics. You may have to use another method of contraception as well, such as the condom, while you are taking these medicines - and for a further seven days afterwards. Your doctor may advise you to use these extra precautions for even longer. In addition, follow the advice for "what to do if you forget to take a Pill" (see later).

If you are taking antibiotics, always ask your doctor's advice about extra precautions. Always mention that you are on the combined pill if you are prescribed any medicines

The herbal remedy, St John's wort (*Hypericum perforatum*), may prevent oral contraceptives from working properly and should not be taken at the same time as this medicine. If you are already taking St John's wort preparation stop taking St John's wort and tell your doctor at your next visit.

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.

Sexually transmitted diseases

Harmonet 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.

TAKING YOUR TABLETS

About the pack:

The memo blister has been designed to help you to remember to take your tablets. Each pill is marked with a number. Start taking Harmonet Tablets on the first day of menstrual bleeding by taking tablet 1 that is beside the word START. Press the blister pocket next to the day of the week on which you have taken the first tablet, ensuring that you break the foil on the other side. This will be your start day for every new pack.

Your start day (day 1) and days 8 and 15 will always fall on the same day of the week. These have a square border so that you can check to see that you are taking the tablets correctly.

It will act as a reminder if you press the blister pocket indicating your start day on any other Harmonet pack that you may have been prescribed.

Pack sizes containing more than 1 blister will have a detachable wallet that can be used to protect your current blister.

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 easiest 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 Harmonet immediately.

If you have had a baby, and had a normal delivery without any later complications, are fully mobile and are not breast-feeding, or you have had an abortion in the second three months of pregnancy, you can start taking Harmonet 28 days after delivery or abortion. Alternative contraception such as the 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 Harmonet 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 Harmonet after childbirth or pregnancy, ask your doctor or pharmacist.

If you are changing to Harmonet after taking another Pill

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

When changing from another 21-day combined Pill, start taking Harmonet the next day after the end of the previous course. If you are changing from a 28-day combined pill, start taking Harmonet the day after you take the last active pill in the previous course. In either of these cases a withdrawal bleed should not be expected until the end of the first course of Harmonet. No additional contraception is required.

If you are changing from a progestogen only pill (POP), you can stop taking the POP any day and start taking Harmonet 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 Harmonet 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.

In case of an overdose

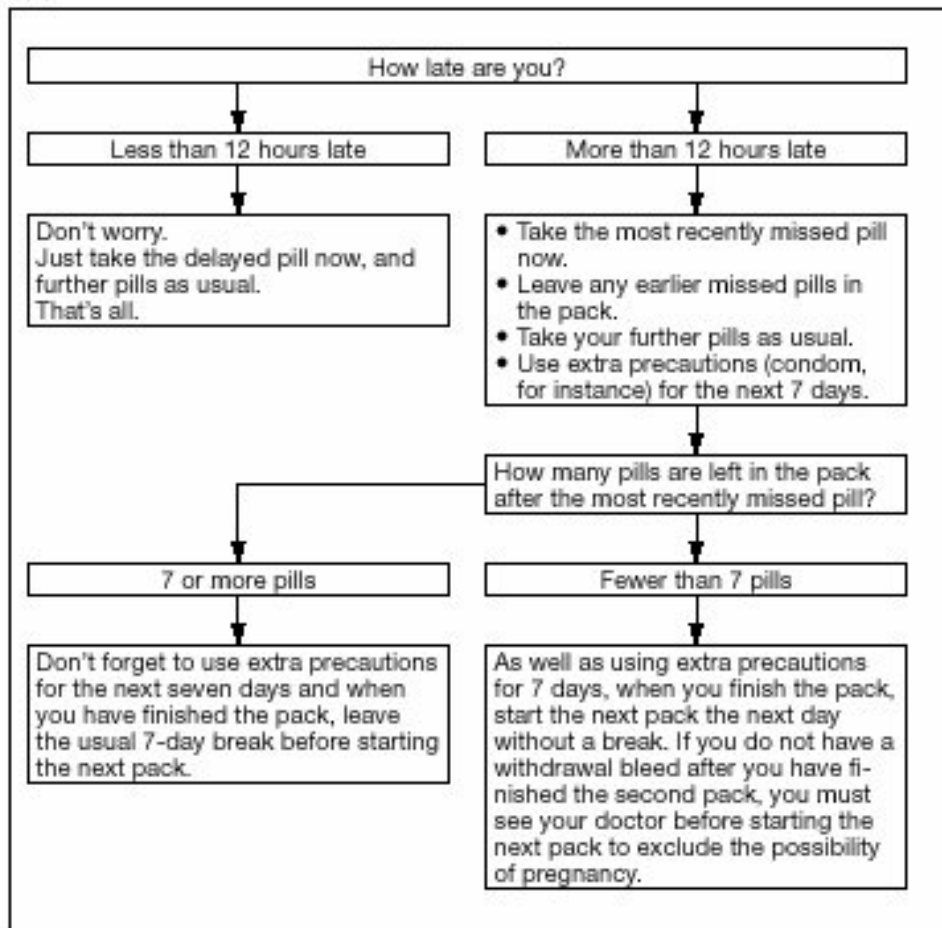
Overdosage may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, and drowsiness/fatigue. Withdrawal bleeding may occur in females. In case of overdose, contact your doctor or pharmacist.

What to do if you forget to take your pill

If you are **less than 12 hours late** in taking your pill, take it as soon as you remember, and further pills as usual.

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 7 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 should not occur until the end of the second pack. If you do not have a withdrawal bleed then, consult your doctor before starting the next pack.

This advice can be summarised by the following diagram:



If you have a stomach upset

If you have been sick or had diarrhoea the Pill may not work. If the sickness or diarrhoea occurs within 4 hours after taking the Pill follow the instructions above 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 occurs 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 intercourse during the stomach upset and until you start your next pack.

THINGS TO BE AWARE OF WHILST TAKING YOUR TABLETS

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.

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

- Abdominal pain/cramps
- Feeling or being sick, changes in appetite
- Changes in body weight
- Changes in interest in sex (libido)
- Depressive moods, nervousness
- Dizziness
- Headaches

- Tender breasts, breast secretions
- Skin problems such as acne or rash, brown patches on the face and body like those that occur in pregnancy (chloasma) itching
- Irregular bleeding or missed bleeds
- Fluid retention or bloating
- Changes in vaginal discharge, vaginal infections such as thrush
- Problems with contact lenses
- Hair thinning or unusual hairiness

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

- 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 Harmonet 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 “What you should know before you take Harmonet”)

Very rare side effects seen with oral contraceptives include gallbladder disease, pancreatitis, haemolytic uraemic syndrome.

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.

Tell your doctor or pharmacist if you get any other unwanted effect not mentioned here.

STORING YOUR TABLETS

Do not use your pack of Harmonet after the expiry date on the pack.

Do not store your tablets above 25°C.

Keep blister in the outer carton to protect from light.

Keep your tablets out of the reach and sight of children. Your tablets could harm them.

Return any unused tablets to your pharmacist. Only keep them if your doctor tells you to.

REMEMBER these tablets are only for you. Only a doctor can prescribe them for you. Never give these tablets to others. They may harm them.

IE HT 007 Grouped Var for DPM, Haupt and excipient commitment

This leaflet was last revised in October, 2013.

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