

PACKAGE LEAFLET: INFORMATION FOR THE USER

# Cimizt

150/30 Tablets

## Desogestrel 150 micrograms & Ethinylestradiol 30 micrograms

- Important things to know about combined hormonal contraceptives (CHCs):**
- They are one of the most reliable reversible methods of contraception if used correctly.
  - They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
  - Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 'Blood Clots').
  - Some women should not take the Pill because of current medical problems or illnesses. Please read this leaflet to make sure Cimizt is right for you.
  - To prevent pregnancy it is important to take Cimizt as instructed and to start each pack on time. Please make sure that you understand what to do if you miss a pill or if you think you are pregnant.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions or need more advice, ask your doctor, family planning nurse or pharmacist.
3. 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.
4. If you get any side effects, talk to your doctor, family planning nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

- What is in this leaflet**
1. What Cimizt Tablets are and what they are used for
  2. What you need to know before you take Cimizt Tablets
  3. How to take Cimizt Tablets
  4. Possible side effects
  5. How to store Cimizt Tablets
  6. Contents of the pack and other information

**1. What Cimizt Tablets are and what they are used for**

Cimizt is a combined oral contraceptive pill ('the Pill'). You take it to prevent pregnancy. This low-dose contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones prevent an egg being released from your ovaries so you can't get pregnant. Cimizt also makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb.

Cimizt is a 21-day pill – you take one each day for 21 days, followed by 7 days when you take no pills.

**The benefits of taking the Pill include:**

- it is one of the most reliable reversible methods of contraception if used correctly
- it doesn't interrupt sex
- it usually makes your periods regular, lighter and less painful
- it may help with pre-menstrual symptoms.

Cimizt will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Cimizt needs to be taken as directed to prevent pregnancy.

**2. What you need to know before you take Cimizt Tablets**

**General notes**

Before you start taking Cimizt you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see section 2 'Blood clots'. It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women, it isn't suitable for everyone.

- **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

**Before you start taking the Pill**

- Your doctor will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination.

- While you're on the Pill**
- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
  - You should go for **regular cervical smear tests**.
  - **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
  - **If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
  - **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again.

**2.1 Do not take tablets**

You should not use Cimizt Tablets if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate. See also section 2.2 'Warnings and precautions'

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section 'Blood Clots');
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - o severe diabetes with blood vessel damage,
  - o very high blood pressure,
  - o a very high level of fat in the blood (cholesterol or triglycerides),
  - o a condition known as hyperhomocysteinaemia;
- if you have (or have ever had) a type of migraine called 'migraine with aura';
- if you have or have recently had a **severe liver disease**;
- if you have (or have ever had) a **liver tumour**;
- if you have or have had a **pancreatitis** (an inflammation of the pancreas) associated with high levels of fatty substances in your blood;
- Known or suspected **pregnancy**;
- if you have cancer affected by sex hormones – such as some **cancers of the breast, womb lining or ovary**;
- if you have **vaginal bleeding** that has not been explained by your doctor;
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voixiaprevir (see also the section on 'Other medicines and Cimizt Tablets');
- if you are allergic to ethinylestradiol or desogestrel, or any of the other ingredients of this medicine (listed in section 6).

**If you suffer from any of these**, or get them for the first time while taking Cimizt Tablets, contact your doctor as soon as possible. Do not take Cimizt Tablets.

**2.2 Warnings and precautions**

When should you contact your doctor?

**Seek urgent medical attention**

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

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

If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing oestrogens may cause or worsen the symptoms of hereditary and acquired angioedema. (see "Tell your doctor if any of the following conditions apply to you" section below)

- Tell your doctor if any of the following conditions apply to you.**
- If the condition develops, or gets worse while you are using Cimizt Tablets, you should also tell your doctor.
- if you have ever had problems with your **heart, circulation or blood clotting**.
  - if you have **diabetes**;
  - if you have ever had **kidney or liver problems**.
  - if you have ever had **severe depression**;
  - if you have ever had **migraines**.
  - if you have had **problems while pregnant or while using the pill**, like:
    - o itching of the whole body (pruritus).
    - o jaundice which was not caused by infection, o gallstones,
    - o systemic lupus erythematosus (SLE),
    - o a blister-like rash, called herpes gestationis,
    - o a hearing problem called otosclerosis,
    - o other rare conditions called porphyria., hereditary and acquired angioedema [ you should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing. Products containing oestrogens may cause or worsen the symptoms of hereditary and acquired angioedema].
  - if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
  - if you have **brown patches on your face or body (chloasma)** – if so avoid too much exposure to the sun or ultraviolet light.
  - if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
  - if you have sickle cell anaemia (an inherited disease of the red blood cells);
  - if you have systemic lupus erythematosus (SLE – a disease affecting your natural defence system);
  - if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas);
  - if you need an operation, or you are off your feet for a long time (see in section 2 'Blood Clots');
  - if you have just given birth. In this case you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Cimizt (see section 2.2.1 The Pill and Thrombosis).
  - if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
  - if you have varicose veins;

**2.2.1 The Pill and Thrombosis**

**Blood Clots**

Using a combined hormonal contraceptive such as Cimizt increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop:

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

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

**It is important to remember that the overall risk of a harmful blood clot due to Cimizt is small.**

**How to recognise a blood clot**

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

Are you experiencing any of these signs?	What are you possibly suffering from?
swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none"> <li>• pain or tenderness in the leg which may be felt only when standing or walking</li> <li>• increased warmth in the affected leg</li> <li>• change in colour of the skin on the leg e.g. turning pale, red or blue.</li> </ul>	Deep vein thrombosis
<ul style="list-style-type: none"> <li>• sudden unexplained breathlessness or rapid breathing;</li> <li>• sudden cough without an obvious cause, which may bring up blood;</li> <li>• sharp chest pain which may increase with deep breathing;</li> <li>• severe light headedness or dizziness;</li> <li>• rapid or irregular heartbeat;</li> <li>• severe pain in your stomach;</li> </ul> If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: <ul style="list-style-type: none"> <li>• immediate loss of vision or</li> <li>• painless blurring of vision which can progress to loss of vision.</li> </ul>	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure, heaviness;</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone;</li> <li>• fullness, indigestion or choking feeling;</li> <li>• upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li> <li>• sweating, nausea, vomiting or dizziness;</li> <li>• extreme weakness, anxiety, or shortness of breath;</li> <li>• rapid or irregular heartbeats.</li> </ul>	Heart attack
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li> <li>• sudden confusion, trouble speaking or understanding;</li> <li>• sudden trouble seeing in one or both eyes;</li> <li>• sudden trouble walking, dizziness, loss of balance or coordination;</li> <li>• sudden, severe or prolonged headache with no known cause;</li> <li>• loss of consciousness or fainting with or without seizure.</li> </ul> Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
<ul style="list-style-type: none"> <li>• swelling and slight blue discolouration of an extremity;</li> <li>• severe pain in your stomach (acute abdomen).</li> </ul>	Blood clots blocking other blood vessels

**Blood clots in a vein**

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

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

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

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

When you stop Cimizt your risk of a blood clot returns to normal within a few weeks.

**What is the risk of developing a blood clot?**

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

- The overall risk of a blood clot in the leg or lung (DVT or PE) with Cimizt is small.
- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
  - Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
  - Out of 10,000 women who are using a combined hormonal contraceptive that contains desogestrel, such as Cimizt, about 9- 12 women will develop a blood clot in a year.
  - The risk of having a blood clot will vary according to your personal medical history (see "Factors that increase your risk of a blood clot" below).

	Risk of developing a blood clot in a year
Women who are <b>not using</b> a combined hormonal pill/patching and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using Cimizt	About 9-12 out of 10,000 women

**Factors that increase your risk of a blood clot in a vein**

- The risk of a blood clot with Cimizt is small but some conditions will increase the risk. Your risk is higher:
- if you are very overweight (body mass index or BMI over 30kg/m<sup>2</sup>);
  - if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50 years). In this case you could have a hereditary blood clotting disorder;
  - if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Cimizt may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Cimizt ask your doctor when you can start using it again;
  - as you get older (particularly above the age of about 35 years);
  - if you gave birth less than a few weeks ago.
- The risk of developing a blood clot increases the more conditions you have.
- Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.
- It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Cimizt needs to be stopped.

If any of the above conditions change while you are using Cimizt, for example a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

**Blood clots in an artery**

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

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

- Factors that increase your risk of a blood clot in an artery**
- It is important to note that the risk of a heart attack or stroke from using Cimizt is very small but can increase:
- with increasing age (beyond about the age of about 35 years);
  - **if you smoke**. When using a combined hormonal contraceptive like Cimizt you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
  - if you are overweight;
  - if you have high blood pressure;
  - if a member of your immediate family has had a heart attack or stroke at a young age (less than about the age of 50 years); in this case you could also have a higher risk of having a heart attack or stroke;
  - if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
  - if you get migraines, especially migraines with aura;
  - if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
  - if you have diabetes.
- If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.
- If any of the above conditions change while you are using Cimizt, for example you start smoking, a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

**2.2.2 The pill and cancer**

The Pill reduces your risk of cancer of the ovary and womb if used in the long term. However, it also seems to slightly increase your risk of cancer of the cervix – although this may be due to having sex without a condom rather than the Pill itself. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you're on the Pill, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40 the extra number of cases of breast cancer in current and recent users of the Pill is small.

- For example:
- Of 10,000 women who have **never taken the Pill**, about 16 will have breast cancer by the time they are 35 years.
  - Of 10,000 women who **take the Pill for 5 years in their early twenties**, about **17-18** will have breast cancer by the time they are 35 years.
  - Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.
  - Of 10,000 women who **take the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

**Your risk of breast cancer is higher:**

- if you have a close relative (mother, sister or grandmother) who has had breast cancer;
- if you are seriously overweight.

**–See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

**–See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice).** You may need to stop taking Cimizt.

**2.2.3 Psychiatric disorders**

Some women using hormonal contraceptives including Cimizt have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

**2.3 Other medicines and Cimizt Tablets**

Tell your doctor, pharmacist or family planning nurse if you are using, have recently used or might use any other medicines or herbal products, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use Cimizt. This is because Cimizt can also affect how well other medicines work, causing either an increase in effect (e.g., ciclosporin) or a decrease in effect (e.g., lamotrigine). Remind your doctor if you are taking these in case your treatment needs to be adjusted.

Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

- Some medicines may stop Cimizt from working properly.** These include medicines used for the treatment of:
- **epilepsy** (primidone, phenytoins, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate, modafinil);
  - **tuberculosis** (rifampicin);
  - **HIV infection** (ritonavir, nelfinavir, nevirapine, efavirenz);
  - **Hepatitis C virus infection** (e.g., bocoprevir, telaprevir);
  - **other infectious disease** (e.g. griseofulvin);
  - **high blood pressure in the blood vessels of the lungs** (bosentan);
  - **depressive moods** (the herbal remedy **St. John's wort**).

If you are taking medicines or herbal products that might make Cimizt less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Cimizt may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

Do not use Cimizt Tablets if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voixiaprevir, as these products may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products. Cimizt Tablets can be restarted approximately 2 weeks after completion of this treatment. See the section on 'Do not take Cimizt Tablets'

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

**2.4 Cimizt Tablets with food and drink**

Cimizt Tablets may be taken with or without food, with a small amount of water as required.

**Laboratory tests:**

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormone contraceptives can affect the results of some tests.

**2.5 Pregnancy and breast-feeding**

Do not use Cimizt if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Cimizt.

Cimizt is not recommended for use during breast-feeding. Ask your doctor or family planning nurse about alternative contraception. Breast-feeding may not stop you getting pregnant.

**2.6 Driving and using machines**

Cimizt has no known effect on the ability to drive or use machines.

**2.7 Cimizt Tablets contain lactose**

This product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take this product.

**2.8 Use in adolescents**

No clinical data on efficacy and safety are available in adolescents below 18 years.

**3. How to take Cimizt Tablets**

To prevent pregnancy, always take this medicine exactly as described in this leaflet or as your doctor, family planning nurse or pharmacist has told you. Take one tablet of Cimizt Tablets every day, with required amount of water. Swallow each pill as a whole, with water if necessary. Do not chew the pill. You may take the tablets with or without food, but you should take the tablets every day around the same time.

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

Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This is so-called "withdrawal bleeding" usually starts on the 2<sup>nd</sup> or 3<sup>rd</sup> day of the gap week.

On the 8<sup>th</sup> day after the last tablet of Cimizt (that is, after the 7-day gap week), you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week on same time and that the withdrawal bleed should occur on the same days each month.

If you use Cimizt Tablets in this manner, you are also protected against pregnancy during the 7 days when you are not taking a tablet.

**When can you start with the first strip?**

- **If you have not used a contraceptive with hormones in the previous month** Begin with Cimizt on the first day of the cycle (that is the first day of your period). If you start Cimizt on the first day of your period you are immediately protected against pregnancy. Or if your period has already begun start taking Cimizt on day 5 (counting the first day of your period as day 1) whether or not your bleeding has stopped. You must use extra protective measures (for example, a condom) until you have taken the pills for first 7 days correctly.
- **Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch** You can start Cimizt preferably on the day after the last active tablet (the last tablet containing active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill). When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.
- **If you are currently on a 21-day Pill:** start taking Cimizt the next day after the end of the previous strip. You will have contraceptive protection with your first pill but you will not have a bleed until after you finish your first strip of Cimizt.
- **If you are currently on a 28-day Pill:** start taking Cimizt the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after you finish your first strip of Cimizt.
- **Or if you are taking a progestogen-only Pill (mini-Pill or POP):** start Cimizt on the first day of bleeding, even if you have already taken the POP for that day. You will have contraceptive cover straight away. If you don't usually have any bleeding while you are taking a progestogen-only Pill, you can stop taking it any day and start Cimizt the next day. You will need to use extra contraception, such as a condom, for seven days.
- **Changing from a progestogen-only method (injection, implant or a progestogen-releasing IUD)** You may switch any day from an implant or an IUD on the day of its removal or from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.





- **After a miscarriage or abortion**  
Follow the advice of your doctor. Your doctor may tell you to start taking Cimizt straight away which means that you will have contraceptive protection with your first pill.
- **After having a baby**  
- If you are not breast-feeding, you can start Cimizt between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Cimizt use. If, after having a baby, you have had sex before starting Cimizt (again), be sure that you are not pregnant or wait until your next period and take your first Cimizt on the first day of your next period.
- **If you are breastfeeding and want to start Cimizt Tablets (again) after having a baby**  
Read the section on "Breast feeding".  
Ask your doctor what to do if you are not sure when to start.

#### What to do if you forget to take Cimizt Tablets

- If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 12 hours** late taking a tablet, the protection against pregnancy may be reduced. Take the most recently missed pill straight away and leave any earlier missed pills in the strip. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant. Use extra precautions (condoms, for instance) for the next 7 days.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or the end of the strip. Therefore, you should keep to the following rules (see the diagram):

#### • More than one tablet forgotten in this strip

Contact your doctor.

#### • One tablet forgotten in week 1

Take the forgotten tablet as soon as you remember, even if that means taking two tablets at the same time. Continue taking the tablets at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor.

#### • One tablet forgotten in week 2

Take the forgotten tablet as soon as you remember, even if that means taking two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

#### • One tablet forgotten in week 3

You can choose between two possibilities:

1. Take the forgotten tablet as soon as you remember, even if that means taking two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the tablet-free period start the next strip.

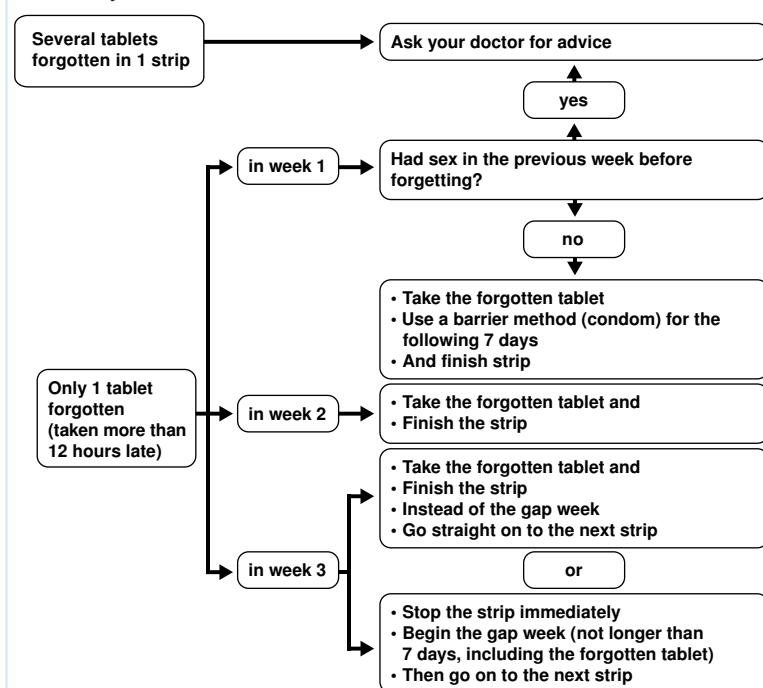
Most likely, you will have a period at the end of the second strip but you may also have light or menstruation like bleeding during the second strip.

2. You can also stop the strip and go directly to the tablet-free period of 7 days (**record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, make the tablet-free period **less than 7 days**.

If you follow one of these two recommendations, you will remain protected against pregnancy.

- If you have forgotten any of the tablets in a strip, and you do not have bleeding in the first tablet-free period, you may be pregnant. Contact your doctor or family planning clinic, or do a pregnancy test yourself before you start the next strip.

If you start a new strip of pills late, or make your "week off" longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor, family planning nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.



A lost pill

If you lose a pill. Either take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After your seven pill-free days you will have a new starting day, one day earlier than before. Or if you do not want to change the starting day of your cycle, take a pill from a spare strip. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

#### What to do in case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea for more than 12 hours after taking Cimizt, there is a risk that the active substances in the tablet are not fully absorbed into your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under "What to do if you forget to take Cimizt Tablets".

Talk to your doctor if your stomach upset carries on or gets worse. He or she may recommend another form of contraception.

Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your family planning clinic or doctors surgery. If you are pregnant, stop taking Bimizza and see your doctor.

#### If you take more Cimizt Tablets than you should

There are no reports of serious harmful results of taking too many Cimizt Tablets. If you take several tablets at once then you may have symptoms of nausea, vomiting or bleeding from the vagina. If you have taken too many Cimizt Tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

#### Delay of menstrual period: what you need to know

Even though it is not recommended, you can delay your menstrual period by starting a new strip of Cimizt Tablets instead of the tablet-free period and finishing it followed by 7 pill free days. You may experience light or menstruation-like bleeding while using this second strip but don't worry. After the usual tablet-free period of 7 days, start the next strip.

#### You might ask your doctor for advice before deciding to delay your menstrual period.

#### Changing of the first day of your menstrual period: what you must know

If you take the tablets according to the instructions, then your period will begin during the tablet-free week. If you have to change this day, reduce the number of the tablet-free days (*but never increase them – 7 is the maximum*). For example, if your tablet-free days normally begin on a Friday, and you want to change this to a Tuesday (3 days earlier) start a new strip 3 days earlier than usual. If you make the tablet-free interval very short (for example, 3 days or less) you may not have any bleeding during these days. You may then experience light or menstruation-like bleeding.

#### If you are not sure what to do, consult your doctor.

#### If you want to stop taking Cimizt Tablets

You can stop taking Cimizt Tablets whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Cimizt Tablets and wait for a proper period before trying to become pregnant. Your doctor or midwife relies on the date of your last natural period before you get pregnant to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, Cimizt Tablets can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Cimizt, please talk to your doctor. An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you take Cimizt tablets".

#### Serious side effects – see a doctor straight away

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "Warnings and precautions").

#### Signs of deep vein thrombosis include:

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

#### Signs of a pulmonary embolism:

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

If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').

#### Signs of retinal vein thrombosis (blood clot in the eye):

- symptoms most commonly occur in one eye:
- immediate loss of vision or
- painless blurring of vision which can progress to loss of vision.

#### Signs of heart attack:

- chest pain, discomfort, pressure, heaviness;
- sensation of squeezing or fullness in the chest, arm or below the breastbone;
- fullness, indigestion or choking feeling;
- upper body discomfort radiating to the back, jaw, throat, arm and stomach;
- sweating, nausea, vomiting or dizziness;
- extreme weakness, anxiety, or shortness of breath;
- rapid or irregular heartbeats.

#### Signs of a stroke:

- sudden weakness or numbness of the face, arm or leg, especially on one side of the body;
- sudden confusion, trouble speaking or understanding;
- sudden trouble seeing in one or both eyes;
- sudden trouble walking, dizziness, loss of balance or coordination;
- sudden, severe or prolonged headache with no known cause;
- loss of consciousness or fainting with or without seizure.

Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.

#### Signs of blood clots blocking other blood vessels:

- swelling and slight blue discolouration of an extremity;
- severe pain in your stomach (acute abdomen).

#### Signs of a severe allergic reaction to Cimizt

- swelling of the face, lips, mouth, tongue or throat.

#### Signs of breast cancer include:

- changes in the nipple;
- any lumps you can see or feel.

#### Signs of cancer of the cervix include:

- vaginal discharge that smells and contains blood;
- unusual vaginal bleeding;
- pelvic pain;
- painful sex.

#### Signs of severe liver problems include:

- severe pain in your upper abdomen;
- yellow skin or eyes (jaundice).

–If you think you may have any of these, see a doctor straight away. You may need to stop taking Cimizt.

#### Possible side effects

**Common** (may affect up to 1 in 10 people):

- **Headache;**
- **Putting on weight;**
- **Breast problems**, such as painful or tender breasts;
- **Depression or mood changes;**
- **Stomach problems**, such as nausea; abdominal pain;
- **Uncommon** (may affect up to 1 in 100 people):
- **Migraine** (see a doctor as soon as possible if this is your first migraine or it's worse than usual, or if the headache is severe, unusual or long lasting);
- **Fluid retention** (swollen hands, ankles or feet – a sign of fluid retention);
- **Decreased sexual desire;**
- **Vomiting;**
- **Diarrhoea;**
- **Skin problems, such as rash or hives;**
- **Breast enlargement;**

**Rare** (may affect up to 1 in 1000 people):

- **Changes in vaginal secretions–Irregular vaginal bleeding** - see section 4.3. Bleeding between periods should not last long;
- **Breasts producing a milky fluid from the nipples;**
- **Hypersensitivity reactions;**
- **Discomfort of the eyes if you wear contact lenses;**
- **Erythema nodosum (bruise-like swelling to the shins);**
- **Erythema multiforme (this is a skin condition);**
- **Decreased weight;**
- **Increased sexual desire;**
- **Harmful blood clots** in a vein or artery for example:
  - o in a leg or foot (i.e. DVT);
  - o in a lung (i.e. PE);
  - o heart attack;
  - o stroke;
  - o mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA);

o blood clots in the liver, stomach/intestine, kidneys or eye.

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

• Severe allergic reaction to Cimizt

#### • Breast cancer

#### • Cancer of the cervix

#### • Severe liver problems

#### • High blood pressure

#### • Gall stones

#### • Chorea (a problem with the nervous system causing jerky movements that you can't control)

• Worsening of **systemic lupus erythematosus** (SLE: when your immune system attacks your body causing, for example, joint ache and tiredness)

#### • Stomach and intestine problems such as pancreatitis; Crohn's disease; ulcerative colitis

• Worsening of **otosclerosis** (a hearing problem)

#### • Problems with blood sugar

• Worsening of a rare condition called **porphyria**

• Worsening of **skin problems**, such as brown patches on your face or body (*chloasma*)

blister-like rash, (*herpes gestationis*)

Unknown (frequency cannot be estimated from the available data):

• angioedema, particularly in patients who already have a (family) history of angioedema.

–**Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Cimizt. Also tell them if any existing conditions get worse while you are taking Cimizt.

#### Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Cimizt, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Cimizt as usual; the problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

–**Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Cimizt for a while
- carries on even after you've stopped taking Cimizt.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store Cimizt Tablets

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

Do not store above 25°C. Store in the original package in order to protect from moisture and light.

#### Expiry date

*Do not use this medicine after the expiry date which is stated on the package after "EXP".*

*The expiry date refers to the last day of that month.*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

#### What Cimizt Tablets contain

The active substances are desogestrel and ethinylestradiol.

The other ingredients are:

- All-rac-alpha-tocopherol, potato starch, povidone (E1201), stearic acid (E570), silica colloidal anhydrous (E551) and lactose anhydrous.

#### What Cimizt tablets look like and contents of the pack

Each tablet is round, white to off-white, uncoated, biconvex, debossed with '142' on one side and other side plain.

Each strip of Cimizt Tablets contains 21 white tablets.

Each box of Cimizt Tablets contains 1, 3 or 6 strips of 21 tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Morningside Healthcare Ltd,

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United Kingdom.

#### Manufacturer

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This leaflet is available in large font or audio format upon request.

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