Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Harmonet®
Coated tablets

Each coated tablet contains:
ethinylestradiol 0.02 mg
gestodene 0.075 mg

Inactive ingredients and allergens: See section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Harmonet® is a preparation for birth control that belongs to a group of medicines called "contraceptive pills".
Each tablet contains two female hormones, estrogen (ethinylestradiol) and progestogen (gestodene).

Therapeutic group: Combined oral contraceptive pills, a combination of estrogen and progestogen.

Several important things to know about combined hormonal contraceptives:

- When used correctly, combined hormonal contraceptives are one of the most reliable reversible contraceptive method.
- They slightly increase the risk of thrombosis (blood clots) in the veins and arteries, especially during the first year or upon resuming intake after stopping for 4 weeks or more.
- Be vigilant and contact your doctor if you are concerned that you suffer from any symptoms of a blood clot (see section 2, "Harmonet® and thrombosis (blood clots)").

2. BEFORE USING THIS MEDICINE

Before you start taking Harmonet®, you should read the information about thrombosis (blood clots) in section 2. It is especially important to read the part about the symptoms of thrombosis (see section 2, "Harmonet® and thrombosis (blood clots)").

Do not use this medicine if:

You are in any of the following situations. If you are in any of the situations listed below, you must tell your doctor. Your doctor will discuss with you other contraceptive methods that are more suitable for you. If any of these situations appears for the first time while using Harmonet®, you should contact your doctor immediately.

- You are sensitive (allergic) to ethinylestradiol or to gestodene or to any of the other ingredients in this medicine (listed in section 6).
- You have (or have ever had) a blood clot in a blood vessel in the leg (deep vein thrombosis, DVT), lung (pulmonary embolism, PE), eyes or any other organ (see "Harmonet® and thrombosis (blood clots)").
- You know that you suffer from a blood coagulation disorder, for example, protein C deficiency, protein S deficiency, antithrombin III deficiency, factor V Leiden mutation or presence of anti-phospholipid antibodies.
- You are going to have an operation or if you are expected to be in a situation of prolonged immobility (see "Harmonet® and thrombosis (blood clots)").
- You have ever had a heart attack or stroke (CVA).

- You suffer from a headache or you have (or have ever had) a type of migraine called "migraine with aura" (with an unusual sensation, such as flashes of light).
- You suffer from heart valve disorders or heart rhythm disorders.
- You have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be an initial sign of a heart attack) or a transient ischaemic attack (TIA - temporary stroke symptoms).
- You have one of the following diseases, which may increase the risk of a blood clot formation in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - very high levels of blood fats (cholesterol and triglycerides)
  - an illness known as hyperhomocysteinaemia
- You have (or have ever had) breast, uterus or liver cancer (see "Contraceptive pills and cancer").
- You have severe liver disease.
- You have unexplained vaginal bleeding.
- If you are pregnant or think you may be pregnant.
- You have or have ever had inflammation of the pancreas, which has been linked to a severe increase in the level of lipids in the blood.

Do not use Harmonet® if you have hepatitis C (viral liver inflammation) and are treated with medicines containing ombitasvir, paritaprevir, ritonavir and dasabuvir or glecaprevir/pibrentasvir (see also "Other medicines and Harmonet®").

Special warnings regarding use of the medicine:

<u>Seek immediate medical attention:</u>

- **If you notice possible symptoms of a blood clot, which could indicate that you have a blood clot in a leg (i.e., deep vein thrombosis), a blood clot in a lung (pulmonary embolism), a heart attack or stroke (see "Harmonet® and thrombosis (blood clots)").**

For information about the symptoms of these serious side effects, see section 2 "How to recognize symptoms of a blood clot"**.**

If you have one or more of the following conditions, consult your doctor before taking Harmonet®.

If one or more of the following conditions develops or gets worse while you are using Harmonet®, you should also consult your doctor.

- If you smoke (especially if you are over the age of 35), see "Harmonet® and thrombosis (blood clots)"
- If someone in your immediate family has had a disease caused by blood clots, such as deep vein thrombosis, pulmonary embolism, heart attack or stroke, see "Harmonet® and thrombosis (blood clots)"
- If you are overweight, see "Harmonet® and thrombosis (blood clots)"
- If you suffer from migraines
- If you have (or have ever had) one or more cysts in the breast and someone from your immediate family has had breast cancer
- If you have uterine fibroids (a benign non-cancerous tumour)
- If you have a disease of the liver or gallbladder (gallstones)
- If you have had a biliary disorder while taking contraceptive pills or during pregnancy
- If you suffer from a hypersensitivity reaction called angioedema
- If you suffer or have suffered from severe depression
- If you have (or have ever had) a chloasma (brown spots on the skin called a "pregnancy mask", particularly on the face). In such case, you should avoid excessive exposure to the sun or UV rays

- If you suffer from Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases)
- If you suffer from systemic lupus erythematosus (SLE - a disease affecting the immune system)
- If you suffer from haemolytic uraemic syndrome (HUS - a blood clotting disorder which may cause kidney failure)
- If you suffer from sickle-cell anaemia (a hereditary disease of the red blood cells)
- If you suffer from high levels of fats in the blood (hypertriglyceridaemia) or a family history of this condition. Hypertriglyceridaemia has been linked to an increased risk of pancreatitis (inflammation of the pancreas)
- If you have given birth several weeks ago, or if you have undergone a second trimester termination of pregnancy, you are at an increased risk of blood clot formation. You should ask your doctor how soon you can start using Harmonet® after giving birth or after a second trimester termination of pregnancy
- If you suffer from an inflammation of the veins under the skin (superficial thrombophlebitis)
- If you have varicose veins

Pay attention to certain conditions which may be worsened while taking the pills, such as asthma, epilepsy, herpes occurring during pregnancy (herpes gestationis), hyperprolactinaemia, a condition called chorea or “Saint Vitus' Dance” (a disease characterized by rapid, uncoordinated jerking body movements primarily affecting the face, feet and hands) and otosclerosis (a disease of the inner ear).

Harmonet® like other contraceptive pills, does not protect against HIV infection (AIDS) or other sexually transmitted diseases.

Psychiatric disorders

Some women who use hormonal contraceptives including Harmonet® have reported depression or a depressed mode. Depression can be severe and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms, contact your doctor as soon as possible for further medical advice.

Harmonet® and thrombosis (blood clots)

Using combined oral contraceptives such as Harmonet® increases the risk of developing blood clots, compared to the risk observed in women not using such contraceptives. In rare cases, a blood clot can block blood vessels and cause serious problems.

Blood clots can develop:

- in the veins [venous thrombosis, venous thromboembolism (VTE)]
- in the arteries [arterial thrombosis, arterial thromboembolism (ATE)].

Full recovery is not always achieved following a blood clot. In rare cases, they can cause serious and lasting damage, and in very rare cases this can be fatal.
It is important to remember that the overall risk of a blood clot due to the use of Harmonet® is low.

How to recognize symptoms of a blood clot

Contact your doctor immediately if you notice one or more of the following symptoms.

Do you experience any of the following signs?	You probably suffer from
• swelling of one leg or along the length of a vein in the leg or foot, especially if this is accompanied by: o pain or sensitivity in the leg, only manifested when standing or walking	Deep vein thrombosis

o sensation of warmth in the affected leg o changes in colour of the skin of the leg, for example, becoming pale, red or blue	
• sudden, unexplained shortness of breath or rapid breathing • sudden cough without apparent cause, which may contain blood • acute pain in the chest, which may be exacerbated by deep breathing • sensation of light-headedness or dizziness • rapid or irregular heartbeat • intense pain in the abdomen If you are not sure, contact your doctor as soon as possible, as some of these symptoms, such as coughing or shortness of breath, may be mistakenly diagnosed as signs of a mild condition such as a respiratory infection (for example the common cold).	Pulmonary embolism
Signs that usually appear in one eye: • immediate loss of vision or • painless blurred vision that can develop into loss of vision	Retinal vein thrombosis (a blood clot in the eye blood vessel)
• pain, discomfort, pressure, heaviness in the chest • sensation of tightness or congestion in the chest, arm or under the breastbone • sensation of congestion, indigestion or suffocation • sensation of discomfort in the upper body, radiating to the back, jaw, throat, arm and abdomen • sweating, nausea, vomiting or dizziness • extreme weakness, anxiety or shortness of breath • rapid or irregular heartbeat	Heart attack
• sudden weakness or numbness in the face, arm or leg, especially on one side of the body • sudden confusion, difficulty speaking or understanding • sudden difficulty seeing in one or both eyes • sudden onset of difficulty walking, dizziness, loss of balance or coordination • sudden severe or prolonged headache with no known cause • loss of consciousness or fainting, with or without seizure Sometimes symptoms of stroke may be very short-lived, with an almost immediate and complete recovery, but you must still seek urgent medical treatment, as you may be at risk of another stroke.	Stroke (CVA)

• swelling and slightly bluish colouring of the extremities • acute pain in the abdomen (“acute abdomen”)	Blood clots blocking other blood vessels (such as those of the liver, intestines or kidneys)

Venous thrombosis

What can happen if a blood clot forms in a vein?

- Use of combined hormonal contraceptives is associated with an increased risk of developing blood clots in the veins (venous thrombosis). However, this side effect is rare. It can most frequently occur during the first year of using a combined hormonal contraceptive.
- When a blood clot develops in a vein in the leg or foot, it may cause deep vein thrombosis.
- If a blood clot migrates from the leg to the lung, it may cause pulmonary embolism.
- In very rare cases, a blood clot may form in a vein in another organ, such as the eye (retinal vein thrombosis).

When is the risk of developing a venous blood clot highest?

The risk of developing a blood clot in a vein is highest during the first year of using a combined hormonal contraceptive for the first time. The risk may also be increased when you resume taking a combined hormonal contraceptive (the same preparation taken previously or a different preparation) after a break of 4 weeks or more.
After the first year, the risk is reduced, but it will always be slightly higher compared to the situation of not taking a combined hormonal contraceptive. When you stop taking Harmonet®, the risk of developing a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your baseline predisposition to venous thrombosis and the type of combined hormonal contraceptive you are taking.
The overall risk of a blood clot in a leg or lung (deep vein thrombosis or pulmonary embolism) due to the use of Harmonet® is low.

- Of 10,000 women using no combined hormonal contraceptive and who are not pregnant, approximately 2 women will develop a blood clot within one year.
- Of 10,000 women using a combined hormonal contraceptive containing levonorgestrel, norethisterone or norgestimate, approximately 5-7 will develop a blood clot within one year.
- Of 10,000 women using a combined hormonal contraceptive containing gestodene, like Harmonet®, approximately 9-12 will develop a blood clot within one year.
- The risk of developing a blood clot will vary depending on your medical history (see “Factors increasing your risk of blood clot formation in a vein” below).

	Risk of developing a blood clot in a year
Women who **do not use** a combined hormonal contraceptive (pill/patch/ring) and who are not pregnant	Approximately 2 women in 10,000
Women who use a combined hormonal contraceptive containing **levonorgestrel, norethisterone or norgestimate**	Approximately 5-7 women in 10,000
Women using Harmonet®	Approximately 9-12 women in 10,000

Factors increasing your risk of blood clot formation in a vein:

The risk of blood clot formation due to the use of Harmonet® is low, but some situations may increase this risk.

The risk will be higher:

- if you are very overweight (BMI greater than 30 kg/m^2).
- if a member of your immediate family has had a blood clot in the leg, lung or another organ at a relatively young age (before 50 years of age). If this is the case, you might have a hereditary blood coagulation disorder.
- if you are going to have an operation, or if you are in a situation of prolonged immobility because of an injury or illness, or at least one of your legs are immobilised (in cast, for example). It may be necessary to stop using Harmonet® several weeks before surgery or while your mobility is reduced. If you need to stop using Harmonet®, ask your doctor when you can start taking Harmonet® again.
- with age (especially over the age of 35 years).
- if you have given birth or if you have undergone a second trimester termination of pregnancy several weeks ago.

The risk of developing a blood clot increases the more risk increasing situations you have.

Air travel (for more than 4 hours) may temporarily increase the risk of a blood clot, especially if you have other risk increasing situations.
It is important to tell your doctor if any of the above situations applies to you, even if you're not certain. Your doctor may decide that you need to stop taking Harmonet®.
If one or more of these situations changes while you are using Harmonet®, for example, if a close family member experiences thrombosis with no known reason, or if you've gained a lot of weight, tell your doctor.

Arterial thrombosis

What can happen if a blood clot forms in an artery?

As with a blood clot in a vein, a blood clot in an artery may cause serious problems. For example, it may cause a heart attack or a stroke.

Factors increasing your risk of blood clot formation in an artery:

It is important to note that the risk of heart attack or stroke due to the use of Harmonet® is very low, but may increase:

- with age (especially over the age of 35 years).
- **if you smoke.** When you are taking a combined hormonal contraceptive such as Harmonet®, it is recommended to stop smoking. If you are unable to stop smoking and if you are over 35 years of age, your doctor may advise you to use a different method of contraception.
- if you are overweight.
- if you have high blood pressure.
- if a member of your immediate family has had a heart attack or stroke at a relatively young age (below the age of 50). If this is the case, the risk of a heart attack or stroke may be higher for you.
- if you or a close family member have a high level of blood fats (cholesterol or triglycerides).
- if you suffer from migraines, especially migraines with aura.
- if you have a heart problem (heart valve disorders, arrhythmia called atrial fibrillation).
- if you are diabetic.

If you have more than one of these situations, or if any one of them is particularly severe, the risk of blood clot formation may be even higher.

If any of these situations changes while you are using Harmonet®, for example if you start smoking, if a member of your immediate family experiences thrombosis with no known reason, or if you've gained a lot of weight, tell your doctor.

Contraceptive pills and cancer

Established risk factors for the development of breast cancer include age, family history, obesity, no childbirth in the past and first pregnancy and childbirth at an older age.

Breast cancer has been diagnosed at a slightly higher incidence in women taking pills compared to women of the same age not taking pills. This moderate increase in the number of

breast cancer diagnoses gradually disappears 10 years after discontinuing the pill. It is not known if this difference is caused by use of the pill. It is possible that women taking pills are examined more carefully and more often, so that breast cancer is detected at an earlier stage. Taking the pill may also increase the risk of cervical cancer, but this has not been scientifically proven.

In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in women taking the pill. The risk of developing such tumours increases with the duration of taking the pill, but remains overall low nevertheless.

When should you contact your doctor?

Tests and follow up
Your doctor will instruct you to arrive for regular medical examinations. In general, the frequency and nature of these examinations will depend on individual medical factors. Your doctor will assess the information obtained and provide you with the necessary explanations.

Contact your doctor immediately in the following cases:

- if you experience any signs of thrombosis (see “How to recognize symptoms a blood clot” above)
- if you feel a lump in or near the breast
- contact your doctor at least four weeks in advance if you are going to have an operation or if you are expected to be in a situation of prolonged immobility (see “Harmonet® and thrombosis (blood clots)”)
- if you have given birth or if you have undergone a second trimester termination of pregnancy several weeks ago (see “Harmonet® and thrombosis (blood clots)”)
- if you experience unusual heavy vaginal bleeding
- if you think you may be pregnant
- if your period does not start during the week without the pill.

Other medicines and Harmonet®

If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

When your doctor, including your dentist, wants to prescribe you a new medicine, you should inform him that you are taking Harmonet®. In certain cases, your doctor will advise you to use another contraceptive for a certain period while taking this medicine.

Certain medicines may decrease the effectiveness of the pill in pregnancy prevention; these include:

- certain medicines for treatment of epilepsy (primidone, phenytoin, barbiturates, topiramate, phenylbutazone, carbamazepine or felbamate)
- griseofulvin (a medicine for treatment of fungal infections)
- some medicines for treatment of HIV/AIDS (protease inhibitors) and other viral infections (ritonavir)
- rifampicin (for treatment of tuberculosis)
- preparations containing the Hypericum perforatum plant (St John's wort)
- modafinil (a medicine for treatment of sleep disorders)
- dexamethasone (a medicine for treatment of certain inflammatory and autoimmune diseases)

Oral contraceptives can influence the results of certain laboratory tests. Inform your doctor that you are taking Harmonet® if you are going to have a blood test.

Do not use Harmonet® if you have hepatitis C (viral liver inflammation) and are taking medicines that contain ombitasvir, paritaprevir, ritonavir and dasabuvir or glecaprevir/pibrentasvir, because this may cause an increase in the value of blood tests results for liver function (increase in the liver enzyme ALT).

Your doctor will prescribe you other contraceptives before starting treatment with these medicines.

Approximately two weeks after the end of treatment with these medicines, Harmonet® use can be started again. See section “Do not use this medicine if”.

Using this medicine and food

Harmonet® may be taken with food or drinks.

Pregnancy, breastfeeding and fertility
Pregnancy
Do not use the medicine if you are pregnant or if pregnancy is suspected.
If you are planning to become pregnant, consult your doctor or pharmacist.

Breastfeeding
Do not use the medicine if you are breastfeeding.

Driving and using machines
The effect on the ability to drive or use machines while using Harmonet® has not been studied.

Important information about some of this medicine’s ingredients
Harmonet® contains lactose and sucrose. If your doctor has told you that you have an intolerance to certain sugars, contact the doctor before taking this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

Each blister pack of Harmonet® contains 21 pills. For each pill, the day of the week when it should be taken is indicated on the pack. **The standard dosage is usually:** one pill each day, at the same time, in the order indicated by the arrows on the blister pack, for 21 days. Do not take any pills for 7 days following the period of 21 days on which you have taken Harmonet®. Your menstrual period will start during the 7 days on which you don't take the pill (usually on the third day after taking the last pill in the blister pack).
After the 7 day break, start a new pack on the eighth day, whether the menstrual period has ended or not. Following these instructions, you will always start a new blister pack on the same day of the week and your menstrual period will start around the same day every four weeks.
Taking the pill is not indicated for women who have not yet had their first menstrual period or for post-menopausal women.
Swallow the pill whole. There is no information about crushing, splitting or chewing the pill.

Starting the first pack

How to start your first pack if you have not used hormonal contraceptives in the last month?
Take the first pill on the first day of your menstrual period in accordance with the day of the week marked on the blister pack. For example, if your menstrual period starts on a Friday, take a pill marked “FRI” on the blister pack.

Switching to Harmonet® from other combined contraceptive pills
Take Harmonet® the day after taking the last active pill from the blister pack of the previous pills.

Switching to Harmonet® from a pill containing progesterone only
If you are switching to Harmonet® from a pill containing progesterone only, you can stop taking the pill containing progesterone only on any day and start taking Harmonet® the day after you stop talking the progesterone only pill. You must use an additional non-hormonal method of contraception (such as a condom or spermicide) during the first 7 days of taking the first blister pack.

Switching to Harmonet® from injectable or implanted contraceptives or an IUD
If you are switching to Harmonet® from an injectable contraceptive, an implant or an IUD, you can start using Harmonet® on the day the implant or IUD is removed or on the day that was scheduled for your next injection. You must use an additional non-hormonal method of contraception (such as a condom or spermicide) during the first 7 days of taking the first blister pack.

If you have undergone a first trimester termination of pregnancy
You can start taking Harmonet® immediately.

If you have given birth or if you have undergone a second trimester termination of pregnancy
Your doctor may advise you to start taking Harmonet® from the 28th day after childbirth or after a second-trimester termination of pregnancy. You must use an additional non-hormonal, method of contraception (such as a condom or spermicide) during the first 7 days of taking the first blister pack. If you have already had sexual intercourse during this period, you must make sure that you are not pregnant before you start taking Harmonet® or wait until the menstrual period begins.

If unexpected bleeding occurs
Unexpected bleeding (spotting) may occur between menstrual periods, especially during the first months of use. In general, this irregular bleeding stops once your body has become used to the pill (after about three blister packs). Nevertheless, if the unexpected bleeding persists or appears for the first time after prolonged use of Harmonet®, contact your doctor immediately.

If no bleeding occurs after completing the blister pack
If menstrual bleeding has not started after 7 days of discontinuing the pill and you have taken all the pills properly, you are unlikely to be pregnant. Start the next blister pack on the eighth day. However, if the menstrual period has not started after taking two complete blister packs, contact your doctor immediately and do not start the next blister pack before you have his approval.

If you have accidentally taken a higher dosage of Harmonet®
There are no known cases of serious harm after taking too many Harmonet® tablets.
Taking too many Harmonet® tablets may cause nausea, vomiting, abdominal pain, dizziness, drowsiness/tiredness, breast tenderness, or slight vaginal bleeding.
Special treatment is probably unnecessary.
If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you**.**
In case of an overdose or any abnormal use, contact your doctor or pharmacist.

If you forget to take Harmonet®
The contraceptive efficacy of the pill is maintained only if **less than 12 hours have passed since the time at which you should have taken the pill**. Take the pill as soon as you remember, and continue taking the next pills at the usual time.
If **more than 12 hours have passed since the time at which you should have taken the pill**, or if you have missed more than one pill, the contraceptive efficacy of the pill may be reduced. In such case:

- Take the last forgotten pill immediately when you remember and continue taking the rest of the pills at the usual time, even if that means taking 2 pills on the same day. Continue taking Harmonet® until the end of the blister pack.
- In addition, use an additional non-hormonal method of contraception (such as a condom or a spermicide) for 7 days. If the 7-day period requiring the use of an additional method of contraception extends beyond the day on which you take the last pill in the current blister pack, start the next blister pack on the day after taking the last pill of the current blister pack (i.e. with no break).

In any case, consult your doctor.

If you experience diarrhoea or vomiting
If you experience diarrhoea or vomiting within 3 to 4 hours after taking the pill, the active ingredients in Harmonet® may have not been absorbed adequately by your body. This situation is similar to forgetting to take a pill. Therefore, after vomiting or diarrhoea, take an

additional pill from a spare blister pack. If the diarrhoea or vomiting persists, consult your doctor.

If you want to stop taking Harmonet®
When you stop taking Harmonet®, your menstrual period may not return spontaneously (post-treatment amenorrhoea). You must consult your doctor in such case.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Harmonet® may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

If you experience any side effect, especially if it is severe or persistent, or if you notice any change in your health and you are concerned that it may result from using Harmonet®, contact your doctor.

There is an increased risk of formation of blood clots in the veins (venous thromboembolism) or in the arteries (arterial thromboembolism) for all women using combined hormonal contraceptives. For more detailed information, see section 2, “Before using this medicine”. The serious side effects associated with the use of the pill are described in the sections “Harmonet® and thrombosis (blood clots)” and “Contraceptive pills and cancer”. Read these sections for more information.

Contact your doctor immediately if you experience any of the following symptoms:

- swelling of one leg or along the length of a vein in the leg or foot
- sudden, unexplained shortness of breath or rapid breathing
- sudden cough without apparent cause, which may contain blood
- acute pain in the chest, which may be exacerbated by deep breathing
- sensation of light-headedness or dizziness
- rapid or irregular heartbeat
- intense pain in the abdomen, acute pain in the abdomen (acute abdomen)
- immediate loss of vision or painless blurred vision which can develop into loss of vision, that usually appear in one eye
- sensation of pain, discomfort, pressure, heaviness in the chest
- sensation of tightness or congestion in the chest, arm or under the breastbone
- sensation of congestion, indigestion or suffocation
- sensation of discomfort in the upper body, radiating to the back, jaw, throat, arm and abdomen
- sweating, nausea or vomiting
- extreme weakness, anxiety or shortness of breath
- sudden weakness or numbness in the face, arm or leg, especially on one side of the body
- sudden confusion, difficulty speaking or understanding
- sudden difficulty seeing in one or both eyes
- sudden onset of difficulty walking, loss of balance or coordination
- sudden severe or prolonged headache with no known cause
- loss of consciousness or fainting, with or without seizure
- swelling and slight cyanosis of the extremities
- if you feel a lump in or near the breast

Additional side effects:

Very common side effects – effects occurring in more than 1 in 10 users:

- Headache, migraine

- Bleeding between menstrual periods (spotting)

Common side effects – effects occurring in 1-10 in 100 users:
- Vaginal infection including vaginal fungal infection
- Changes in mood (e.g. depression) or changes in sexual drive
- Nervousness or dizziness
- Nausea, vomiting or abdominal pain
- Acne
- Pain, tension, enlargement of the breasts and secretion from breasts
- Painful menstrual bleeding or changes in the menstrual blood flow, absence of menstrual periods
- Changes in secretions from the cervix
- Fluid retention or oedema
- Weight gain or loss

Uncommon side effects – effects occurring in 1-10 in 1,000 users:
- Changes in appetite
- Abdominal cramps, bloating
- Rash, appearance of dark spots on the face which may persist, excessive hair growth, hair loss
- Increased blood pressure, changes in lipid levels in the blood

Rare side effects – effects occurring in 1-10 in 10,000 users:
- Allergic reactions, including very rare cases of urticaria, allergic oedema of the face (angioedema), severe respiratory and circulatory disorders
- Glucose intolerance
- Intolerance to contact lenses
- A blood clot in a vein or an artery, for example:
  - in a leg or foot (deep vein thrombosis)
  - in a lung (pulmonary embolism)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack
  - in very rare cases, blood clots in the liver, stomach/intestine, kidneys or one eye

The risk of developing a blood clot may be higher if you have other conditions that increase the risk (see section 2 for more information on factors that increase the risk of blood clots and the symptoms of blood clots).
- Jaundice due to obstruction of bile ducts
- Nodular erythema (erythema nodosum)
- Decrease in folic acid levels in the blood (This is very important if you become pregnant immediately after discontinuing Harmonet®)

Very rare side effects – effects occurring in less than one in 10,000 users:
- Increased risk of benign liver tumour, malignant liver tumour
- Aggravation of lupus erythematosus
- Aggravation of porphyria (accumulation of porphyrin in the tissues)
- Aggravation of chorea (a movement disorder)
- Inflammation of the optic nerve (may lead to partial or complete blindness)
- Aggravation of varicose veins
- Inflammation of the pancreas, inflammation of the colon due to lack of oxygen
- Gallstones, decreased bile secretion (Harmonet® may aggravate existing gallbladder disorders or lead to the onset of such disorders)
- Blistering rash (erythema multiforme)
- Haemolytic uraemic syndrome (a condition of renal failure caused by blood clots)

Side effects of unknown frequency:
- Inflammatory bowel disease (Crohn's disease, ulcerative colitis)
- Liver damage (for example liver inflammation, abnormal liver function)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- **Prevent poisoning!** This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in a dry place, below 25˚C.
- Keep the blister pack in the carton packaging or in the carrying case in order to protect from light.

6. FURTHER INFORMATION

In addition to the active ingredients, this medicine also contains:
Lactose hydrouse 80 Mesh, sucrose, maize starch, calcium carbonate, talc, polyethylene glycol 6000, povidone K-25, magnesium stearate, povidone K-90, wax pharma E.

Each tablet also contains 37.505 mg lactose and 19.661 mg sucrose.

What the medicine looks like and contents of the pack:
- A carton package containing one blister pack of 21 white tablets.
- A carton package containing 3 blister packs, each blister pack contains 21 white tablets.

The carton package contains a carrying case intended to protect the blister you are using.

Not all pack sizes may be marketed.

Registration holder and address:
Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach 46725

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 121-88-30272

Revised in 10/2021 according to MOH guidelines.