

PACKAGE LEAFLET: INFORMATION FOR THE USER

TRIQUILAR

Film-coated tablets

LEVONORGESTREL, ETHINYLESTRADIOL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TRIQUILAR is and what it is used for
2. Before you take TRIQUILAR
3. How to take TRIQUILAR
4. Possible side effects
5. How to store TRIQUILAR
6. Further information

1. WHAT TRIQUILAR IS AND WHAT IS IT USED FOR

TRIQUILAR is a contraceptive medicine (a “pill”).

- Each tablet contains a small amount of two different female sex hormones, i.e. levonorgestrel and ethinylestradiol.
- Pills containing two hormones are called combined pills. TRIQUILAR is also called a low-dose pill, as it contains only a small amount of hormones.

2. BEFORE YOU TAKE TRIQUILAR

General notes

Please read the information about blood clots in section 2 before you start using TRIQUILAR. It is particularly important to read the information about the symptoms of a blood clot (see section 2, “Blood clots”).

Before you use TRIQUILAR, your treating doctor will ask you in detail about your medical history and that of your close relatives. The doctor will measure your blood pressure and, depending on your personal situation, will carry out further tests.

This leaflet describes various cases in which you should stop TRIQUILAR or the reliability of TRIQUILAR may be reduced. In these cases, you should either not have sexual intercourse or use other, non-hormonal methods of contraception, e.g. a condom or another barrier method. However, do not use the calendar or temperature method. These methods may fail because TRIQUILAR alters the monthly fluctuations in body temperature and cervical mucus.

Like all hormonal contraceptives, TRIQUILAR offers no protection against HIV infection (AIDS) or other sexually transmitted diseases.

When TRIQUILAR must not be taken:

TRIQUILAR must not be used if any of the following points apply to you. You must tell your doctor if any of the following points apply to you. Your doctor will then discuss with you which other forms of contraception are better suited for you.

- if you have a **blood clot** in a blood vessel of the legs (deep vein thrombosis, DVT), lungs (pulmonary embolism, LE) or any other organ (or have had one in the past)
- if you are known to suffer from a blood-clotting disorder – for example, protein C deficiency, protein S deficiency, antithrombin III deficiency, Factor V Leiden or antiphospholipid antibodies
- if you need surgery or have been bedridden for a prolonged period of time (see section “Blood clots”)
- if you have ever had a **heart attack** or **stroke**
- if you have (or have ever had) **angina pectoris** (a condition that causes severe chest pain and may be the first sign of a heart attack) or a transient ischaemic attack (TIA - temporary symptoms of stroke)
- if you suffer from any of the following diseases which may increase the risk of a blood clot in an artery:
 - severe diabetes with damage to the blood vessels
 - very high blood pressure
 - very high blood fat levels (cholesterol or triglycerides)
 - a disease known as hyperhomocysteinaemia
- if you suffer from a certain form of **migraine** (called “migraine with aura”) (or have done so in the past)
- if you have a past or present history of severe **liver disorders**, unless your liver counts have returned to normal
- if you have a past or present history of **liver tumours**
- if you have a past or present history of **breast cancer** or **genital cancer**, or suspicion thereof
- if you have any **unexplained vaginal bleeding**
- if you are missing your monthly period, possibly due to diet or physical activity
- if you are allergic to ethinylestradiol, levonorgestrel or any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling.

Warnings and precautions

Talk to your doctor or pharmacist before taking TRIQUILAR.

When special care is needed when taking TRIQUILAR

When should you contact your doctor?

Seek immediate medical help

- if you notice possible signs of a blood clot which might mean that you have a blood clot in your leg (i.e. deep vein thrombosis), a blood clot in the lungs (i.e. pulmonary embolism), or you are having a heart attack or stroke (see section “Blood clots” [thrombosis] below).

For a description of the symptoms of these serious side effects, see the section “How to recognise a blood clot”.

Inform your doctor if any of the following points apply to you.

In some situations, special care is needed when taking TRIQUILAR or other combined pills and regular check-ups by your doctor may be necessary.

If the disease breaks out or gets worse whilst using TRIQUILAR, you should likewise tell your doctor.

- if a close relative has, or has ever had, breast cancer
- if you are known to have a liver or gallbladder disease
- if you suffer from diabetes mellitus
- if you suffer from depression
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (SLE - a disease that affects your natural defence system)
- if you have a haemolytic uraemic syndrome (HUS - a blood-clotting disorder which leads to kidney failure)
- if you have sickle cell anaemia (a hereditary disease of the red blood cells)
- if you have high blood fat levels (hypertriglyceridaemia) or a family history of this disease. Hypertriglyceridaemia has been associated with an increased risk of pancreatitis (inflammation of the pancreas)
- if you need surgery or have been bedridden for a prolonged period of time (see section 2 "Blood clots")
- if you have recently given birth, your risk of blood clots is increased. Ask your doctor how soon after childbirth you can start using TRIQUILAR
- if you have inflammation in the veins beneath the skin (superficial thrombophlebitis)
- if you have varicose veins (varices)
- if you suffer from epilepsy (see "Other medicines and TRIQUILAR")
- if you have ever experienced a disorder that occurred for the first time during pregnancy or previous use of sex hormones, e.g. hardness of hearing, a blood disease called porphyria, a blister-type rash during pregnancy (herpes gestationis), a nerve disorder where sudden, involuntary body movements occur (Sydenham's chorea)
- if you have a past or present history of yellowish-brown pigment patches (chloasma), also known as the "mask of pregnancy", mainly on the face. In this case, it is advisable to avoid exposure to direct sunlight or ultraviolet light.
- if you suffer from hereditary angioedema (sudden swelling of the skin, mucous membranes, internal organs or brain): medicines containing oestrogens can trigger or worsen the symptoms. You should consult your doctor immediately if you notice symptoms of angioedema, such as swelling of the face, tongue and/or throat and/or swallowing difficulties or skin rash together with breathing problems.

BLOOD CLOTS

When using a combined hormonal contraceptive such as TRIQUILAR, your risk for blood clot formation is higher than if you do not use one. In rare cases, a blood clot can block blood vessels and cause serious problems.

Blood clots can occur

- in veins (known as "venous thrombosis", "venous thromboembolism" or VTE)
- in the arteries (known as "arterial thrombosis", "arterial thromboembolism" or ATE).

A blood clot does not always heal completely. Rarely, it may lead to serious persistent symptoms and blood clots can be fatal in very rare cases.

It is important not to forget that the overall risk of a harmful blood clot due to TRIQUILAR is low.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical assistance if you notice any of the following signs or symptoms.

Are you experiencing one of these signs?	What might you be suffering from?
<ul style="list-style-type: none"> • swelling of a leg or along a vein in the leg or foot, especially if the following occurs at the same time: • pain or tenderness in the leg, which may only be noticed when standing or walking • warmth of the affected leg • changes in skin colour of the leg, e.g. turning pale, red or blue in colour 	Deep leg vein thrombosis
<ul style="list-style-type: none"> • sudden unexplained shortness of breath or rapid breathing; • sudden cough with no apparent cause, during which blood may be coughed up; • stabbing chest pain that increases when you breathe in deep; • severe light-headedness or dizziness; • rapid or irregular heartbeat; • severe stomach pain. <p>If you are not sure, talk to a doctor, as some of these symptoms such as cough or shortness of breath may be confused with a milder disorder, e.g. inflammation of the airways (e.g. flu infection).</p>	Pulmonary embolism
<p>Symptoms that usually occur in one eye:</p> <ul style="list-style-type: none"> • immediate loss of vision or • painless blurred vision, which can progress to loss of vision. 	Thrombosis in a retinal vein (blood clot in a vein in the eye)
<ul style="list-style-type: none"> • chest pain, discomfort, pressure, heaviness • tightness or fullness in the chest, arm or below the breastbone; • bloating, indigestion or choking sensation; • discomfort in the upper body, radiating to the back, jaw, neck, arm and stomach; • sweating, nausea, vomiting or dizziness; • extreme weakness, anxiety or shortness of breath; • rapid or irregular heartbeats 	Heart attack
<ul style="list-style-type: none"> • sudden weakness or numbness of the face, arm or leg, which is particularly marked on one side of the body; • sudden confusion, difficulties in speaking or understanding; • sudden visual disturbances in one or both eyes; • sudden difficulties in walking, dizziness, loss of balance or coordination problems; • sudden, severe or prolonged headache of unknown origin; • loss of consciousness or fainting with or without seizure. <p>In some cases, the symptoms may be short-lasting and associated with a virtually immediate and complete recovery. However, you should still seek urgent medical treatment, as you might suffer another stroke.</p>	Stroke
<ul style="list-style-type: none"> ☒ swelling and slight bluish discoloration of an extremity; ☒ severe stomach pain (acute abdomen) 	Blood clots blocking other blood vessels

BLOOD CLOT IN A VEIN

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

- Use of combined hormonal contraceptives has been associated with a higher risk of blood clots in a vein (venous thrombosis). However, these side effects rarely occur. They usually happen in the first year of using a combined hormonal contraceptive.
- If a blood clot occurs in a vein in the leg or foot, this can cause deep vein thrombosis (DVT).
- If a blood clot migrates from the leg to the lung and gets stuck there, it can cause a pulmonary embolism.
- Very rarely, a blood clot may form in a vein of another organ, e.g. the eye (retinal vein thrombosis).

When is the greatest risk of developing a blood clot in a vein?

The risk of developing a blood clot in a vein is greatest during the first year of first-time use of a combined hormonal contraceptive. The risk may also be increased if you start using a combined hormonal contraceptive again (same or different medicinal product) after a break of 4 or more weeks. The risk decreases after the first year, but always remains slightly higher than if no combined hormonal contraceptive has been used.

If you stop using TRIQUILAR, the risk of a blood clot returns back to normal within a few weeks.

How great is the risk of blood clot formation?

The risk depends on your natural risk for VTE and the type of combined hormonal contraceptive you are using.

The overall risk of a blood clot in the leg or lungs (DVT or PE) with TRIQUILAR is low.

- Around 2 out of 10,000 women who are neither pregnant nor using a combined hormonal contraceptive will suffer a blood clot during the course of a year.
- Around 5-7 out of 10,000 women using a levonorgestrel-containing combined hormonal contraceptive will suffer a blood clot during the course of a year.
- The risk of blood clot formation varies according to your personal medical history (see following section "Factors increasing the risk of a blood clot in a vein").

	Risk of blood clot formation per year
Women not using a combined hormonal preparation in the form of a pill/patch/ring and not pregnant	Around 2 out of 10,000 women
Women using a combined hormonal pill containing levonorgestrel	Around 5-7 out of 10,000 women
Women using TRIQUILAR	Around 5-7 out of 10,000 women

Factors increasing the risk of a blood clot in a vein

The risk of a blood clot with TRIQUILAR is low, but is increased as a result of some diseases and risk factors. The risk is increased:

- if you are severely overweight (Body Mass Index or BMI over 30 kg/m²);
- if one of your close relatives has experienced a blood clot in the leg, lung or any other organ at a young age (i.e. below 50 years). In this case, you might have a hereditary blood-clotting disorder;
- if you need surgery or have been bedridden for a prolonged period of time due to injury or illness or your leg is in plaster. You may have to stop using TRIQUILAR several weeks prior to surgery or if your mobility is impaired. If you have to stop using TRIQUILAR, ask your doctor when you can start using it again.
- if you are of a certain age (especially from about 35 years of age);

- if you have had a baby within the last few weeks.

The risk of blood clot formation increases with the number of diseases and risk factors present.

Air travel (> 4 hours) can temporarily increase your risk of blood clots, especially if you have any other of the factors listed.

It is important that you tell your doctor if any of these points apply to you, even if you are not sure. Your doctor may then decide to discontinue TRIQUILAR.

Tell your doctor if any of the above-mentioned points occurs whilst using TRIQUILAR; for example, if a close relative experiences thrombosis of unknown cause or if you put on a lot of weight.

BLOOD CLOTS IN AN ARTERY

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

Just like a blood clot in a vein, a clot in an artery can cause serious problems. It can cause a heart attack or stroke, for example.

Factors increasing the risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke due to TRIQUILAR use is very low, but may rise:

- with increasing age (over 35 years of age);
- **if you smoke.** When using a combined hormonal contraceptive such as TRIQUILAR, it is advised that you stop smoking. If you cannot stop smoking and are over 35 years of age, your doctor may advise you to use a different type of contraception;
- if you are overweight;
- if you have high blood pressure;
- if one of your close relatives has had a heart attack or stroke at a young age (below 50 years). In this case, you might also be at increased risk of heart attack or stroke;
- if you or one of your close relatives have high blood fat levels (cholesterol or triglycerides);
- if you have migraine and especially migraine with aura;
- if you suffer from heart problems (heart valve disease, a heart rhythm disorder called atrial fibrillation);
- if you have diabetes.

If more than one of these points apply to you or one of these disorders is particularly severe, your risk for blood clot formation may be additionally increased.

Tell your doctor if there is a change in any of the above-mentioned points during TRIQUILAR use, for example, if you start smoking, if a close relative experiences thrombosis of unknown cause or if you put on a lot of weight.

TRIQUILAR and cancer

- Cervical cancer has been observed somewhat more frequently in long-term users than in non-users of oral contraceptives; however, it is not clear to what extent differences in sexual behaviour or other factors such as the human papillomavirus (HPV) play a role.
- Breast cancer is observed somewhat more frequently in women taking combined pills, but it is not known whether this is caused by the treatment. The incidence of breast tumours decreases after discontinuation of hormonal combined pills. It is important that you examine your breasts regularly. If you feel any lumps, you must consult your doctor.
- In rare cases, benign (non-cancerous) liver tumours and, rarer still, malignant (cancerous) liver tumours have been found in users of combined pills. Consult your doctor if you experience unusually severe abdominal pain.

Bleeding between periods

When using TRIQUILAR, unexpected bleeding (bleeding outside the tablet-free interval) may occur within the first few months. If this bleeding continues to occur after more than 3 months or if it starts again after a few months, your doctor must determine the cause.

Points to consider if there is no bleeding during the tablet-free interval

If you have taken all your tablets correctly, have not had vomiting or severe diarrhoea and have not taken any other medicines, pregnancy is very unlikely.

However, if bleeding is absent for two cycles in a row, you may be pregnant. You should then contact your doctor immediately, as pregnancy must be excluded before you take any further pills. Do not start a new blister strip until you are sure that you are not pregnant.

Other medicines and TRIQUILAR

Always tell your doctor about which medicines you are already using or have recently used. Also, tell any other doctor or dentist prescribing you other medicines (or the pharmacist) that you are taking TRIQUILAR. They can tell you whether you need to take extra contraceptive precautions (e.g. condoms) and, if so, for how long.

Some medicines can have an effect on the blood levels of TRIQUILAR and lead to a **reduction in the contraceptive effectiveness** or to unexpected bleeding. These include:

- medicines for the treatment of:
- gastrointestinal motility disorders (e.g. metoclopramide)
- epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate or felbamate)
- tuberculosis (e.g. rifampicin)
- HIV and hepatitis C viral infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine)
- fungal infections (griseofulvin, azole antifungals such as itraconazole, voriconazole, fluconazole)
- bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
- certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
- arthritis, osteoarthritis (etoricoxib)
- the herbal remedy St. John's wort

Taking the pill at the same time as the antibiotic troleandomycin can increase the risk of bile accumulation.

TRIQUILAR can influence the effectiveness of certain other medicines, e.g.

- medicines containing ciclosporin
- lamotrigine, an antiepileptic (this could lead to an increased frequency of seizures)
- melatonin
- midazolam
- theophylline
- tizanidine

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

TRIQUILAR with food and drink

TRIQUILAR can be taken with or without food, if necessary with some water. TRIQUILAR should not be taken together with grapefruit juice.

Laboratory tests

Hormonal contraceptives can affect the results of certain laboratory tests. So, if you need to have a blood test, tell your doctor or the laboratory staff that you are taking the pill.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, you must not take TRIQUILAR. If you become pregnant while taking TRIQUILAR, you must stop taking TRIQUILAR immediately and consult your doctor. If you wish to become pregnant, you can stop TRIQUILAR at any time (see also "If you wish to stop taking TRIQUILAR").

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

Breast-feeding

Women should not use TRIQUILAR during breast-feeding except on medical advice. Ask your doctor if you are breast-feeding and would like to take the pill.

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

Driving and using machines

There are no indications that taking TRIQUILAR has any influence on the ability to drive and use machines.

TRIQUILAR contains lactose and sucrose.

For this reason, if you have been told that you have an intolerance to some sugars, please consult your doctor before taking TRIQUILAR.

3. HOW TO TAKE TRIQUILAR

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

Each blister contains 21 tablets. The foil is marked with the particular day of the week when the tablet should be taken. For example, if you are to start taking the tablets on a Tuesday, push the tablet through the aluminium foil marked "TUE". Take the tablets in the sequence indicated by the arrows.

Take 1 TRIQUILAR tablet daily for 21 days, if necessary together with some water. The tablets should be taken at about the same time each day. It does not matter whether you take the tablets on an empty stomach or with meals.

After you have taken all 21 tablets, do not take any tablets for the next 7 days. Your monthly period (withdrawal bleed) will start during these 7 days, usually 2-3 days after taking the last TRIQUILAR tablet.

Start on the next blister on the eighth day, even if you are still bleeding. This means, on the one hand, that you will start the new strip always on the same day of the week and, on the other hand, that your withdrawal bleed should occur on the same days each month.

When to start on the first strip

- *If you have not been using any hormone-based contraceptive in the past month:*

Start taking TRIQUILAR on the first day of your cycle (i.e. on the first day of your monthly period). If you start taking TRIQUILAR on this day (the first day of your monthly period), you will be immediately protected against

pregnancy. You can also start between days 2 and 5 of your cycle, but you must then use extra contraceptive measures (e.g. a condom) during the first 7 days of tablet-taking.

- *If you are switching from another combined hormonal contraceptive (pill with two hormonal active substances) or a contraceptive vaginal ring or patch:*

You can start taking TRIQUILAR preferably on the day after taking the last active tablet (the last tablet containing active substances) of your previous pill or on the day after removing the vaginal ring or patch, but by no later than on the day after the tablet-free (ring- or patch-free) days of your previous product (or after taking the last active tablet of your previous product).

- *If you are switching from a product containing only one hormone (progesterone) (the so-called “mini-pill”, an injectable, an implant or a progestogen-releasing intrauterine system (“coil”)):*

You can stop the “mini-pill” on any day you choose and start taking TRIQUILAR immediately on the day after. After switching from an implant or “coil”, start taking TRIQUILAR on the day when the implant or “coil” is removed or, after an injectable, at the time when the next injection would normally be due. In all cases, you must use an extra method of contraception for the first 7 days of tablet-taking (e.g. a condom).

- *If you have had a miscarriage or abortion in the first three months of pregnancy:*

Please talk to your doctor.

- *If you have just had a baby or a miscarriage after the third month of pregnancy:*

Do not start taking TRIQUILAR any earlier than 21 to 28 days after the birth or miscarriage. If you start taking it after Day 28, you must additionally use a barrier method of contraception (e.g. a condom) during the first 7 days of taking TRIQUILAR.

If you have already had sexual intercourse after childbirth before starting to take TRIQUILAR, you must make sure that you are not pregnant, or you must wait for your first monthly period before taking TRIQUILAR.

- *If you are breast-feeding after childbirth and wish to start taking TRIQUILAR (again):*

Read the section “Breast-feeding”.

If you are not sure when you can start, ask your doctor.

If you take more TRIQUILAR than you should

There are no reports of serious harmful consequences after taking too many TRIQUILAR tablets.

Nausea and vomiting may occur if you have taken several tablets at once. Young girls may experience vaginal bleeding.

If you have taken too many TRIQUILAR tablets or discover that a child has accidentally swallowed some tablets, ask your doctor or pharmacist for advice.

If you forget to take TRIQUILAR

- If you are **less than 12 hours late** in taking any one tablet, the contraceptive effect is still assured. You must take the forgotten tablet as quickly as possible and then continue to take the next tablets at the usual time.

- If you are **more than 12 hours late** in taking your tablet, the contraceptive effect will no longer be assured. The more tablets you have missed, the greater the risk of pregnancy.

For this reason, you should bear in mind the following rules:

- Tablet-taking should never be interrupted for more than 7 days.
- The effectiveness of TRIQUILAR is assured only after 7 days of uninterrupted tablet-taking.

- **If you are more than 12 hours late in taking a tablet between Days 1 and 7 (please also see the diagram):**

Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual. However, you must additionally use a contraceptive barrier method, e.g. a condom, for the next 7 days. If you have had sexual intercourse in the week prior to forgetting the tablet, the possibility of pregnancy must be considered. The more tablets you have missed and the nearer this has occurred to the tablet-free interval, the greater the risk of pregnancy. In this case, tell your doctor.

- **If you are more than 12 hours late in taking a tablet between Days 8 and 14 (please also see the diagram):**

Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your tablets as usual. Provided you have taken the tablets correctly over the 7 days before the missed tablet, you need not take any extra protective measures. However, if you have not taken these tablets correctly or if more than one tablet has been missed, you must use additional contraceptive protection (e.g. a condom) during the next 7 days.

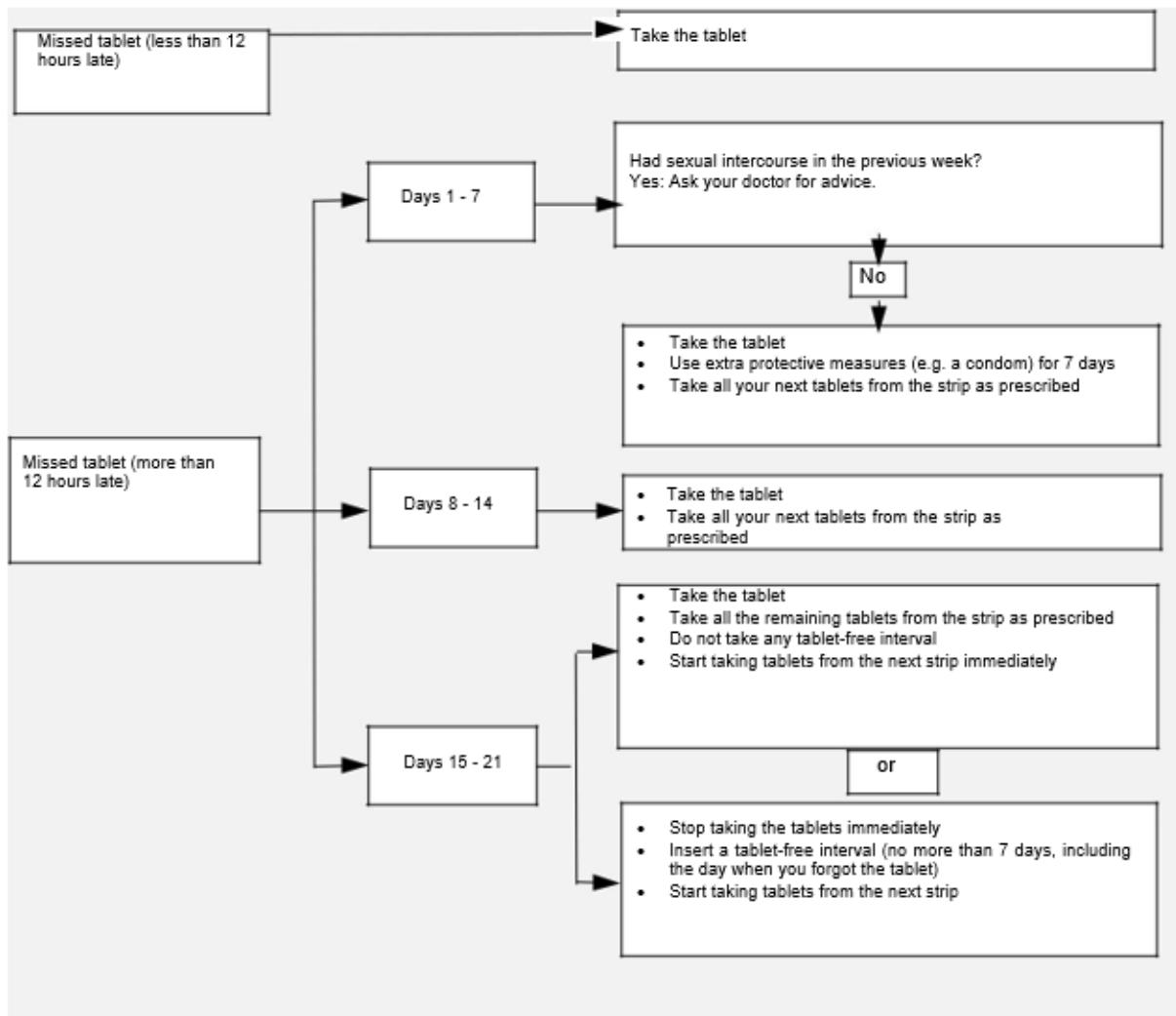
- **If you are more than 12 hours late in taking a tablet between Days 15 and 21 (please also see the diagram):**

The closer you are to the tablet-free interval, the greater the likelihood of pregnancy. However, pregnancy can still be prevented by adjusting the dosing schedule.

If you observe the following instructions, you need not take any extra contraceptive measures, provided you have been using the tablets correctly over the 7 days before the missed tablet. If you have not taken these tablets correctly or if you have missed more than one tablet, you should opt for the first of the two following possibilities only and use extra contraceptive protection during the next 7 days.

1. Take the tablet as quickly as possible, even if this means having to take two tablets at the same time. Then continue taking your next tablets at the usual time. Instead of observing a subsequent 7-day tablet-free interval, start on the next strip straight away. Most probably, you will not experience withdrawal bleeding until the end of the second strip. However, you may experience mild or menstruation-like bleeding whilst on the second strip.
2. You can also stop taking the tablets and immediately start the 7-day tablet-free interval, which should also include the day when the tablet was forgotten, and then carry on taking tablets from a new strip.

If you have forgotten more than one tablet and no withdrawal bleeding occurs during the normal tablet-free interval, the possibility of pregnancy must be considered.



Points to consider if you suffer vomiting or severe diarrhoea

If you experience vomiting or severe diarrhoea within the first 3 to 4 hours of taking a tablet, the active substances in the pill may not have been completely absorbed by your body. This situation is like forgetting a tablet. After vomiting or diarrhoea, you must take a tablet from another strip as quickly as possible; if possible, within 12 hours of when you usually take the pill. If this is not possible or more than 12 hours have passed, follow the instructions in the section “If you forget to take TRIQUILAR”.

Delaying your period days: points to consider

Even though it is not recommended, you can delay your monthly period by leaving out the tablet-free interval and continuing with the next TRIQUILAR strip straight away, until you have completed it. Whilst on this second strip, mild or menstruation-like bleeding may occur. As soon as you have completed this second strip, you must observe a 7-day tablet-free interval.

You should ask your doctor for advice before deciding to delay bleeding.

Changing the day of the week when your monthly period starts: points to consider

If you want to change the day of the week when your period starts, you can shorten the tablet-free interval by as many days as you wish. The shorter the tablet-free interval, the greater the likelihood that no withdrawal bleeding will occur and that there will be mild or menstruation-like bleeding whilst you are on the next strip. However, never lengthen the tablet-free interval.

If you are not sure about what to do, ask your doctor.

If you wish to stop taking TRIQUILAR

You can stop taking TRIQUILAR at any time. If you do not wish to become pregnant, talk to your doctor about other safe contraceptive methods. If you wish to become pregnant, stop taking TRIQUILAR and wait until your monthly period before trying to conceive. In this way, you will be able to calculate the estimated delivery date more easily.

If you have any 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 side effects, especially if they are serious and persistent, or if there is a change in your state of health and you think this is due to TRIQUILAR, please talk to your doctor.

All women using combined hormonal contraceptives are at increased risk of blood clots in the veins (venous thromboembolism [VTE]) or arteries (arterial thromboembolism [ATE]). For more details on the various risks associated with the use of combined hormonal contraceptives, see section 2 “What you need to know before you take TRIQUILAR”.

The use of pills containing the same active substances as TRIQUILAR is most commonly associated with side effects of headache, spotting and bleeding between periods.

Other possible side effects that may occur when using these pills are:

Common side effects (up to 1 in 10 users may be affected):

- Mood swings, depressive moods
- Headache
- Nausea, abdominal pain
- Breast pain or sensitive breasts
- Weight gain

Uncommon side effects (up to 1 to 100 users may be affected):

- Decreased sex drive (reduced libido)
- Migraine
- Vomiting, diarrhoea
- Skin rash
- Nettle rash (itching)
- Swollen breasts
- Fluid accumulation (fluid retention)

Rare side effects (up to 1 in 1,000 users may be affected):

- Contact lens intolerance
- Hypersensitivity
- Increased sex drive (increased libido)
- Vaginal or breast discharge
- Skin redness, blotches or lumps beneath the skin

- Weight loss
- Harmful blood clots in a vein or artery, for example:
 - in a leg or foot (i.e. DVT) o in a lung (i.e. PE)
 - heart attack
 - stroke
 - mini-stroke or temporary symptoms similar to a stroke, called a transient ischaemic attack (TIA)
 - blood clots in the liver, stomach/intestines, kidneys or the eye.

The likelihood of a blood clot may be increased if you suffer from other diseases that increase this risk (for more information on disorders that increase the risk of a blood clot and symptoms of a blood clot, see section 2).

The following severe side effects have been reported somewhat more frequently in women taking the pill, although it is not clear whether this increase in frequency is triggered by its use (see also section 2 “When special care is needed when taking TRIQUILAR”)

- Cervical cancer, breast cancer
- Increased blood pressure
- Liver dysfunction, liver tumours

The following disorders have also been associated with the pill:

Crohn's disease, ulcerative colitis, epilepsy, migraine, endometriosis (with symptoms of very painful monthly periods), benign womb tumours, porphyria (a metabolic disorder causing abdominal pain and neurological disorders), systemic lupus erythematosus (when the body's own organs and tissues are attacked and damaged by the immune system), herpes in late pregnancy, chorea minor (Sydenham's chorea; rapid, involuntary twitching or jerking movements), haemolytic-uraemic syndrome (a disorder that occurs following *E. coli*-induced diarrhoea), liver problems manifesting as jaundice, metabolic disorders, a form of hearing loss (otosclerosis).

In women with inherited sudden swelling of the skin, mucous membranes, internal organs or brain (hereditary angioedema), the oestrogens in the pill can trigger or worsen the symptoms of angioedema (see section 2 “When special care is needed when taking TRIQUILAR”).

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 to the *Bundesinstitut für Arzneimittel und Medizinprodukte* (= Federal Institute for Drugs and Medical Devices), *Abt. Pharmakovigilanz* (Department of Pharmacovigilance), Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: <http://www.bfarm.de>. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRIQUILAR

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and strip after “Expiry date” or “EXP”. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What TRIQUILAR contains

- The active substances are ethinylestradiol and levonorgestrel.
- Each light-brown coated tablet contains 30 micrograms of ethinylestradiol and 50 micrograms of levonorgestrel.
- Each white coated tablet contains 40 micrograms of ethinylestradiol and 75 micrograms of levonorgestrel.
- Each ochre-coloured coated tablet contains 30 micrograms of ethinylestradiol and 125 micrograms of levonorgestrel.
- The other ingredients are:
- Tablet core: lactose monohydrate (see also section 2 “Important information about some of the other ingredients of TRIQUILAR”), maize starch, povidone K25, talc, magnesium stearate (Ph.Eur.) [vegetable] (E470b)
- Coating – light-brown tablet: sucrose (see also section 2 “Important information about some of the other ingredients of TRIQUILAR”), povidone 700,000, macrogol 6,000, calcium carbonate, talc (E553b), glycerol 85%, montan glycol wax, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172)
- Coating – white tablet: sucrose (see also section 2 “Important information about some of the other ingredients of TRIQUILAR”), povidone 700,000, macrogol 6,000, calcium carbonate, talc (E553b), glycerol 85%, montan glycol wax, titanium dioxide (E171)
- Coating – ochre-coloured tablet: sucrose (see also section 2 “Important information about some of the other ingredients of TRIQUILAR”), povidone 700,000, macrogol 6,000, calcium carbonate, talc (E553b), glycerol 85%, montan glycol wax, titanium dioxide (E171), yellow iron oxide (E172)

What TRIQUILAR looks like and contents of the pack

- TRIQUILAR tablets are 6 light-brown, 5 white and 10 ochre-coloured, round coated tablets
- TRIQUILAR is available in packs of 1, 3 and 6 blisters, each with 21 tablets.

Marketing Authorisation Holder

Bayer Vital GmbH, D-51368 Leverkusen

Co-distributor:*

Jenapharm GmbH & Co. KG Otto-Schott-Strasse 15 , D-07745 Jena

* Co-distributor stated depending on the batch

Manufacturer

Bayer Pharma AG, D-13342 Berlin, Germany