Package leaflet: Information for the user

Maxim®
0.030 mg/2.0 mg coated tablet

Active substances: Ethinylestradiol and Dienogest

Read the entire package leaflet carefully before you start taking this medicine.
- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This package leaflet includes:

1. What is Maxim® and what is it used for?

Maxim® is a hormonal combination preparation for women for contraception (combined oral contraceptive, commonly referred to as the "pill"). It contains a progestogen (dienogest) and an estrogen (ethinylestradiol).

In women where an increased effect of male hormones (so-called "androgens") leads to the occurrence of acne, clinical trials have shown that Maxim® improves these conditions.

Maxim® is used for
- contraception
- Treatment of women with moderate acne who have no contraindications for therapy with oral contraceptives, and after failure of appropriate local treatments.

2. What must you consider before taking Maxim® ?

2.1 Maxim® must not be taken

in the presence of existing or previous blood clots (thrombosis, thromboembolism) in veins (e.g., deep vein thrombosis or pulmonary embolism),
in the presence of existing or previous blood clots in arteries (e.g., heart attack) or in the precursors of such diseases caused by blood clots in the arteries (e.g., angina pectoris or transient disturbances caused by insufficient blood flow to the brain such as visual disturbances or muscle paralysis),
with a known predisposition for the formation of blood clots in veins or arteries (e.g., resistance to activated protein C or deficiency of antithrombin III, protein C, or protein

S, or another blood coagulation disorder associated with a tendency to thrombosis),
heart valve disease or heart rhythm disorder,
after a previous stroke,
if you smoke (see 2.2.3 "The 'Pill' and Vascular Diseases"),
if you suffer from high blood pressure and it is not satisfactorily treated,
if you suffer from diabetes mellitus and your blood vessels are already damaged as a result,
with migraine accompanied by sensory, perceptual, and/or movement disorders (so-called aura),
in the presence of existing or previous inflammation of the pancreas if it is associated with a severe lipid metabolism disorder,
in the presence of existing or previous liver dysfunction, as long as liver values in the blood have not normalized (also in Dubin-Johnson and Rotor syndrome),
in the presence of existing or previous liver tumors (benign or malignant),
in suspected, existing, or previous cancers (e.g., of the breast or endometrium) that are influenced by sex hormones,
in case of vaginal bleeding of unknown cause,
in case of absence of withdrawal bleeding, if the cause is not clarified,
if you are hypersensitive (allergic) to ethinylestradiol, dienogest, or any of the other ingredients of Maxim® .

If there is a serious risk factor or multiple risk factors for the formation of blood clots, this may constitute a contraindication.

2.2 Special caution is required when taking Maxim® is required:

If during the use of Maxim® any of the conditions or circumstances listed under 2.1 "Maxim® must not be taken" occur for the first time, you must discontinue Maxim® .

2.2.1 You should also immediately stop taking Maxim® also terminate immediately,

if you suspect or are certain that you are pregnant,
if you experience signs of phlebitis or a blood clot (see 2.2.3 'The 'Pill' and Vascular Diseases'),
if your blood pressure consistently rises above 140/90 mmHg (The resumption of 'Pill' use can be considered once blood pressure values have normalized under antihypertensive treatment.),
if surgery is planned (at least 4 weeks in advance) or in case of prolonged immobilization (see also 2.2.3 'The 'Pill' and Vascular Diseases'),
if migraine occurs for the first time or worsens,
if there are unusually frequent, persistent, or severe headaches, also suddenly occurring with signs of aso-called aura,
if severe pain in the upper abdomen occurs (see also 2.2.4 'The 'Pill' and Cancer'),
if your skin and the whites of your eyes turn yellow, your urine becomes brown, and your stool becomes very light (so-called jaundice), or if your skin itches all over your body,
if you have diabetes mellitus and your blood sugar levels suddenly increase,
if you suffer from a certain disorder of blood pigment formation (porphyria) that occurs in episodes and reappears under the use of Maxim® reoccurs.

2.2.2 Special medical supervision is required,

if you have heart or kidney disease,
if you have a tendency to inflammation in superficial veins (phlebitis) or pronounced varicose veins,
if you have circulatory disorders in your hands/feet,
if you have repeatedly had a blood pressure reading over 140/90 mmHg,
if you have a known lipid metabolism disorder,
if you have known sickle cell anemia,
if you have previously had a liver disease,
if you have a known gallbladder disease,
if you suffer from migraines,
if you suffer from depression,
if you are diabetic (diabetes mellitus) or if your ability to break down glucose is impaired (reduced glucose tolerance).
It may be that under the use of Maxim® the required dose of medications for the treatment of diabetes changes,
if you smoke (please refer to 2.2.3 "The 'Pill' and vascular diseases"),
if you have epilepsy. If there is an increase in epileptic seizures under Maxim® the use of other contraceptive methods should be considered.
if you have a certain form of chorea (Sydenham's chorea),
if you suffer from a chronic inflammatory bowel disease (Crohn's disease, ulcerative colitis),
if you have a known hemolytic-uremic syndrome (a certain blood disorder that leads to kidney damage),
if you suffer from a benign tumor in the muscle layer of the uterus (uterine fibroid),
if you suffer from a certain form of hearing loss (otosclerosis),
with prolonged immobilization (see 2.2.3 "The 'Pill' and vascular diseases"),
if you are overweight,
if you have a certain immune system disorder known as lupus erythematosus,
if you are 40 years or older.

2.2.3 The "Pill" and Vascular Diseases

The use of the "pill" carries an increased risk of venous blockages caused by a blood clot (thromboembolism) compared to non-use. This increased risk with the use of the "pill" is lower than the risk of thrombosis during pregnancy, which is estimated at 60 cases per 100,000 pregnancies. In 1 - 2% of cases, such a vascular blockage leads to death.

The frequency of venous blockage with "pills" containing the active ingredient levonorgestrel and 0.03 mg ethinylestradiol is approximately 20 cases per 100,000 women who have used the "pill" for one year.
Results from application studies showed no indication of a different risk for Maxim® compared to levonorgestrel-containing combination preparations for contraception.

A vascular blockage can also occur in an artery, such as in the coronary arteries or in the arteries supplying the brain, leading to a heart attack or stroke. Vascular blockages can also occur in the blood vessels of the liver, intestines, kidneys, or eyes.

The following signs may indicate a thromboembolism. If you notice any of these signs in yourself, stop taking the pill immediately and consult a doctor without delay:
unusual pain or swelling in one leg,
pain and tightness in the chest, possibly radiating to the left arm,
sudden shortness of breath,
severe cough without a clear cause,
unusual, severe, or persistent headaches,
sudden partial or complete loss of vision,
double vision,
slurred speech, problems speaking or loss of speech,dizziness,
Dizziness,
sudden weakness or numbness of one side of the body or in a body part,
sudden weakness or numbness of one side of the body or in a body part,
Movement disorders (impaired motor skills),
severe, unbearable abdominal pain.

The risk of vascular occlusions in the veins increases:
with increasing age,
when vascular occlusions occur in close family members (parents or siblings) at a young age,
with prolonged immobilization, major surgery, surgery on the legs, or major injuries. In these cases, the use of the "pill" should be interrupted (at least four weeks before the procedure) and resumed only two weeks after the end of immobilization. If Maxim® was not discontinued in time, thrombosis prophylaxis should be considered.
in obesity (Body Mass Index over 30 kg/m^2),
in the first three to four weeks after childbirth or after a miscarriage in the second trimester of pregnancy.

There is no consensus on the significance of varicose veins and inflammation in superficial veins (phlebitis) for the development or progression of venous thrombosis.

The risk of vascular occlusions in the arteries increases:
through smoking. With increasing age and rising cigarette consumption, the risk increases even further. Women over 30 years of age should therefore not smoke if they use hormone-containing medications for contraception. If smoking is not given up, other contraceptive methods should be used, especially in the presence of additional risk factors,
with increasing age,
in lipid metabolism disorders,
in case of significant overweight,
in case of high blood pressure,
in case of diabetes (Diabetes mellitus),
in case of heart diseases (e.g., heart valve disease, atrial fibrillation),
in the occurrence of vascular occlusions in close family members (parents or siblings) at an early age,
in case of migraine, especially migraine with so-called aura.

Other diseases that may involve blood vessels include lupus erythematosus (systemic lupus erythematosus, a specific immune system disorder), hemolytic-uremic syndrome (a specific

blood disorder leading to kidney damage), and chronic inflammatory bowel diseases (Crohn's disease and ulcerative colitis).

The presence of a serious risk factor or multiple risk factors for venous or arterial vascular occlusions can also constitute a contraindication.

The increased risk of vascular occlusion during the postpartum period must be considered.

2.2.4 The "pill" and cancer

A slightly increased risk of breast cancer has been observed in users of the "pill" compared to women of the same age who do not use the "pill" for contraception. After discontinuing the "pill," this risk gradually decreases, and after 10 years, no difference is detectable between former users of the "pill" and other women of the same age.
Since breast cancer is rare in women under 40, the number of additional breast cancer cases in women who are currently using or have previously used the "pill" is small compared to their overall risk for breast cancer.

Some studies suggest that long-term use of hormonal contraceptives is a risk factor for the development of cervical cancer in women whose cervix is infected with a certain sexually transmitted virus (human papillomavirus).
However, it is not yet clear to what extent this result is influenced by other factors (e.g., differences in the number of sexual partners or in the use of mechanical contraceptive methods).

Very rarely, benign but still dangerous liver tumors can occur, which can rupture and cause life-threatening internal bleeding. Studies have shown an increased risk of developing liver cell cancer with long-term use of the "pill," although this type of cancer is very rare.

2.2.5 Other diseases

High blood pressure
An increase in blood pressure has been reported in women taking the "pill." This occurs more frequently in older users and with continued use. The frequency of high blood pressure increases with the content of progestogen. Use another
contraceptive method if you have already developed diseases due to high blood pressure or suffer from certain kidney diseases (please consult your doctor about this; see also 2.1 "Maxim® must not be taken", 2.2.1 "You should also stop taking Maxim® immediately" and 2.2.2 "Special medical supervision is required").
Pigment spots
Occasionally, yellowish-brown pigment spots (chloasma) may appear on the skin, especially in women who have had them during pregnancy. Women with this predisposition should not expose themselves directly to the sun or ultraviolet light (e.g., in a solarium) during the entire period of taking the "pill". Hereditary angioedema
If you suffer from hereditary angioedema, medications containing estrogens can trigger or worsen symptoms of angioedema. You should immediately consult your doctor if you notice symptoms of angioedema, such as swelling of the face, tongue, and/or throat and/or difficulty swallowing or a rash together with breathing problems.
Irregular bleeding

With all "pills", irregular bleeding (spotting or breakthrough bleeding) may occur, especially in the first few months. Please consult your doctor if these irregular bleedings continue after 3 months or if they reoccur after previously having a regular cycle.

It is possible that some users may not experience withdrawal bleeding during the pill-free interval. If Maxim® was taken as described under 3. "How to take Maxim® ", pregnancy is unlikely. However, if the intake was not according to instructions before the first missed withdrawal bleeding or if the withdrawal bleeding has been missed for the second time, a pregnancy must be definitely ruled out before continuing the intake of Maxim® is continued.

After stopping the "pill", it may take a longer time for a normal cycle to resume.

2.2.6 Reduced effectiveness

The contraceptive effect can be reduced by forgetting to take it, vomiting, intestinal diseases with severe diarrhea, or the simultaneous intake of other medications.

When Maxim® and St. John's wort preparations are taken simultaneously, an additional barrier method of contraception (e.g., condom) is recommended.

Please also refer to 2.3 "When taking Maxim® with other medications" and 3.5 "What to consider if you suffer from vomiting or diarrhea?"

2.2.7 Medical consultation/examination

Before using Maxim® , your attending physician will carefully inquire about your medical history and that of your close relatives. A thorough general and gynecological examination, including breast examination and cervical smear, will be conducted. Pregnancy must be excluded. If you are taking the "pill," these examinations should be repeated regularly. Please inform your doctor if you smoke and if you are taking other medications.

Maxim® does not protect you from HIV infections or other sexually transmitted diseases.

2.3 When taking Maxim® with other medications

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used other medications, even if they are non-prescription medications.

2.3.1 Interactions between Maxim® and other medications can lead to the loss of contraceptive effectiveness of Maxim® and/or cause breakthrough bleeding.

The following medications can affect the effectiveness of Maxim® impair:

- Medications that increase intestinal motility (e.g., metoclopramide),
- Medications for the treatment of epilepsy such as hydantoins (e.g., phenytoin), barbiturates, barbexaclone, primidone, carbamazepine, oxcarbazepine, topiramate, and felbamate,
- Some antibiotics for the treatment of tuberculosis (e.g., rifampicin, rifabutin), certain other bacterial infections (e.g., ampicillin, tetracycline), or fungal infections (e.g., griseofulvin),
- Certain medications for the treatment of an HIV infection (e.g., ritonavir, nevirapine),

Modafinil (a medication for the treatment of narcolepsy, a nervous system disorder),
Herbal preparations containing St. John's Wort (Hypericum perforatum).

If you are being treated with any of the above medications, a barrier method of contraception (e.g., condom) should be used in addition to Maxim® . For some of the above medications, these additional contraceptive measures should be used not only during concurrent use but also for 7 to 28 days thereafter, depending on the medication. Consult your doctor or pharmacist if necessary.

If the barrier method needs to be used longer than there are "pills" in the current blister pack, then the intake of "pills" from the next Maxim®blister pack should be continued without a 7-day break.

If long-term treatment with one of the above-mentioned medications is required, you should preferably choose a non-hormonal method of contraception.

2.3.2 Interactions between Maxim® and other medications can also lead to increased or intensified occurrence of side effects of Maxim® .

The following medications can impair the tolerability of Maxim® impair:
Paracetamol (a remedy for pain and fever),
Ascorbic acid (Vitamin C),
Atorvastatin (a remedy for lowering blood lipids),
Troleandomycin (an antibiotic),
Imidazole antifungals (remedies for fungal infections) such as fluconazole,
Indinavir (a remedy for the treatment of HIV infection).

2.3.3 Maxim® can also affect the metabolism of other medications.

The efficacy or tolerability of the following medications can be affected by Maxim® be affected:
Ciclosporin (a medicine to suppress the immune system),
Theophylline (a treatment for asthma),
Glucocorticoids (e.g., cortisone),
some benzodiazepines (tranquilizers) such as diazepam, lorazepam,
Clofibrate (a drug to lower blood fats),
Paracetamol (a drug for pain and fever),
Morphine (a very strong painkiller),
Lamotrigine (a treatment for epilepsy).

Please also refer to the package leaflets of all other preparations you are using.

In diabetic women (women with diabetes), the need for blood sugar-lowering agents (e.g., insulin) may change.

2.3.4 Interactions with laboratory tests

The use of the "pill" can affect the results of certain lab tests, including liver, adrenal cortex, kidney, and thyroid function values, as well as the amount of certain proteins in the blood,

such as proteins that affect fat metabolism, carbohydrate metabolism, or coagulation and fibrinolysis. In general, however, these changes remain within the normal range.

2.4 Pregnancy and lactation

Consult your doctor or pharmacist before taking/using any medicines.

2.4.1 Pregnancy

Maxim® must not be used during pregnancy.
Before starting the use of Maxim® you must not be pregnant. If pregnancy occurs during the use, you must stop taking Maxim® immediately and consult your doctor.

2.4.2 Lactation

You should not use Maxim® during lactation, as it can reduce milk production and small amounts of the active ingredient can pass into breast milk. You should use non-hormonal methods of contraception during lactation.

2.5 Ability to drive and use machines

Maxim® has no effect on the ability to drive and use machines.

2.6 Important information about certain other ingredients of Maxim®

This medicine contains dextrose (glucose) and sugar (sucrose).
Please take Maxim® therefore only after consulting your doctor if you know that you suffer from an intolerance to certain sugars.
For other ingredients, see 6.1 "What Maxim® contains".

3. How should Maxim® be taken?

Take Maxim® exactly as directed by your doctor. Please consult your doctor or pharmacist if you are unsure.

Unless otherwise prescribed by the doctor, the usual dose is:

1 "pill" of Maxim® daily.

3.1 How and when should you use Maxim® ?

The "pill" should be swallowed whole, possibly with some liquid.

The "pill" must be taken every day at about the same time, in the order specified on the blister pack, for 21 consecutive days.

The first "pill" is taken from the field of the blister pack labeled with the day of the week the intake begins (e.g., "Mo" for Monday).

Another "pill" is then taken daily in the direction of the arrow until the blister pack is used up.

Then you do not take a "pill" for 7 days. During this 7-day break, bleeding occurs (withdrawal bleeding). This usually happens 2 to 4 days after taking the last "pill".

Start taking from the next blister pack on the 8th day, regardless of whether the bleeding is still ongoing or not. This means, on the one hand, that you always start a new blister pack on the same day of the week and, on the other hand, that you have your bleeding approximately on the same days of the week each month.

Contraceptive protection also exists during the 7-day intake breaks.

3.2 When to start taking Maxim®?

If you have not taken a "pill" for contraception in the past month:
Start taking Maxim® on the first day of your cycle, i.e., on the first day of your menstrual bleeding. If used correctly, contraceptive protection exists from the first day of intake.
If you start taking it between days 2 and 5, an additional barrier method of contraception should be used during the first 7 days of taking the "pill".

If you are switching from another "pill" (with two hormonal active ingredients), a vaginal ring, or a patch to Maxim® :

If you have previously taken a "pill" where a "pill"-free interval follows the use of the last active "pill" once a month, start taking Maxim® the day after the "pill"-free interval.
If you have previously taken a 'pill' whose cycle pack contains both active and inactive 'pills', meaning you did not have a break from taking them, start taking Maxim® on the day after taking the last inactive 'pill'. If you are not sure which 'pill' is the last inactive 'pill', please ask your doctor or pharmacist.
If you have previously used a vaginal ring or a patch, start taking Maxim® on the day after the usual ring-free or patch-free interval.

If you are switching from a 'pill' that contains only one hormone (progestogen), known as the mini-pill, to Maxim® :
You can stop the 'mini-pill' on any day. Start taking Maxim® the following day. During the first 7 days, an additional non-hormonal method of contraception (e.g., condom) should be used.

If you are switching from an injectable preparation (known as the 'three-month injection'), an implant, or the 'coil' to Maxim® :
Start taking Maxim® at the time when the next injection would normally be due, or on the day the implant or 'coil' is removed. Use an additional non-hormonal method of contraception (e.g., condom) during the first 7 days.

If you have just had a baby and are not breastfeeding:
Do not start taking it earlier than 21 to 28 days after birth. During the first 7 days of taking it, an additional barrier method should be used.
Contraception (e.g., condom) should be used. If you have already had sexual intercourse, pregnancy must be ruled out or the first menstrual period must be awaited before starting to take Maxim® a
pregnancy must be ruled out or the first menstrual period must be awaited. For use during breastfeeding, see 2.4 "Pregnancy and
Breastfeeding".

If you have just had a miscarriage or an abortion:
Please talk to your doctor about the possibility of taking Maxim®.

3.3 Duration of use

Maxim® can be taken as long as a hormonal method of contraception is desired and there are no health risks (see 2.1 "Maxim® must not be taken" and 2.2.1 "You should also stop taking Maxim® immediately"). Regular check-ups are strongly recommended (see 2.2.7 "Medical advice/examination").

3.4 If you have taken more Maxim® than you should:

Possible signs of an overdose include nausea, vomiting (usually after 12 to 24 hours, possibly lasting several days),
breast tenderness, dizziness, abdominal pain, drowsiness/fatigue; vaginal bleeding may occur in women and girls. If larger amounts are taken, you must consult a doctor.

3.5 If you forget to take Maxim® forgotten:

If the intake time is exceeded by less than 12 hours, the contraceptive effect of Maxim® is still ensured. You must make up for the missed "pill" as soon as possible and then take the following "pills" at the usual time.
If the intake time is exceeded by more than 12 hours, the contraceptive effect is no longer fully ensured. If no bleeding occurs during the following intake break after finishing the current blister pack, you may be pregnant. You must then consult your doctor before starting a new blister pack. In general, you should consider two points:

The intake of the "pill" should never be interrupted for more than 7 days.

1. For sufficient contraceptive protection after an interruption, continuous intake of
2. the "pill" for 7 daysis required. required.

You missed 1 "pill" in week 1:

You missed 1 "pill" in week 1:
Make up the missed dose as soon as possible, even if it means taking two "pills" at the same time. Then continue taking them as usual. However, an additional barrier method of contraception (e.g., condom) must be used for the next 7 days. If you had sexual intercourse in the week before the missed "pill," there is a possibility that you are pregnant. The likelihood of pregnancy is higher the closer both events are to the usual break in taking the pill.

You missed 1 "pill" in week 2:
Make up for the missed dose as soon as possible, even if it means taking two "pills" at the same time. Then take the following "pills" again at the usual time. If you had taken Maxim in the 7 days prior to the missed "pill"® If you have taken it regularly, the contraceptive effect of the "pill" is ensured and you do not need to use additional contraceptive measures. If this was not the case or more than 1 "pill" was missed, the use of an additional barrier method of contraception (e.g., condom) is recommended for 7 days.

You forgot 1 "pill" in week 3:
Due to the upcoming 7-day break in taking the pill, contraceptive protection is no longer fully guaranteed. By adjusting the
intake schedule, the contraceptive effect can still be maintained. By following one of the two procedures explained below,
there is therefore no need for additional contraceptive measures, but only if the intake on the 7 days before the first missed "pill" was correct. If this was not the case, you should proceed as described below under point 1. Additionally, a barrier method of contraception (e.g., condom) should be used for the next 7 days.

You can choose between two options:
1. Make up for the missed dose as soon as possible, even if it means taking two "pills" at the same time. Then take the following "pills" at the usual time. Skip the break and start taking the "pills" from the next blister pack immediately. It is most likely that you will not have a withdrawal bleed until you have finished this second blister pack, but spotting and breakthrough bleeding may occur during the intake from the second blister pack.
Or
2. You can also stop taking the current blister pack immediately and, after a break of no more than 7 days (the day the "pill" was missed must be counted!), start taking the next blister pack directly. If you want to start taking the new blister pack on your usual weekday, you can shorten the break accordingly.

You have forgotten more than 1 "pill" in the current blister pack:
If you have forgotten to take more than 1 "pill" of Maxim® in the current blister pack, contraceptive protection is no longer reliably provided.

The likelihood of pregnancy is higher the more "pills" you have forgotten and the closer this is to the normal
break in taking the pill. Until the next usual withdrawal bleed occurs, an additional barrier method of contraception (e.g., condom) should be used. If no withdrawal bleed occurs during the break after finishing the current blister pack, you may be pregnant. In this case, you must consult your doctor before starting a new blister pack.

What should be considered
... if you suffer from vomiting or diarrhea?
If you experience digestive disorders such as vomiting or diarrhea within 4 hours after taking the "pill," the
Active ingredients may not have been fully absorbed yet. In such cases, follow the instructions applicable when the intake of the "pills" was forgotten and noticed within 12 hours. If you do not want to deviate from your intake rhythm, take the replacement "pill" from another blister pack. If gastrointestinal complaints persist or recur over several days, you or your partner should additionally use a barrier method of contraception (e.g., condom) and inform your doctor.

... if you want to postpone the withdrawal bleeding:
To postpone the withdrawal bleeding, you should continue taking the "pill" from the next blister pack of Maxim® without a break. The withdrawal bleeding can be postponed for as long as desired, but no longer than until the second blister pack is used up. During this time, breakthrough or spotting may occur more frequently. After the subsequent regular 7-day break, the intake of Maxim® can be continued as usual.

3.6 If you stop taking Maxim® :

You can stop taking Maxim® at any time after finishing a blister pack. If you do not wish to become pregnant, ask your doctor about other reliable contraceptive methods.

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

4. What side effects are possible?

Like all medicines, Maxim® can have side effects, but they do not have to occur in everyone.

The serious side effects associated with the "pill" are listed under section 2.2 "Special caution when taking Maxim® is required:". There you will find more detailed information. Please consult your doctor immediately if necessary.

The following side effects were observed in clinical studies with Maxim® observed:
Common side effects (between 1 and 10 out of 100 users may be affected):

- Headaches
- Breast pain including breast discomfort and breast tenderness

Occasional side effects (between 1 and 10 out of 1,000 users may be affected):

- Inflammation of the genitals (vaginitis/vulvovaginitis), vaginal yeast infections (candidiasis, vulvovaginal infections)
- Increased appetite
- Depressive mood
- Dizziness
- Migraine
- High or low blood pressure, in rare cases increased diastolic blood pressure(lower blood pressure value)
- Abdominal pain (including pain in the upper and lower abdomen, discomfort/bloating)also, complaints/flatulence)
- Nausea, vomiting or diarrhea
- Acne
- Hair loss (alopecia)
- Rash (including spot-like rash)
- Itching (sometimes over the entire body)
- Irregular withdrawal bleeding including heavy bleeding (menorrhagia), light bleeding (hypomenorrhea), infrequent bleedingn (oligomenorrhea) and absence of bleeding (amenorrhea)
- Intermenstrual bleeding (vaginal hemorrhage and metrorrhagia)
- Painful menstruation (dysmenorrhea), pelvic pain
- Breast enlargement including breast swelling, breast edema
- Vaginal discharge
- Ovarian cysts
- Fatigue including weakness, tiredness and general malaise
- Weight changes (increase, decrease or fluctuation)

Rare side effects (between 1 and 10 out of 10,000 users may be affected):

- Inflammation in the fallopian tube or ovary
- Inflammation of the cervix (cervicitis)
- Urinary tract infections, cystitis
- Breast inflammation (Mastitis)
- Fungal infections (e.g., Candida), viral infections, cold sores
- Flu (Influenza), bronchitis, upper respiratory tract infections, sinusitis (Sinusitis)
- Asthma
- Increased respiratory rate (Hyperventilation)
- Benign growths in the uterus (Myomas)
- Benign growths in the breast's fatty tissue (Breast lipoma)
- Anemia
- Allergic reactions (Hypersensitivity)
- Masculinization (Virilism)
- Loss of appetite (Anorexia)
- Depression, mood swings, irritability, aggression
- Insomnia, sleep disturbances
- Circulatory disorders of the brain or heart, stroke
- Dystonia (muscle disorder that can cause abnormal posture, for example)
- Dry or irritated eyes
- Visual disturbances
- Sudden hearing loss, impairment of hearing
- Tinnitus
- Balance disorders
- Rapid heart rhythm
- Thrombosis, pulmonary embolism
- Vein inflammation (thrombophlebitis)
- Varicose veins (varicosis), venous complaints or pain
- Dizziness or fainting when standing up from sitting or lying down (orthostatic dysregulation)Hot flashes
- Hot flashes
- Upset stomach (dyspepsia)
- Upset stomach (Dyspepsia)
- Excessive sweating
- Excessive sweating
- PigmentationOily skin (seborrhea)
- Dandruff
- Male-pattern hair growth (hirsutism)
- Cellulite
- Spider nevus (net-like blood vessels with a central red spot on the skin)
- Orange peel skin (Cellulite)
- Spider nevus (Net-like blood vessels with a central red spot on the skin)
- Back pain, chest pain
- Complaints of bones and muscles, muscle pain (myalgia), pain in arms and legs
- Cervical dysplasia (abnormal growth of cells on the surface of the cervix)
- Pain or cysts in the adnexa (fallopian tubes and ovaries)
- Cysts in the breast, benign growths in the breast (fibrocystic mastopathy), swelling of congenitaladditional mammary glands
- outside the breasts (accessory breasts)
- Pain during intercourse

- Mammary gland secretion, breast discharge
- Menstrual disorders
- Peripheral edema (fluid accumulation in the body)
- Flu-like illnesses, inflammation, pyrexia (fever)
- Increase in triglyceride and cholesterol levels in the blood (hypertriglyceridemia, hypercholesterolemia)

Other side effects observed in pill users, whose exact frequency is unknown, are:
Increased or decreased sexual desire (libido), contact lens intolerance, hives, erythema nodosum or multiforme.

If you suffer from hereditary angioedema, medications containing estrogens can trigger or worsen symptoms of angioedema (see section 2.2 “Special precautions when taking Maxim® is required“).

Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects not listed in this leaflet.

5. How to store Maxim® to store?

Keep medicines out of the reach of children.

Do not use the medicine after the expiry date stated on the carton and blister pack after 'use by:'. The expiry date refers to the last day of the month.

No special storage conditions are required for this medicine.

6. Further information

6.1 What Maxim® contains

The active substances are ethinylestradiol and dienogest.
One coated tablet contains 0.03 mg ethinylestradiol and 2.0 mg dienogest. The other ingredients are:
Microcrystalline cellulose, corn starch, pregelatinized corn starch, maltodextrin, magnesium stearate (Ph.Eur.), sucrose, glucose syrup (Ph.Eur.), calcium carbonate, povidone K25, povidone K90, macrogol 35,000, macrogol 6,000, talc, carnauba wax, titanium dioxide (E 171)

6.2 What Maxim® looks like and contents of the pack

White coated tablets
Maxim® is available in packages with 1 blister pack of 21 coated tablets (cycle pack), with 3 blister packs each containing 21 coated tablets, and with 6 blister packs each containing 21 coated tablets.

6.3 Pharmaceutical entrepreneur and manufacturer:

Jenapharm GmbH & Co. KG
Otto-Schott-Straße 15
07745 Jena

Phone 03641 648888
Fax 03641 648889
Email: frauengesundheit@jenapharm.de

This package leaflet was last revised in

April 2013