Package leaflet: Information for the user

Mistra 2 mg / 0.03 mg film-coated tablets
dienogest and ethinylestradiol

Important things to know about combined hormonal contraceptives (CHCs):
- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots").

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mistra 2 mg/0.03 mg film-coated tablets is and what it is used for

Mistra 2 mg/0.03 mg film-coated tablets is a medicinal product
- to prevent pregnancy (contraceptive "pill").
- For treatment of women with moderate acne who agree to receive a contraceptive pill after failure of suitable local or oral antibiotic treatments.

Mistra 2 mg/0.03 mg film-coated tablets is a combined oral contraceptive (COC), one of a group of drugs often referred to as the pill.
Each tablet contains two types of female hormones: an oestrogen ethinylestradiol, and a progestogen, dienogest.
The combined contraceptive pill protects you against getting pregnant in three ways:
1. stop the ovary from releasing an egg each month (ovulation).
2. also thicken the fluid (at the neck of the womb) making it more difficult for the sperm to reach the egg.
3. alter the lining of the womb to make it less likely to accept a fertilised egg.

Mistra 2 mg/0.03 mg film-coated tablets belongs to the group of drugs often referred to as "micro pills" due to its low hormone content, "combined pills" due to the two types of hormone in the pill and monophasic oral contraceptives due to the identical composition of each tablet.

Mistra 2 mg/0.03 mg film-coated tablets alleviates pimples (acne) in women caused by the excessive quantity of male sex hormones called "androgens" that are present in every woman.

2. What you need to know before you take Mistra 2 mg/0.03 mg film-coated tablets

General notes
Before you start using Mistra 2 mg/0.03 mg film-coated tablets you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see Section 2 "Blood clots").

In this leaflet there are some cases when you need to stop taking the Mistra 2 mg/0.03 mg film-coated tablets or the effectiveness of the pill may reduce. In these cases either do not have sex, or use extra non-hormonal contraceptive precautions (such as condoms or another barrier method) during intercourse to ensure effective contraception. Do not use the calendar method or measurement of body temperature on waking because oral contraceptives may influence body temperature and the cyclical change of composition of the mucus of the neck of womb.

Remember, combined oral contraceptive pills like Mistra 2 mg/0.03 mg film-coated tablets will not protect you against sexually-transmitted diseases (such as AIDS). Only condoms can help to do this.

Mistra 2 mg/0.03 mg film-coated tablets in acne
Your acne will usually improve between three and six months of treatment, and could continue to improve even after six months. You should discuss with your doctor the need to continue your treatment three to six months after the start and regularly thereafter.

Do not use Mistra 2 mg/0.03 mg film-coated tablets
You should not use Mistra 2 mg/0.03 mg film-coated tablets if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

Do not use Mistra 2 mg/0.03 mg film-coated tablets
- if you are allergic to dienogest or ethinylestradiol or any of the other ingredients of this medicine (listed in section 6);
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance protein C deficiency, protein S deficiency, antithrombin-III-deficiency, Factor V Leiden, antiphospholipid-antibodies;
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots)';
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia;
- if you have or ever had severe liver disease, yellowing of the skin (jaundice). Jaundice or itching of your whole body can be the signs of liver disease;
- if you have liver tumours or if you have ever had these;
- if you have or may have breast cancer or other cancer, for example ovarian cancer, cervical cancer, or cancer of the uterus (womb);
- if you have unusual bleeding from your vagina;
- if you have (or have ever had) a type of migraine called 'migraine with aura'.
- if you have (ever had) an inflammation of the pancreas (pancreatitis).

Do not use Mistra 2 mg/0.03 mg film-coated tablets if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or

sofosbuvir/velpatasvir/voxilaprevir (see also in section “Other medicines and Mistra 2 mg/0.03 mg film-coated tablets”).

If you get any of the above conditions while you are taking Mistra 2 mg/0.03 mg film-coated tablets, do not take any more pills and contact your doctor immediately. In the meantime, use another, non-hormonal method of contraception. See also section “What you need to know before you take Mistra 2 mg/0.03 mg film-coated tablets”.

Tell your doctor before starting to take Mistra 2 mg/0.03 mg film-coated tablets if you know you suffer from any of the above conditions. Your doctor may advise you to use another method of contraception.

Warnings and precautions
Talk to your doctor or pharmacist before taking Mistra 2 mg/0.03 mg film-coated tablets.

When should you contact your doctor?

Seek urgent medical attention
- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see ‘Blood clots’ section below).

For a description of the symptoms of these serious side effects please go to “How to recognise a blood clot”.

Tell your doctor if any of the following conditions apply to you
In certain cases combined oral contraceptives should be taken under strict medical supervision. If you do have any of the following conditions, you must tell your doctor before taking Mistra 2 mg/0.03 mg film-coated tablets.
If the condition develops, or gets worse while you are using Mistra 2 mg/0.03 mg film-coated tablets you should also tell your doctor:
- if you have diabetes;
- if you are very overweight (obese);
- if you have high blood pressure;
- if you have a heart valve disorder or a certain heart rhythm disorder;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins;
- if you or any member of your close family have any medical condition which makes you more at risk of developing blood clots;
- if you have migraine;
- if you have the movement disorder called Sydenham's chorea;
- if you or any member of your close family have a disorder of blood-fat (lipid) metabolism, or other very rare blood disorders;
- if you have liver and/or gall bladder disease (yellowing of the skin, gallstones);
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases);
- if you have jaundice or itching of your whole body;
- if you have systemic lupus erythematosus - SLE (a disease affecting your natural defence system);
- if you have a haemolytic uraemic syndrome - HUS (a disorder of blood clotting causing failure of the kidneys);
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
- if you need an operation, or you are off your feet for a long time (see in section 2 ‘Blood clots’);
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Mistra 2 mg/0.03 mg film-coated tablets;

- if you have the inherited disease called porphyria;
- if you have had the rash known as herpes gestationis;
- if you have the inherited form of deafness known as otosclerosis;
- if you have brown patches on your face and body (chloasma), which you can reduce by staying out of the sun and not using sunbeds or sunlamps;
- if you are smoking: in smokers combined oral contraceptives increase the risk of severe cardiovascular conditions (such as myocardial infarction, stroke); the risk increases with age and the number of cigarettes smoked.
- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- if you have depression or mood changes.

Women over 35 years should be strongly advised not to smoke if they wish to use a COC. If the woman would not quit smoking, other method of contraception should be used, especially when concomitant risk factors are also present.

If any of the above conditions do get worse or you have them for the first time, tell your doctor as soon as you can.

BLOOD CLOTS
Using a combined hormonal contraceptive such as Mistra 2 mg/0.03 mg film-coated tablets increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop
- in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of having a harmful blood clot due to any Mistra 2 mg/0.03 mg film-coated tablets is small.

How to recognise a blood clot

Seek urgent medical attention if you notice any of the following signs or symptoms:

Are you experiencing any of these signs?	What are you possibly suffering from?

- swelling of one leg or along a vein in the leg or foot especially when accompanied by:
  - pain or tenderness in the leg which may be felt only when standing or walking
  - increased warmth in the affected leg
  - change in colour of the skin on the leg e.g. turning pale, red or blue
	Deep vein thrombosis

- sudden unexplained breathlessness or rapid breathing; - sudden cough without an obvious cause, which may bring up blood; - sharp chest pain which may increase with deep breathing; - severe light headedness or dizziness; - rapid or irregular heartbeat - severe pain in your stomach;	Pulmonary embolism

If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	
Symptoms most commonly occur in one eye: - immediate loss of vision or - painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
- chest pain, discomfort, pressure, heaviness - sensation of squeezing or fullness in the chest, arm or below the breastbone; - fullness, indigestion or choking feeling; - upper body discomfort radiating to the back, jaw, throat, arm and stomach; - sweating, nausea, vomiting or dizziness; - extreme weakness, anxiety, or shortness of breath; - rapid or irregular heartbeats	Heart attack
- sudden weakness or numbness of the face, arm or leg, especially on one side of the body; - sudden confusion, trouble speaking or understanding; - sudden trouble seeing in one or both eyes; - sudden trouble 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 the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
- swelling and slight blue discolouration of an extremity; - severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?
- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?
The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Mistra 2 mg/0.03 mg film-coated tablets your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.
The overall risk of a blood clot in the leg or lung (DVT or PE) with Mistra 2 mg/0.03 mg film-coated tablets is small.

- Out of 10 000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10 000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10 000 women who are using a combined hormonal contraceptive that contains dienogest and ethinylestradiol such as Mistra 2 mg/0.03 mg film-coated tablets between about 8 and 11 women will develop a blood clot in a year. The risk of having a blood clot will vary according to your personal medical history (see "Factors that increase your risk of a blood clot" below).

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10 000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10 000 women
Women using Mistra 2 mg/0.03 mg film-coated tablets	About 8-11 out of 10 000 women

Factors that increase your risk of a blood clot in a vein
The risk of a blood clot with Mistra 2 mg/0.03 mg film-coated tablets is small but some conditions will increase the risk. Your risk is higher:
- if you are very overweight (body mass index or BMI over 30 kg/m^2);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Mistra 2 mg/0.03 mg film-coated tablets may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Mistra 2 mg/0.03 mg film-coated tablets ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

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

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Mistra 2 mg/0.03 mg film-coated tablets needs to be stopped.

If any of the above conditions change while you are using Mistra 2 mg/0.03 mg film-coated tablets, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight.

BLOOD CLOTS IN AN ARTERY

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

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using Mistra 2 mg/0.03 mg film-coated tablets is very small but can increase:
- with increasing age (beyond about 35 years);
- **if you smoke**. When using a combined hormonal contraceptive like Mistra 2 mg/0.03 mg film-coated tablets you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- 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 young age (less then about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using Mistra 2 mg/0.03 mg film-coated tablets, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

Mistra 2 mg/0.03 mg film-coated tablets and cancer
Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Psychiatric disorders
Some women using hormonal contraceptives including Mistra 2 mg/0.03 mg film-coated tablets have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Children and adolescents
Mistra 2 mg/0.03 mg film-coated tablets is not indicated for use before the first menstrual bleeding (menarche).

Elderly women
Mistra 2 mg/0.03 mg film-coated tablets is not indicated after menopause.

Other medicines and Mistra 2 mg/0.03 mg film-coated tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Also tell any other doctor or dentist who prescribes another medicine that you use Mistra 2 mg/0.03 mg film-coated tablets. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

Do not use Mistra 2 mg/0.03 mg film-coated tablets if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these products may cause increases in liver function blood test results (increase in ALT liver enzyme).
Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.
Mistra 2 mg/0.03 mg film-coated tablets can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Mistra 2 mg/0.03 mg film-coated tablets".

Some medicines can have an influence on the blood levels of Mistra 2 mg/0.03 mg film-coated tablets and can make it **less effective in preventing pregnancy**, or can cause unexpected bleeding. These include medicines used for the treatment of:
- epilepsy (e.g. barbiturates, carbamazepine, phenytoin, primidone, felbamat, oxcarbazepine, topiramate);
- tuberculosis (e.g. rifampicin);
- HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapin, efavirenz);
- fungal infections (e.g. griseofulvin);
- the herbal remedy St. John's wort. If you want to use herbal products containing St. John's wort while you are already using Mistra 2 mg/0.03 mg film-coated tablets you should consult your doctor first.

Interactions of {Invented Name} with other medicines may likewise lead to increased or pronounced occurrence of side effects.
The following medicines may impair the tolerability of {Invented Name}:
- etoricoxib (for the treatment of arthritis, arthrosis).

Mistra 2 mg/0.03 mg film-coated tablets may influence the efficacy of other medicines, e.g.
- ciclosporin (medicine for suppression of the immune system);
- lamotrigin (a medicine for the treatment of epilepsy);
- tizanidine (medicine used for the treatment of muscle spasticity);
- theophyllin (a medicine for the treatment of asthma).

In women with diabetes the dose of medicines lowering blood sugar (e.g. insulin) may need to be changed.

Ask your doctor or pharmacist for advice before taking any medicine.

Before you have any blood tests
Tell your doctor or the laboratory staff that you are taking the pill, because oral contraceptives can affect the results of some tests.

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

Pregnancy
You must not use Mistra 2 mg/0.03 mg film-coated tablets when you are pregnant. If you become pregnant or you think you might be pregnant, stop taking Mistra 2 mg/0.03 mg film-coated tablets and talk to your doctor immediately.

Breast-feeding

If you are taking Mistra 2 mg/0.03 mg film-coated tablets while you are breast-feeding, the tablet may reduce the quantity and change the composition of breast milk. Small amounts of the contraceptive steroids and/or their metabolites may be excreted with the milk. These amounts may affect the child. Therefore, Mistra 2 mg/0.03 mg film-coated tablets should not be taken during breast-feeding.

Driving and using machines
Mistra 2 mg/0.03 mg film-coated tablet has no influence on the ability to drive and use machines.

Mistra 2 mg/0.03 mg film-coated tablet contains lactose
This medicinal product contains 47.66 mg lactose monohydrate per film-coated tablet. 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 Mistra 2 mg/0.03 mg film-coated tablets

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

The blister pack has been designed to help you remember to take your pills.

The strip contains 21 tablets. Next to each tablet is printed the day of the week that it should be taken. If, for example you start on a Wednesday, take a tablet with "WE" next to it.
Follow the direction of the arrow on the strip until all tablets have been taken.

You should try to take your pill at about the same time each day; if necessary with a little liquid, in the order shown on the blister pack. One tablet is to be taken daily until you have finished all 21 pills in the pack. Then you have 7 days when you do not take a pill. During the 7 pill-free days, on day 2 or 3, you will have menstruation-like withdrawal bleeding, i.e. your monthly period.

Start your next pack on the 8th day (following the 7 pill-free days) – even if the bleeding has not yet ended. As long as you take Mistra 2 mg/0.03 mg film-coated tablets correctly, you will always start each new pack on the same day of the week, and you will always have your monthly period on the same day of the month.

If you take your pills correctly, you will have contraception protection at once.

Starting the first pack

If no oral contraception has been used during the preceding cycle
Take the first pill on the first day of your period. This is the first day of your cycle - the day when bleeding starts. Take a pill marked for that day of the week.
You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

Changing from another combined hormonal contraceptive (combined oral contraceptive (COC), or vaginal ring or transdermal patch)
Start taking Mistra 2 mg/0.03 mg film-coated tablets on the day after you take the last pill from the strip of your previous contraceptive, but at the latest on the day after the tablet-free days of your previous pill.
If your previous pill strip also contains dummy pills, you should start with Mistra 2 mg/0.03 mg film-coated tablets on the day after the last active hormonal intake, but at the latest on the day after the last inactive tablet of your previous pill.

When changing from a vaginal ring or transdermal patch, follow the advice of your doctor.

If you are unclear or have further questions, ask your doctor or pharmacist.

Changing from a progestogen-only method (Progestogen only pill, or minipill, injection, implant or a progestogen releasing intrauterine system IUS)
You can switch from pills only containing progestogen any time, and start taking Mistra 2 mg/0.03 mg film-coated tablets the next day at the usual time, from an implant or IUS on the day of its removal, from an injectable when the next injection would be due, but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

Starting after miscarriage in the first three months of pregnancy
Follow the advice of your doctor.

Starting after having a baby or abortion during the second three months of pregnancy
After having a baby or second-trimester abortion, you can start Mistra 2 mg/0.03 mg film-coated tablets between 21 and 28 days later. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first seven days of Mistra 2 mg/0.03 mg film-coated tablets use. If, after having a baby, you have had intercourse before starting Mistra 2 mg/0.03 mg film-coated tablets (again), you must first be sure that you are not pregnant or you must wait until the next menstrual bleed.

Let your doctor advise you in case you are not sure when to start.

If you are breast-feeding you are allowed to take Mistra 2 mg/0.03 mg film-coated tablets on the instructions of your doctor.

If you think the effect of Mistra 2 mg/0.03 mg film-coated tablets is too weak or too strong for you, consult your doctor.

If you take more Mistra 2 mg/0.03 mg film-coated tablets than you should
No data are available on the overdose with Mistra 2 mg/0.03 mg film-coated tablets. The acute oral toxicity of an overdose with other combined oral contraceptives in adults and children is low. Symptoms that may possibly occur in this case are: nausea, vomiting, breast tension, dizziness, stomach ache, sleepiness, tiredness and, in young girls, slight vaginal bleeding. In general there is no need of special treatment; if necessary, treatment should be symptomatic.

If you notice that a child has taken more than one tablet, turn to a doctor.

If you forget to take Mistra 2 mg/0.03 mg film-coated tablets

*If you are **less than 12 hours** late taking the pill*
You are still protected against pregnancy if you take the late pill as soon as you remember, and keep taking your next pills at the usual time. This may mean taking two pills in one day.

*If you are **more than 12 hours** late taking the pill*
If you are more than 12 hours late taking the pill, your protection against pregnancy might be reduced. The risk of a pregnancy is higher if you forget to take the pill at the start of a pack or before the end of a pack.

In this case you should follow the following rules.

If you have missed more than one pill
If you have missed more than one pill, ask your doctor for advice. Please remember, that your contraceptive protection is failed.

What to do if you miss the pill at the first week
You must take the last missed tablet as soon as you remember, even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You must also use a barrier method of contraception, e.g. a condom, for the next 7 days. If

intercourse has taken place during the preceding 7 days, the possibility of pregnancy must be considered. Contact your doctor as soon as possible for advice.

What to do if you miss the pill at the second week
You must take the last missed tablet as soon as you remember even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. Provided that the tablets have been taken in a correct manner during the 7 days preceding the missed tablet, it is not necessary to take further contraceptive measures.

What to do if you miss the pill at the third week
Provided that all tablets have been taken correctly during the 7 days preceding the first missed tablet and you follow one of the following two alternatives, it is not necessary to take further contraceptive precautions.

1. You should take the last missed tablet as soon as you remember, even if it means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You should then start the next pack immediately after taking the last tablet in the current pack, i.e. without a tablet-free interval between the packs. Withdrawal bleeding is unlikely until the end of the second pack, but there may be some spotting, or breakthrough bleeding, on the days you are taking tablets.

2. You may also stop taking tablets from the current pack. In that case, you should keep a period without tablets of up to 7 days, including those days when you forgot to take your tablets, and thereafter continue with the next pack. If you want to start the new pack on the usual day of the week, you can have a *shorter than 7-day* tablet-free period.

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. In this case you must talk to your doctor before you start the next pack.

What to do if you have a stomach upset
If you have been sick or had diarrhoea within 3-4 hours after taking the pill, the active substances in the pill may not be fully absorbed into your body. In this case the advice concerning missed pills, described above should be followed. Take another pill as soon as possible, *not later than within 12 hours*. If more than 12 hours have elapsed, follow the instructions in section "If you forget to take Mistra 2 mg/0.03 mg film-coated tablets".

What to do if you want to delay your period
If you want to delay your period, you should continue the next pack of Mistra 2 mg/0.03 mg film-coated tablets, after taking the last tablet in the current pack, without a pill-free interval. You can take as many pills from this next pack as you want, until the end of the second blister pack. When you use the second pack, you may have breakthrough bleeding or spotting. Regular intake of Mistra 2 mg/0.03 mg film-coated tablets is resumed after the usual 7-day tablet-free interval.

What to do if you want to shift your period
If you take Mistra 2 mg/0.03 mg film-coated tablets correctly, you will always have your monthly period on the same day of the month. If you want to shift your period to another day of the week, rather than the one you are used to with the present pill intake, you may shorten (but never lengthen) the forthcoming pill-free interval by as many days as you like. For example, if your monthly period usually starts on Friday and you want it to start on Tuesday (i.e. three days earlier), you should start the next pack of Mistra 2 mg/0.03 mg film-coated tablets three days earlier. The shorter the pill-free interval, the greater the possibility that you will not have a withdrawal bleeding, and that you may have breakthrough bleeding or spotting during the second pack.

If you have bleeding between periods
A small number of women may have a little breakthrough bleeding or spotting while taking the pill, especially during the first few months. Normally, this bleeding is nothing to worry about, and will stop in a day or two. You may need to have a sanitary pad or tampon, but keep taking the pills as usual, and

the problem should disappear after the first few packs.

If the bleeding keeps on returning, is annoying or long-lasting, talk to your doctor.

If you miss a period
If you have taken all your pills correctly, and you have not had a stomach upset, or used other medicines, then you are very unlikely to be pregnant. Continue to take Mistra 2 mg/0.03 mg film-coated tablets as usual.

If you have missed your period twice in a row, then you might be pregnant and you should see your doctor immediately. You are only allowed to continue taking the pill after doing a pregnancy test and on your doctor's advice.

If you stop taking Mistra 2 mg/0.03 mg film-coated tablets
You can stop taking Mistra 2 mg/0.03 mg film-coated tablets at any time. If you don't want to become pregnant straight away, ask your doctor for another reliable contraceptive method.

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 side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Mistra 2 mg/0.03 mg film-coated tablets, please talk to your doctor.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "Warnings and precautions").
An increased risk of blood clots in your veins (venous thromboembolism [VTE]) or blood clots in your arteries (arterial thromboembolism [ATE]) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you use Mistra 2 mg/0.03 mg film-coated tablets".
The following adverse drug reactions have been reported during the combined use of dienogest and ethinylestradiol in clinical studies:

Common side effects (may affect up to 1 in 10 people):
- headache,
- breast pain including breast discomfort and breast tenderness.

Uncommon side effects (may affect up to 1 in 100 people):
- inflammation of genitals (vaginitis/vulvovaginitis), fungal infections in the vagina (candidiasis, vulvovaginal infections)
- increased appetite
- depressed mood
- dizziness
- migraine
- high or low blood pressure
- abdominal pain (including pain in the upper and lower abdomen, discomfort/bloating)
- nausea, vomiting, diarrhoea
- acne
- hair loss (alopecia)
- skin rash (including spotty skin rash)
- itching (in some cases of the whole body)
- irregular withdrawal bleedings including strong bleedings (menorrhagia), weak bleedings (hypomenorrhea), rare bleedings (oligomenorrhea) and absence of withdrawal bleeding

(amenorrhea)
- intermenstrual bleeding (vaginal haemorrhagia and metrorrhagia)
- menstrual pain (dysmenorrhea), pelvic pain
- breast enlargement including swelling of the breast, breast edema
- vaginal secretion
- ovarian cysts
- exhaustion including weakness, tiredness and general indisposition
- weight gain.

Rare side effects (may affect up to 1 in 1 000 people):
- inflammation in the uterine tube or ovary
- inflammation of the uterine cervix (cervicitis)
- inflammation of the urinary tract, inflammation of the bladder (cystitis)
- inflammation of the breast (mastitis)
- fungal infections (e.g. candida), virus infections, labial herpes
- flu (influenza), bronchitis, infections of the upper respiratory tract, paranasal infection (sinusitis)
- benign proliferation in the uterus (myoma)
- benign proliferation in the fat tissue of the breast (lipoma of the breast)
- anaemia
- allergic reactions (hypersensitivity)
- masculinisation (virilism)
- loss of appetite (anorexia)
- depression, irritability, mental disorders, aggression
- sleeplessness, sleep disturbances,
- circulation disorders of the brain or of the heart, stroke
- dystonia (muscle disorder, causing e.g. an abnormal posture)
- dry or irritated eyes
- vision disorders (oscillopsia [objects appear to jump, jiggle, or vibrate], deterioration of sight)
- sudden deafness (hearing loss), impairment of the sense of hearing
- tinnitus (ringing in the ears)
- spinning sensation, vertigo
- accelerated heart rate
- increased diastolic blood pressure (the lower blood pressure value increased)
- dizziness or fainting after rising from sitting or lying (orthostatic dysregulation)
- hot flushes
- inflammation of the veins (thrombophlebitis)
- varicose veins (varicoses), vein disorders or vein pain
- asthma
- increase of the respiratory frequency (hyperventilation)
- inflammation of the stomach lining(gastritis), intestinal inflammation (enteritis)
- upset stomach (dyspepsia)
- skin reactions/disorders, including allergic reactions, neurodermatitis (patches of thick, irritated, extremely itchy skin) /atopic dermatitis (itchy, red, swollen, and cracked skin), eczema, psoriasis
- excessive sweating
- golden brown pigment patches (so called pregnancy patches), especially on the face (chloasma), pigment disorders/increased pigmentation
- fatty skin (seborrhoea)
- dandruff
- excessive body hair (hirsutism)
- orange skin (cellulitis)
- spider nevus (a central red spot and reddish extensions which radiate outwards like a spider's web)
- backache, chest pain
- discomfort of bones and muscles, muscle pain (myalgia), pain in the arms and legs
- cervical dysplasia (abnormal growth of cells on the surface of the uterine cervix)

- pain or cysts in the uterine tube and ovaries
- cysts in the breasts, benign proliferations in the breasts (fibrocystic mastopathy), manifestation of additional mammary glands outside of the breast (accessory breasts)
- pain during intercourse
- secretion from mammary glands, (inappropriate production of milk)
- menstruation disorders
- peripheral edema (accumulations of fluid in the body)
- flu-like disease, inflammations, pyrexia (fever)
- increased levels of triglycerides or cholesterol in the blood (hypertriglyceridemia, hypercholesterolemia)
- weight loss or weight changes (increase, decrease or fluctuation)
- harmful blood clots in a vein or artery for example:
    - in a leg or foot (i.e. DVT)
    - in a lung (i.e. PE)
    - heart attack
    - stroke
    - mini-stroke or temporary stroke-like symptoms known as a transient ischaemic attack (TIA)
    - blood clots in the liver, stomach/intestine, kidneys or eye.

  The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

Not known (cannot be estimated from the available data):
- mood changes
- increased or decreased sexual desire (libido)
- eye irritation when wearing contact lenses
- hives (itching)
- erythema nodosum (painful reddish skin nodules)
- erythema multiforme (target-shaped reddish rash or blisters)
- breast discharge
- fluid retention.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Mistra 2 mg/0.03 mg film-coated tablets

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 carton and blister after Exp. The expiry date refers to the last day of that month.

Store below 25ºC. Store in the original packaging in order to protect from light.

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 Mistra 2 mg/0.03 mg film-coated tablets contains?

The active substances are dienogest and ethinylestradiol. Each film-coated tablet contains 2 mg dienogest and 0.03 mg ethinylestradiol.
The other ingredients are:

Tablet core:
Lactose monohydrate
Maize starch
Hypromellose type 2910
Talc
Polacrilin potassium
Magnesium stearate

Film-coating:
Polyvinyl alcohol
Titanium dioxide (E 171)
Macrogol 3350
Talc

What Mistra 2 mg/0.03 mg film-coated tablets looks like and contents of the pack?

White or almost white, round, biconvex film-coated tablets, diameter about 5.5 mm. Engraving on one side: “G53”; other side: without engraving.

Mistra 2 mg / 0.03 mg film-coated tablets are packaged in white PVC/PE/PVDC// Aluminium blisters. The blisters are packed into folding box with package leaflet and etui storage bag is enclosed in each box.

Pack sizes:
21 film-coated tablets
3x21 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Hungary:	Sibilla
Ireland:	Mistra
United Kingdom (Northern Ireland):	Mistra

This leaflet was last revised in 12/2022