

## Consumer Medicine Information

# TRIQUILAR<sup>®</sup> ED

### *Three-phase hormonal preparation:*

*6 tablets each containing 0.05 mg levonorgestrel + 0.03 mg ethinylestradiol*

*5 tablets each containing 0.075 mg levonorgestrel + 0.04 mg ethinylestradiol*

*10 tablets each containing 0.125 mg levonorgestrel + 0.03 mg ethinylestradiol*

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## What is in this leaflet

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Please read this leaflet carefully before you start using TRIQUILAR ED. It will advise you about how to take TRIQUILAR ED properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider or pharmacist.

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## What is TRIQUILAR ED used for and how does it work

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TRIQUILAR ED is a combined oral contraceptive (often called "the Pill") consisting of 21 small hormonal tablets which contain a small amount of two different female hormones. These are levonorgestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amount of hormones, TRIQUILAR ED is considered a low-dose combined oral contraceptive preparation. The TRIQUILAR ED blister pack contains 3 different kinds of active tablets, each kind featuring different amounts of two hormones. These tablets emulate the natural cycle by generating three distinct hormonal stages. This is why TRIQUILAR ED is called a triphasic combined oral contraceptive.

TRIQUILAR ED also contains 7 large white non-hormonal tablets that do not contain any active ingredients.

### ***How does TRIQUILAR ED work?***

Combined oral contraceptive Pills, such as TRIQUILAR ED, provide one of the most effective reversible methods of contraception known. Usually, when TRIQUILAR ED is taken according to the instructions, the egg cells (normally released by the ovary each month) are prevented from maturing to the point where they can be fertilised. In addition, the cervical mucus remains thick, so it is more difficult for a man's sperm to enter the womb. Also, the lining of the womb is not prepared sufficiently for a fertilised egg to grow in.

### ***What is TRIQUILAR ED used for?***

TRIQUILAR ED is used to prevent pregnancy. Combined oral contraceptives are a very effective method of birth control. When taken correctly (without missing tablets) the chance of becoming pregnant is very low (approximately 1% per year). The failure rate may increase when tablets are missed or taken incorrectly.

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## Before you use TRIQUILAR ED

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Do not use TRIQUILAR ED if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use TRIQUILAR ED. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

### ***You must not use TRIQUILAR ED if:***

- you have, or have ever had a disorder affecting the blood circulation, in particular those conditions relating to thrombosis. Thrombosis is the formation of a blood clot. This may occur in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), the brain (stroke), or other parts of the body. (See also the section later in this leaflet called "*TRIQUILAR ED and thrombosis*").
- you have or have ever had a stroke (caused by a rupture of a blood vessel in the brain).
- you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischemic attack or small reversible stroke).
- you have diabetes mellitus with blood vessel damage.
- you have or have had pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- you or someone in your immediate family have or have had high blood levels of cholesterol or triglycerides (fatty substances).
- you have or have had jaundice (yellowing of the skin) or severe liver disease as long as liver function values have not returned to normal.
- you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- you have or have had a benign or malignant liver tumor.
- you have a history of migraine accompanied by visual symptoms or speech disability or weakness or numbness in any part of your body.
- you have any unexplained vaginal bleeding.
- you are pregnant or think you might be pregnant.
- you are hypersensitive (allergic) to any of the ingredients of TRIQUILAR ED.

If any of these conditions appear for the first time while using TRIQUILAR ED, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures.

### ***Tell your doctor if:***

If TRIQUILAR ED is used in the presence of any of the conditions listed below or they appear for the first time or recur or worsen during treatment, you may need to be kept under close observation. Your doctor can explain this to you. You should tell your doctor if:

- you smoke
- you have diabetes
- you are overweight
- you have high blood pressure

- you have a heart valve disorder or a certain heart rhythm disorder
- you have an inflammation of your veins (superficial phlebitis)
- you have varicose veins
- anyone in your immediate family has had thrombosis, a heart attack or a stroke
- you suffer from headaches
- you suffer from epilepsy
- anyone in your immediate family has had breast cancer
- you have liver, kidney or gallbladder disease
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body)
- you have hemolytic uremic syndrome (HUS; a disorder of blood clotting causing failure of the kidneys)
- you have sickle cell disease
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea);
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation
- you have hereditary angioedema; exogenous estrogens may induce or exacerbate symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

### ***What else you should know***

**TRIQUILAR ED does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

In this leaflet, several situations are described where you should stop taking TRIQUILAR ED, or where the reliability of TRIQUILAR ED may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because TRIQUILAR ED alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

### **TRIQUILAR ED and thrombosis**

Thrombosis is the formation of a blood clot which may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". Deep venous thrombosis is a rare occurrence. The risk is highest during the first year a woman ever uses the Pill.

Venous thrombosis can develop whether or not you are using the Pill. It can also happen if you become pregnant. The risk is higher in Pill users than in non-users but not as high as the risk during pregnancy.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely, blood clots can occur in the liver, gut, kidney or eye.

Very occasionally a thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke.

**When using TRIQUILAR ED you should stop smoking, especially if you are older than about 35 years of age.**

If you develop high blood pressure while using TRIQUILAR ED, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilization (for example, when you have your leg or legs in plaster or splints). In women who use the Pill (such as TRIQUILAR ED) the risk may be even higher. Tell your doctor you are using TRIQUILAR ED well in advance of any expected hospitalization or surgery. Your doctor may tell you to stop taking TRIQUILAR ED several weeks before surgery or at the time of immobilization. Your doctor will also tell you when you can start taking TRIQUILAR ED again after you are back on your feet.

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately (See also the section called "*Tell your doctor if:*")

### **TRIQUILAR ED and cancer**

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the ten years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

In rare cases, benign, and even more rarely, malignant liver tumors have been reported in users of the Pill. These tumors may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

The most important risk factor for cervical cancer is persistent human papilloma virus infection. Some studies have indicated that long-term use of the Pill may further contribute to this increased risk but there continues to be controversy about the extent to which this finding is attributable to other factors, e.g., cervical screening and sexual behaviour including use of barrier contraceptives.

### **TRIQUILAR ED and other medicines**

Some oral medicines may stop TRIQUILAR ED from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate) and tuberculosis (e.g. rifampicin, rifabutin); HIV infections (e.g. ritonavir, nevirapine); antibiotics (e.g. ampicillin,

tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John's wort (primarily used for the treatment of depressive moods).

The Pill may also interfere with the working of other medicines, e.g. medicines containing cyclosporin, or the anti-epileptic lamotrigine.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed.

Always tell the doctor who prescribes TRIQUILAR ED which medicines you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use TRIQUILAR ED. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

### **TRIQUILAR ED and breast-feeding**

TRIQUILAR ED is generally not recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please seek the advice of your doctor.

### **TRIQUILAR ED and pregnancy**

TRIQUILAR ED must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using TRIQUILAR ED, you should consult your doctor as soon as possible.

### **TRIQUILAR ED and ability to drive and use machines**

There are no observed effects.

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## **How to use TRIQUILAR ED properly**

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When you follow the starting instructions and continue to take TRIQUILAR ED correctly, the contraceptive protection provided by TRIQUILAR ED is continuous. This includes the week when you take the non-hormonal tablets.

Additional contraceptive precautions are only required when special circumstances (e.g. forgetting tablets) reduce the reliability of the preparation.

Remember that TRIQUILAR ED has been prescribed for you personally. Do not share it with others.

### ***When and how to take the tablets***

Take your tablet at about the same time each day, with some water if necessary. Follow the direction of the arrows until all the tablets have been taken (you will find detailed instructions on the preparation of the blister pack in the section "*How to prepare the blister pack of TRIQUILAR ED - Day of the week stickers*"). A period (the withdrawal bleed) should begin during the 7 days of taking the larger white non-hormonal tablets. Start taking your next pack on the very next day after you have completed your last pack. This means that you will always start new packs on the same day of the week, and also that you will have your withdrawal bleed on about the same day each month.

## **How to prepare the blister pack of TRIQUILAR ED - Day of the week stickers**

The TRIQUILAR ED pack holds 3 memo-packs, each containing 21 small, round hormonal tablets (i.e. 6 light-brown, 5 small white and 10 ochre tablets) and 7 large white non-hormonal tablets.

In addition to the memo-packs, the outer carton contains a sheet of stickers divided, by perforated lines, into three sections. Separate each section along the perforated lines to give you 3 single sheets of stickers. Each of the 3 sticker sheets hold 7 self-adhesive strips showing the days of the week.

When you are ready to start a new memo-pack, look below the start arrow on the left of one of the sticker sheets and choose one strip that starts with the day that you will begin tablet taking. For example, if you start the tablets on a Wednesday, use the strip that starts with "Wed".

Peel the required strip off the sheet and stick it onto the area indicated on the front of the memo-pack so that the first day is above the tablet to which the arrow marked "Start" is pointing.

Throw the unused portion of this sticker away. Repeat the process above with the other sticker sheets just before you begin each memo-pack.

## **Starting your first pack of TRIQUILAR ED**

First prepare the blister pack with the day of the week sticker using the instructions above "*How to prepare the blister pack of TRIQUILAR ED - Day of the week stickers*"

**START WITH THE TABLET FROM THE GREEN SECTION MARKED WITH THAT DAY OF THE WEEK**, in accordance with one of the following:

### **When no hormonal contraceptive has been used in the past month**

Start taking TRIQUILAR ED on the first day of your menstrual bleeding. Then follow the days in order. TRIQUILAR ED will work immediately, it is not necessary to use an additional contraceptive method.

You may also start on days 2 - 3 of your cycle, but in that case make sure that you also use an additional contraceptive method (barrier method such as condoms) for the first 7 days of tablet-taking in the first cycle.

### **When changing from a combined Pill, vaginal ring, or transdermal (contraceptive) patch**

You can start taking TRIQUILAR ED the day after you take the last tablet from your present Pill pack (this means no tablet-free break). Follow the instructions as described under "*Starting your first pack of TRIQUILAR ED*". If your present Pill pack also contains non-hormonal tablets you can start TRIQUILAR ED on the day after taking the last **hormonal** tablet (if you are not sure which this is, ask your doctor or pharmacist). In case you have used a vaginal ring or transdermal patch, you should start using TRIQUILAR ED preferably on the day of removal, but at the latest when the next application would have been due. If you follow these instructions it is not necessary to use an additional contraceptive method.

### **When changing from a progestogen-only Pill (minipill)**

You can stop taking the minipill any day and start taking TRIQUILAR ED the next day, at the usual time. Follow the instructions as described under "*Starting your first pack of TRIQUILAR ED*". But make sure you also use an additional contraceptive method (a barrier method such as condoms) for the first 7 days of tablet taking when having intercourse.

### **When changing from an injectable, an implant, or a progestogen-releasing intrauterine device (IUD)**

Start using TRIQUILAR ED when your next injection is due or on the day that your implant or IUD is removed. Follow the instructions as described under "*Starting your first pack of TRIQUILAR ED*". But make sure you also use an additional contraceptive method (a barrier method such as condoms) for the first 7 days of tablet taking when having intercourse.

### **After having a baby**

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking TRIQUILAR ED. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take TRIQUILAR ED, you should discuss this first with your doctor.

### **After a miscarriage or an abortion**

Your doctor will advise you.

### ***Special circumstances***

The following describes special circumstances that could alter the way you take TRIQUILAR ED. In all situations where the reliability of TRIQUILAR ED is reduced (such as missing tablets) additional contraceptive precautions are required following the advice given below. This advice should also be followed in situations where other medicines may stop TRIQUILAR ED from working properly and in the case of vomiting or severe diarrhea after taking TRIQUILAR ED.

### **If you forget to take your tablets**

If you forget to take your tablets, follow the instructions below. This is often called the "*7 day rule*". The more tablets you have missed, the higher the risk that the contraceptive effect is decreased. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning or at the end of the pack.

#### ***WHAT TO DO IF .....***

##### **..... you forget tablets**

- If you have forgotten to take one or more of the **large white non-hormonal tablets** - there is no need to be concerned, simply take your next tablet, the next day as usual. However to make sure that you do not change your Pill taking rhythm, which is important for the contraceptive reliability of your Pill, you should proceed with your next tablet the next day at the normal time and discard the forgotten non-hormonal tablet(s) to avoid any confusion.

- If you are **less than 12 hours late** in taking one of the small hormonal TRIQUILAR ED tablets, you are still protected against pregnancy. Take the tablet as soon as you remember and take the next one at your usual time. This may mean that you are taking 2 tablets in one day.
- If you are **more than 12 hours late** in taking one of your small hormonal TRIQUILAR ED tablets, you will not be protected. Take the last tablet as soon as you remember and take the next one at your normal time. This may mean taking 2 tablets in one day. You must take extra contraceptive precautions and you must follow the 7 day rule. Read the section on "*Extra contraceptive precautions*" and "*The 7 day rule*" carefully.
- If you forget tablets in the first week after taking the large non-hormonal tablets and had intercourse in the seven days before, consult your doctor as the possibility of pregnancy should be considered.
- If you have forgotten to take your small hormonal TRIQUILAR ED tablets for a few days, consult your doctor to be sure you are not pregnant, then discard the missed tablets and follow the 7 day rule.

### ***Extra contraceptive precautions***

When you need extra contraceptive precautions, either:

- don't have sex; or
- use a cap plus spermicide; or
- use a condom

Do not use the rhythm or temperature methods as extra contraceptive precautions. This is because oral contraceptives alter the usual menstrual cycle changes, such as changes in temperature and cervical mucus.

### ***The 7 day rule***

- Continue taking your Pills
- You will not be protected from pregnancy until you have taken your daily small hormone Pill for the next 7 days in a row
- Use another method of contraception (*Extra contraceptive precautions*) such as condoms or do not have sexual intercourse for these next 7 days
- If there are fewer than 7 small hormone Pills left before the non-hormonal pills, go straight on to the small hormone Pills in the green section of the next pack. This means you miss out the large white non-hormonal pills. You may not have a period until the end of the next pack. This is not harmful.

### **If you vomit or have severe diarrhea after taking TRIQUILAR ED**

If you vomit or have severe diarrhea within 3 to 4 hours after taking your TRIQUILAR ED hormonal tablets, the active ingredients may not have been completely absorbed. This is like missing a tablet. Therefore, follow the advice for missed tablets. If vomiting or diarrhea occurs while taking the non-hormonal tablets, this does not have an influence on the contraceptive reliability.

### **If you are taking medicines that affect TRIQUILAR ED**



Some medicines may stop TRIQUILAR ED from working properly. These medicines are listed in an earlier section. For the time that you are taking the medicine and for the next 7 days follow the advice for missed tablets. If you are taking rifampicin, or you are taking these medicines continuously, your doctor will advise you on the length of time you need to take extra contraceptive precautions.

### **If you want to delay a period**

You can delay your period if you continue with the last 10 **ochre colored hormonal** tablets of another pack of TRIQUILAR ED **immediately after finishing** the ochre colored hormonal tablets of your current pack. (Do not take the large white non-hormonal tablets from your current pack). Continue with the second pack until this pack is empty. Your period will start while you are taking the large white non-hormonal tablets in the second pack. You may have some breakthrough bleeding or spotting while you are taking the small hormonal tablets.

The extension can be carried on for a maximum of 10 days until the end of the ochre colored hormonal tablets of your second pack.

### **If you want to change the starting day of your period**

If you take your tablets as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten (never lengthen) the duration of taking the large white non-hormonal tablets. For example if your period usually starts on a Friday and in future you want to start on Tuesday (3 days earlier) you should now start your next pack 3 days sooner than you usually do, discard the 3 remaining large white non-hormonal tablets of your previous pack and then continue with the next pack without having a break between the packs. If you make the duration of taking the large non-hormonal tablets very short (e.g. 3 days or less), you may not have a bleed during the break. You may have some breakthrough bleeding or spotting during the use of the next pack.

### **If you have unexpected bleeding**

As with other Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) with TRIQUILAR ED between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to TRIQUILAR ED (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

### **If you have missed a period**

If you have taken all of your tablets at the right time, and you have not vomited, had severe diarrhea while taking the small hormonal tablets or used other medicines, then you are very unlikely to be pregnant. Continue to take TRIQUILAR ED as usual.

If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of TRIQUILAR ED until your doctor has checked you are not pregnant.

### **When you want to stop taking TRIQUILAR ED**

You can stop taking TRIQUILAR ED at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have a natural period before trying to conceive. This helps you to work out when the baby is due.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

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## Overdosage

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There have been no reports of serious harmful effects from taking too many TRIQUILAR ED hormonal tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken TRIQUILAR ED, ask your doctor for advice. Taking the large white non-hormonal tablets is harmless because they do not contain active ingredients.

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## When using TRIQUILAR ED

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***Tell your doctor immediately if:***

**You should stop treatment and see your doctor immediately if you get a blood clot, heart attack or stroke while you are taking TRIQUILAR ED. Warning signs for a blood clot, heart attack or stroke to look out for are:**

- an unusual cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or prolonged headache or migraine attack;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

***Tell your doctor if:***

**Contact your doctor as soon as possible if:**

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet. Do not forget about the items related to your immediate family;
- you feel a lump in your breast;
- you are going to use other medications (See also the section called "*TRIQUILAR ED and other medicines*");
- you are to be immobilized or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;

- you forgot tablets in the first week of the pack and had intercourse in the seven days before;
- you have severe diarrhea;
- you have missed your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor).

### **Regular check-ups**

When you are using TRIQUILAR ED, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

## **Side effects**

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by TRIQUILAR ED.

### **Serious side effects**

Serious reactions associated with the use of combined oral contraceptives such as TRIQUILAR ED, as well as the related symptoms, are described in the section "*Before you use TRIQUILAR ED*". Please read this section carefully and consult your doctor where appropriate.

### **Other possible side effects**

The following side effects have been reported in users of combined oral contraceptives such as TRIQUILAR ED, although they may not be caused by the contraceptive Pill. Such side effects that occur in the first few months that you are using TRIQUILAR ED will probably lessen with time.

<b>System Organ Class</b>	<b>Common (≥ 1/100)</b>	<b>Uncommon (≥ 1/1000 and &lt; 1/100)</b>	<b>Rare (&lt; 1/1000)</b>
Eye disorders			Contact lens intolerance
Gastrointestinal disorders	Nausea, abdominal pain	Vomiting, diarrhea	
Immune system disorders			Hypersensitivity
Investigations	Increased weight		Decreased weight
Metabolism and nutrition disorders		Fluid retention	
Nervous system disorders	Headache	Migraine	
Psychiatric disorders	Depression, altered mood	Decreased libido	Increased libido
Reproductive system and	Breast pain, breast	Breast	Vaginal discharge,

<b>System Organ Class</b>	<b>Common (≥ 1/100)</b>	<b>Uncommon (≥ 1/1000 and &lt; 1/100)</b>	<b>Rare (&lt; 1/1000)</b>
breast disorders	tenderness	enlargement	breast discharge
Skin and subcutaneous tissue disorders		Rash, urticaria	Erythema nodosum, erythema multiforme

If you have hereditary angioedema, taking estrogens may induce or exacerbate symptoms of angioedema. (See also "*Before you use TRIQUILAR ED*").

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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## **Storage**

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Do not use after the expiry date stated on the package.

Store all medicines properly and keep them out of reach of children.

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## **Further information**

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Like other combined oral contraceptive Pills, TRIQUILAR ED may also have non-contraceptive health benefits.

- Your period may be lighter and shorter. As a result, the risk of anemia may be lower. Your period pains may become less severe or may completely disappear.
- Some serious disorders have been reported to occur less frequently in users of "high-dose" oral contraceptive Pills. These are benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease or PID), ectopic pregnancy (pregnancy in which the embryo implants outside of the womb) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for "low-dose" Pills such as TRIQUILAR ED, but so far this has only been confirmed for endometrial and ovarian cancer.

### ***TRIQUILAR ED tablets contain:***

#### **active substances (per tablet):**

- levonorgestrel 0.05 mg and ethinylestradiol 0.03 mg (6 light-brown tablets)
- levonorgestrel 0.075 mg and ethinylestradiol 0.04 mg (5 small white tablets)
- levonorgestrel 0.125 mg and ethinylestradiol 0.03 mg (10 ochre tablets)

#### **other substances:**

lactose monohydrate, maize starch, polyvidone 25 000, magnesium stearate, sucrose, polyvidone 700 000, macrogol 6000, calcium carbonate, talc, glycerol 85%, ferric oxide pigment yellow, ferric oxide pigment red, titanium dioxide, montanglycol wax.

**If you have any further questions please consult your doctor or pharmacist.**

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## **Name and Address**

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## **Date of Preparation**

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1st February 2007