

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills.

Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills.

If you are relying on this medicine to prevent pregnancy, always take Teragezza as described here. You don't need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.

Start your next strip on day eight

Start taking your next strip of Teragezza after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time.

As long as you take Teragezza correctly, you will always start each new strip on the same day of the week.

Starting Teragezza

New users or starting Teragezza after a break

It is best to take your first Teragezza pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Teragezza from another contraceptive Pill

• **If you are currently taking a 21-day Pill:** start Teragezza the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Teragezza.

- **If you are taking a 28-day Pill:** start taking Teragezza the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Teragezza.

- **If you are taking a progestogen-only Pill** (POP or ‘mini Pill’): start Teragezza on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Teragezza after a miscarriage or abortion

If you have had a miscarriage or an abortion **during the first three months** of pregnancy, your doctor may tell you to start taking Teragezza straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Teragezza should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Teragezza and for the first 7 days of pill taking.

Do not take Teragezza if you are breast-feeding

3.3 A missed pill

If you are less than 12 hours late with a pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don't worry – your contraceptive protection should not be reduced.

- If you are more than 12 hours late with a pill**, or you have missed more than one pill, your contraceptive protection may be reduced.
- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.
- **Continue to take a pill every day for the next seven days** at your usual time.
- **If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won't have a bleed until after you finish the second strip of pills, but don't worry. If you finish the second strip of pills and don't have a bleed, do a pregnancy test before starting another strip.
- **Use extra contraception for seven days after missing a pill**, such as condoms.

- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you have missed any of the pills in a strip, and you do not bleed in the first pill-free break, you may be pregnant. Contact your doctor or do a pregnancy test yourself.

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 or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

3.4 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 if you have one. 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.

If you are sick or have diarrhoea

If you are sick (vomit) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. **If you are better within 12 hours of taking Teragezza**, follow the instructions in section 3.4 A lost pill, which describes how to take another pill.

If you are still sick or have diarrhoea **more than 12 hours after taking Teragezza**, see section 3.3, A missed pill.

- **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 doctor's surgery. If you are pregnant, stop taking Teragezza and see your doctors.

Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping Teragezza until you have had a proper period. Your doctor or midwife relies on the date of your last natural period 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 Teragezza”.

→**Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Teragezza.

Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Teragezza, some women have reported feeling depressed whilst taking Teragezza. In very rare cases this has been associated with thoughts of ending their lives. If you develop severe depression, you should stop Teragezza as a precaution, and see your doctor straight away.

Signs of a blood clot:

- an unusual sudden cough;

- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or long-lasting headache or worsening of migraine;
- 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.

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- **swelling of the hands, face, lips, mouth, tongue** or throat. A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (hives) and itching

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/or contains blood
- **unusual vaginal bleeding**
- **pelvic pain**
- **painful sex**.

Signs of severe liver problems include:

- severe **pain in your stomach**
- **yellow skin or eyes** (jaundice)
- **inflammation of the liver** (hepatitis)
- your whole body starts **itching**.

If you think you may have any of these, see a doctor straight away.

You may need to stop taking Teragezza.

Less serious side effects

Common side effects (may affect up to 1 in 10 people)

- **feeling sick**
- **stomach ache**
- **putting on weight**
- **headaches**
- **depressive moods or mood swings**
- **sore or painful breasts**

Uncommon side effects (may affect up to 1 in 100 people)

- **being sick and stomach upsets**
- **fluid retention**
- **migraine**
- **loss of interest in sex**
- **breast enlargement**
- **skin rash, which may be itchy**

Rare side effects (may affect up to 1 in 1,000 people)

- **poor tolerance of contact lenses**
- **losing weight**
- **increase of interest in sex**
- **vaginal or breast discharge**
- **venous blood clot**

Other side effects reported

- **bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Teragezza. If it continues, becomes heavy or starts again, contact your doctor
- **chloasma** (yellow brown patches on the skin). This may happen even if you have been using Teragezza for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- occurrence or deterioration of the movement disorder **chorea**
- **Crohn's disease or ulcerative colitis**
- **conditions that may worsen during pregnancy or previous use of the Pill:**
 - **yellowing of the skin** (jaundice)
 - **persistent itching** (pruritus)
 - kidney or liver problems
 - gall stones
 - certain rare medical conditions such as **systemic lupus erythematosus**

- **blister-like rash** (herpes gestationis) whilst pregnant
- an inherited form of **deafness** (otosclerosis)
- a personal or family history or a form of **sickle cell disease**
- swelling of body parts (hereditary angioedema)
- an inherited disease called **porphyria**
- **cancer of the cervix**
- epilepsy

Tell your doctor or pharmacist if you are worried about any side effects which you think may be due to Teragezza. Also tell them if any existing conditions get worse while you are taking Teragezza.

Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Teragezza, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Teragezza 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 Teragezza for a while
- carries on even after you've stopped taking Teragezza.

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 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 Teragezza

Keep all medicines out of the sight and reach of children. Store in the original package in order to protect from light.

Do not use Teragezza after the expiry date shown on the strip.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6. Contents of the pack and other information

What Teragezza contains

The active substances are Cyproterone acetate and Ethinylestradiol. The other ingredients are Lactose monohydrate, Maize starch, Povidone, Talc, Magnesium Stearate, Hypromellose (E464), Macrogol (E1521), Titanium Dioxide (E171) and Iron Oxide Red (E172).

What Teragezza looks like and contents of the pack
Round, light pink, biconvex, film coated tablets debossed ‘T’ on one side and other side plain.

Teragezza tablets are packed in an aluminium backed blister consisting of clear, transparent PVC film coated with PVdc optionally in an aluminium foil pouch.

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	Description	Teragezza Leaflet	■ Black
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