



- **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.

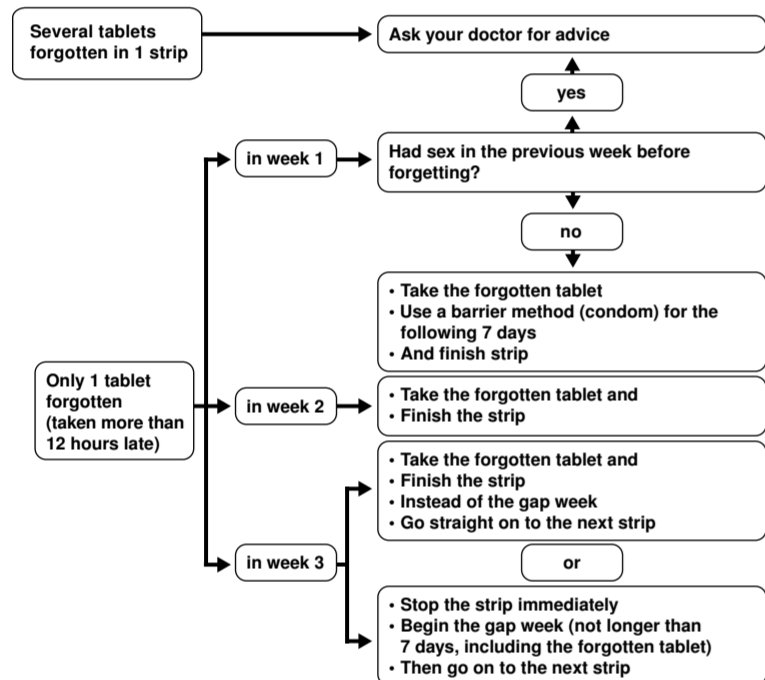
Most likely, you will have a period at the end of the second strip but you may also have light or menstruation like bleeding during the second strip.

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 discoloration 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:

- dimpling of the skin;
- 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.
- liver enzymes increased (transaminase elevation).

–**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

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