

## Akizza 75/20 microgram Tablets

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### Gestodene/Ethinylestradiol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**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').

**What is in this leaflet**

- What Akizza is and what it is used for
- What you need to know before you take Akizza
- How to take Akizza
- Possible side effects
- How to store Akizza
- Contents of the pack and other information

### Akizza 75/20 microgram Tablets

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### Gestodene & Ethinylestradiol

This contraceptive contains two types of female sex hormones called ethinylestradiol and gestodene. Both hormones prevent the monthly release of an egg from the ovaries and thicken the mucus in the neck of the womb thereby making it more difficult for the sperm to reach the egg. Akizza also affects the lining of the womb to make it less likely to accept a fertilised egg.

Akizza will not protect you against sexually transmitted infections, such as AIDS. Only condoms can help to do this.

### 2. What you need to know before you take Akizza

#### General notes

Before you start using Akizza 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'.

Before you start using Akizza, your doctor is likely to take a full medical history of you and members of your family, check your blood pressure and make sure you are not pregnant. Your doctor may also give you a comprehensive medical examination.

Once you have started using Akizza, your doctor or prescriber may carry out regular check-ups, usually this will occur when you request an additional prescription.

You should not use Akizza 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.

**Do not use Akizza**

- 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:
  - severe diabetes with blood vessel damage,
  - very high blood pressure,
  - a very high level of fat in the blood (cholesterol or triglycerides),
  - 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 ever had) breast cancer;
- if you have ever had a severe liver disease, and you have been told by your doctor that your liver function test results are not yet back to normal;
- if you have ever had liver tumours;
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir / pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section Other medicines and Akizza).
- if you are allergic to gestodene, ethinylestradiol, or to any of the other ingredients of this medicine (listed in section 6).

Akizza should not be used by children or after menopause.

**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 the paragraph "How to recognise a blood clot".

Some of the conditions listed below can be made worse by taking the Pill or they may mean it is less suitable for you. You may still be able to take Akizza but you need to take special care and have check-ups more often.

**Tell your doctor if any of the following conditions apply to you.**

If the condition develops, or gets worse while you are using Akizza, you should also tell your doctor.

- 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 estrogens 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 systemic lupus erythematosus (SLE – a disease affecting your natural defence system);
- 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 inflammation of the pancreas (pancreatitis);
- 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 you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Akizza;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins; if you have diabetes mellitus (diabetes) or susceptibility to its creation;
- if you or your close family have ever had problems with your heart, or circulation such as high blood pressure;
- if you or your close family have ever had problems with blood clotting;
- if you have the inherited disease called porphyria;
- if you are overweight (obese);
- if you have migraines;
- if you have any illness that worsened during pregnancy or previous use of the Pill.

**Psychiatric disorders**

Some women using hormonal contraceptives including Akizza 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.

**Blood Clots**

Using a combined hormonal contraceptive such as Akizza increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block 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 having a harmful blood clot due to Akizza is small.**

**HOW TO RECOGNISE A BLOOD CLOT**

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

<b>Are you experiencing any of these signs?</b>	<b>What are you possibly suffering from?</b>
<ul style="list-style-type: none"><li>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></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>	Pulmonary embolism
<p>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').</p> <p>Symptoms most commonly occur in one eye:</p> <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></ul>	Heart attack
<ul style="list-style-type: none"><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> <ul style="list-style-type: none"><li>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.</li></ul>	Stroke
<ul style="list-style-type: none"><li>Swelling and slight blue discoloration 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 Akizza 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 Akizza 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 gestodene such as Akizza between about 9-12 women will develop a blood clot in a year.

- The risk of having a blood clot in a vein will vary according to your personal medical history (see paragraph, "Factors that increase your risk of a blood clot" below).

	<b>Risk of developing a blood clot in a year</b>
Women who are <b>not using</b> a combined hormonal pill/patch/ ring 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 <i>Akizza</i>	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 Akizza 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). 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 Akizza may need to be stopped at least 4 weeks before surgery or while you are less mobile. If you need to stop Akizza ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases with 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 Akizza needs to be stopped.

If any of the above conditions change while you are using Akizza, 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 Akizza is very small but can increase:

- with increasing age (beyond about 35 years);
- if you smoke.** When using a combined hormonal contraceptive like Akizza 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 50). 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 Akizza, 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.

**What to do if you experience irregular bleeding / spotting**

During the use of Akizza, if you observe irregular bleeding or spotting, especially during the first three months and if bleeding continues or repeats, stop taking Akizza, use a non-hormonal method of contraception and consult your doctor.

**What to do if there is no regular bleeding**

Some women may not experience regular bleeding during the tablet-free break. If there is failure of two consecutive regular bleedings, or if the product is not used according to directions before the first regular bleeding that fails, you should discontinue use of Akizza and use any non-hormonal method of contraception to prevent pregnancy.

**Like all oral contraceptives Akizza does not protect against HIV infection (AIDS) and other sexually transmitted diseases. Only condoms can help to do this.**

**The Pill and cancer**

Breast cancer has been observed slightly more often in women using oral contraceptives than in women of the same age who do not use them. It is not known whether this difference is caused by oral contraceptives. For example it may be that more tumours are detected in users of combined oral contraceptives because they tend to be examined more often. The occurrence of breast tumours becomes gradually less after stopping the Pill. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

The risk of cervical cancer of the uterus is higher in women taking oral contraceptives. The most important risk factor for cervical cancer is persistent infection with the human papillomavirus (HPV). These findings may also have something else in common other than the use of oral contraceptives (e.g. differences in sexual behavior). In case of abnormal vaginal bleeding with unknown cause, consult your doctor.

**The Pill and blood pressure**

The increase in blood pressure was observed in women taking oral contraceptives. Tell your doctor if you have or had hypertension (high blood pressure).

**The Pill and diseases of the gallbladder and liver**

If you have or ever had cholestasis (accumulation of bile in the gallbladder) while using hormonal contraceptives or during pregnancy, you are more likely to develop the disorder when taking Akizza. You should therefore be carefully monitored while taking Akizza. Very rarely the use of oral contraceptives causes benign liver tumors, which may rupture and cause life-threatening internal bleeding. The risk of liver cancer is extremely low.

**The Pill and eye disorders**

While using Akizza, blood clots have been observed in the blood vessels of the eye (ocular vascular thrombosis), which may lead to partial or complete loss of vision. If you experience sudden partial or complete loss of vision, or a sudden onset of abnormal vision, you should inform your doctor immediately.

**The Pill and migraine / headache**

If you feel the onset or worsening of migraine or development of headache with new symptoms that recur, persist or are severe, contact your doctor immediately. During the use of Akizza, if you have a migraine (particularly migraine with aura), you may be subject to an increased risk of stroke.

**The Pill and diabetes**

Changes in glucose tolerance are observed in women using Akizza. If you have diabetes, your doctor should carefully monitor the use of Akizza.

If you have high triglycerides (fat) levels, your doctor should carefully monitor the use of Akizza, since there have been rare cases where a massive increase in triglycerides leads to pancreatitis (inflammation of the pancreas).

**Other medicines and Akizza:**

**Tell your doctor if you are taking, have recently taken or might use any other medicine.**

It is also important to tell your doctor or dentist that you are taking Akizza because taking certain other medicines could alter the effectiveness of Akizza or the other medicines.

During use of Akizza with certain other medicines, it is recommended to use additional non-hormonal methods of contraception (such as condoms with spermicide) along with the use of Akizza. It is recommended to use additional non-hormonal contraceptive method for at least another 7 days after stopping certain other medicines while using Akizza.

Medicines that can make Akizza less effective in preventing pregnancy include:

- Medicines for digestive problems (e.g. laxatives);
- Medicines for psychological disorders or epilepsy, such as barbiturates, phenytoin, primidone, topiramate, modafinil, dexamethasone and hypericum perforatum (St. John's wort);
- Medicines for infections such as ritonavir, rifampicin, rifabutin, tetracycline, ampicillin and other penicillins;
- Antifungal medicines (griseofulvin);
- Medicines for pain and anti-inflammatory drugs (e.g. phenylbutazone);
- Drugs used after transplant (cyclosporin);
- Vitamin C or paracetamol;
- Cholesterol-lowering drugs (atorvastatin);
- Medicines such as asthma medications (theophylline).

Medicines containing troleandomycin may increase the risk of cholestasis (accumulation of bile in the gallbladder) when taken with the Pill.

If you are taking a medication containing flunarizine at the same time as Akizza, this may cause production of breast milk in women who have not yet had children.

Do not use Akizza if you have Hepatitis C and are taking the medicinal products containing ombitasvir/ paritaprevir/ ritonavir, dasabuvir, glecaprevir / pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, 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. Akizza can be restarted approximately 2 weeks after completion of this treatment. See section ‘Do not use Akizza’.

#### Akizza with food and drink

Akizza may be taken with or without food, if necessary with a small amount of water.

#### Pregnancy, breast-feeding and fertility

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

**If you are breast-feeding**, your doctor or family planning nurse may advise you not to take Akizza They will be able to suggest alternative contraception. Breast-feeding may not stop you getting pregnant.

#### Driving and using machines

There is no information suggesting that the use of Akizza affects driving or use of machines.

#### Akizza contains lactose

If you have been told by your doctor that you have an intolerance to lactose, contact your doctor before using Akizza.

### 3. How to take Akizza

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

Take one tablet (Akizza) daily with a little water if necessary. You may take the tablets with or without food, but you should take the tablets every day around the same time.

Each strip contains 21 tablets. At each tablet, the day of the week is printed on the back of the blister. For example, if you start on a Wednesday, take a tablet where ‘Wednesday’ is stated. Follow the direction of the arrow on the strip until all 21 tablets have been taken.

After you have taken all 21 pills in the strip, you have a seven day break during which you take no pills. In the course of these 7 pill-free days, bleeding should begin, so called ‘withdrawal bleeding’. Usually bleeding starts on the second or third day of the gap week.

On the eighth day i.e. after the seven-day gap you should start the next strip of tablets, whether your bleeding has stopped or not. This means that each strip begins on the same day of the week and withdrawal bleeding every month coincides.

Correct use of your tablets will ensure protection against pregnancy whilst you take the tablets and also during the 7 days break.

#### When can you start with the first strip of Akizza

- No hormonal contraceptive has been taken in the previous menstrual cycle:*

You can start taking Akizza on the first day of your menstrual cycle and you immediately get protection against pregnancy. You may also start taking Akizza on 2<sup>nd</sup> to 5<sup>th</sup> day of the menstrual cycle, but in this case, an additional contraceptive method (e.g. condom) is recommended for the first 7 days.

- Changing from a combined hormonal contraceptive, combined vaginal ring or patch:*

You can start the use of Akizza on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but not later than the day following the tablet-free days of your previous pill (or after the last inactive-tablet of your previous pill). If you switch from a combined contraceptive vaginal ring or patch, follow the advice given by your doctor.

- Changing from a progestogen-only pill (also called ‘mini-pill’) or injection or implant or a progestogen-releasing IUS:* You may switch any day from the progestogen-only pill (from an implant or an IUS on the day of its removal, from an injectable when the next injection would be due) but in all of these cases the use of extra protective measures (for example, a condom) for the first 7 days of taking Akizza is recommended.

- After a miscarriage or abortion:*

Follow the advice given by your doctor.

- After childbirth:*

You can start taking Akizza after 21 to 28 days of childbirth. If you start taking pill after 28 days, an additional contraceptive method is recommended for the first seven days. After childbirth, if you have had sex before starting Akizza, you must first be sure that you are not pregnant or wait until your next period.

- If you are breast-feeding:*

Read the section ‘Pregnancy, breast - feeding and fertility’.

*Ask your doctor what to do if you are not sure when to start Akizza.*

#### Use in children and adolescents

There is no data available for use in adolescents below 18 years.

#### If you take more Akizza than you should

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. Other symptoms may include tender breasts, dizziness, stomach pain, drowsiness and feeling tired.

Talk to your doctor if you have any of these symptoms. If you have taken too many tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

#### If you forget to take Akizza

- 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. The greater the number of tablets you have forgotten, the greater is the risk of becoming pregnant.

**The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the strip. Therefore, you must follow the following rules:**

- More than one tablet forgotten in this strip**

Please contact your doctor.

- One tablet forgotten in week 1**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the

tablets again at the usual time and for the next seven days use an additional contraceptive method such as a condom.

If you had sex in the week prior to the missed tablet, you may be pregnant. In this case please contact your doctor.

- One tablet forgotten in week 2**

Take the forgotten tablet as soon as you remember, even if that means that you have two tablets at the same time. Take the tablets again at the usual time. Contraceptive protection is not reduced and you need not take extra contraceptive precautions.

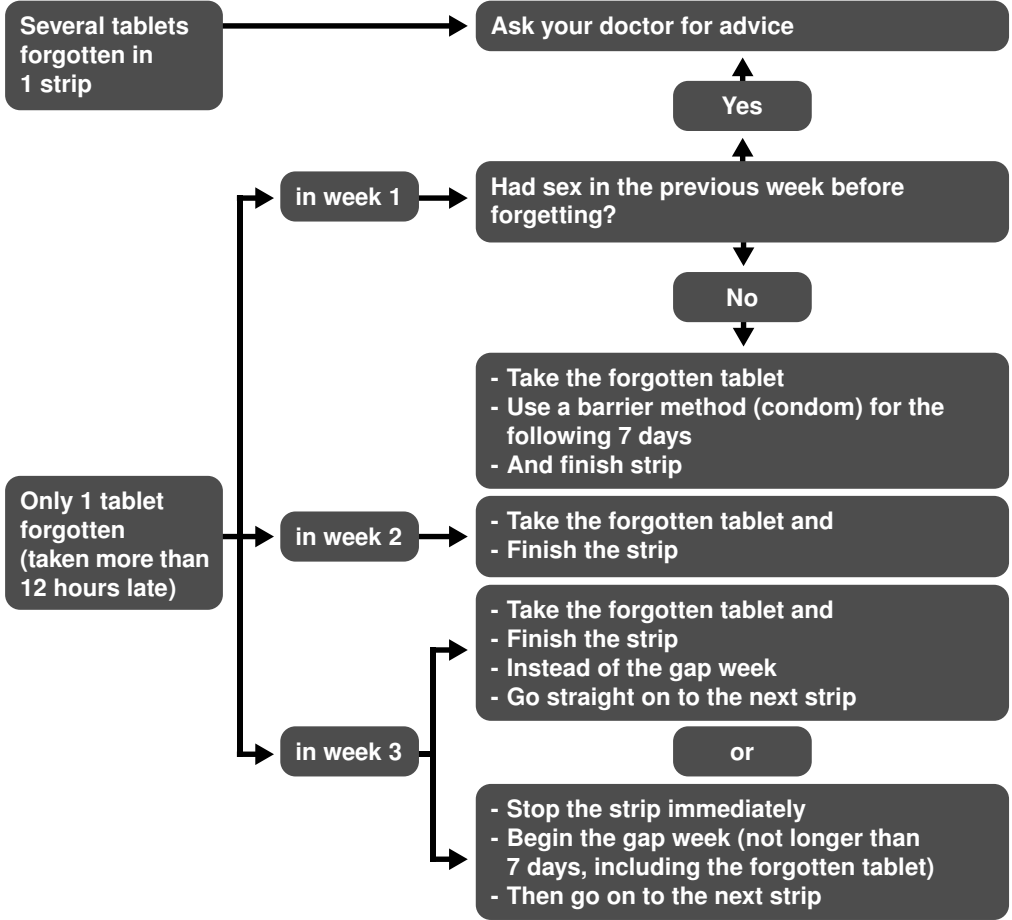
- One tablet forgotten in week 3**

You have two options:

- Take the forgotten tablet as soon as you remember (even if this means taking two tablets at the same time) and take the tablets at the usual time. Start the next pack as soon as the previous pack is completed, so no break between packs. You may not have menstrual period until the end of the second pack, but you may have spotting or breakthrough bleeding during the days of tablet-taking.
- Stop taking the pills from your current pack, leave an interval of 7 tablet-free days or less (count also the day when you forget a tablet) and continue with the next pack. With this method you can always start your next pack on the same day of the week as usual.

With the above two recommendations, you will remain protected against pregnancy if you forgot one pill in week 3.

- If you forgot one of the tablets in a strip and no bleeding occurs during the tablet-free gap period, you may be pregnant. Then consult your doctor before starting the next strip.



#### 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, there is a risk that the active substances in the pill will not be fully taken up by 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 that is not possible or 12 hours have passed, you should follow the advice given under section ‘What to do if you forget to take Akizza’.

#### Postponing your period:

Although it is not recommended, you can postpone your period by directly consuming Akizza without taking a break from the next blister and continue this till the end. During the administration of the second blister you can experience minor or menstrual-like bleeding. Begin by following the regular 7-day rest as usual with your next blister.

*You should ask your doctor for advice before you decide to postpone your menstrual period.*

#### Change in first day of bleeding:

If you take the tablets as directed, your period / withdrawal bleeding starts during the week off between taking tablets. If you need to change that day, you can do shorter (but never stretching!) rest interval between taking tablets. For example, if your rest interval between taking tablets starts on Friday, and you want to change to Tuesday (3 days earlier), you should start a new pack 3 days earlier than usual. If you make the rest interval between taking tablets very short (for example, 3 days or less) bleeding may not occur during this period. You can then experience spotting (drops or flecks of blood) or breakthrough bleeding.

*If you are unsure how to do this, ask your doctor for advice.*

#### If you stop using Akizza:

You can stop taking Akizza 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 using Akizza and wait until you have a menstrual period, before trying to get pregnant. You can then easily calculate the expected date of birth.

*If you have any questions on the use of this medicine, ask your doctor or pharmacist or nurse.*

### 4. Possible side effects

Like all medicines, Akizza 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 Akizza, 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 use Akizza’.

#### Serious side effects

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’).

#### Tell your doctor straight away if you get any of these symptoms after taking your tablets.

Rare side effects (between 1 and 10 in every 10,000 users may be affected):

- harmful blood clots in a vein or artery, for example:
  - in a leg or foot (i.e. DVT),
  - in a lung (i.e. PE),
  - heart attack,
  - stroke,
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA),
  - 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 ‘Blood Clots’ for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

Signs of a blood clot (see section 2 ‘Blood Clots’)

- 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:

- dimpling of the skin,
- changes in the nipple,
- any lumps you can see or feel.

Signs of cancer of the cervix:

- vaginal discharge that smells and/or contains blood,
- unusual vaginal bleeding,
- pelvic pain,
- painful sex.

Signs of severe liver problems:

- severe pain in your upper abdomen,
- 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 Akizza.

Akizza may cause some other side effects and these are shown below:-

#### Common side effects (between 100 and 1000 in every 10,000 users may be affected)

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

#### Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- being sick and stomach upsets,
- fluid retention,
- migraine,
- loss of interest in sex,
- breast enlargement,
- skin rash, which may be itchy
- hair thinning (alopecia).

#### Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- poor tolerance of contact lenses,
- losing weight,
- increase of interest in sex,
- vaginal or breast discharge.

#### 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 Akizza. If it continues, becomes heavy or starts again, contact your doctor (see section 4.3).
- Chloasma (yellow brown patches on the skin). This may happen even if you have been using Akizza for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps.

#### 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,
- occurrence or deterioration of the movement disorder chorea,
- blister-like rash (herpes gestationis) whilst pregnant,
- an inherited form of deafness (otosclerosis),
- Crohn’s disease,
- ulcerative colitis,
- a personal or family history of a form of sickle cell disease,
- swelling of body parts (hereditary angioedema),
- an inherited disease called porphyria,
- cancer of the cervix.

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

#### 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 Akizza

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

Do not use this medicine after the expiry date stated on the blister / carton after EXP. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions. Keep in the original package.

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 to protect the environment.

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

#### What Akizza contains

The active substances are gestodene and ethinylestradiol.

Each tablet contains either

Gestodene 75 microgram and Ethinylestradiol 20 microgram or

Gestodene 75 microgram and Ethinylestradiol 30 microgram

#### The other ingredients are:

##### Tablet core:

Lactose monohydrate

Maize starch

Polyvinyl pyrrolidone

Magnesium stearate

##### Tablet film-coating:

##### Composition of Opadry white 03F58750:

HPMC 2910/Hypromellose (E464)

Titanium dioxide (E171)

Macrogol 6000

Talc (E553b)

#### What Akizza looks like and contents of the pack

##### For Akizza 75/30 microgram Tablets

Round, white to off white, biconvex, film-coated tablet debossed ‘B’ on one side and other side plain.

##### For Akizza 75/20 microgram Tablets

Round, white to off white, biconvex, film-coated tablet debossed ‘A’ on one side and other side plain.

Each carton contains 1, 3, or 6 blister strips of 21 tablets each.

Each carton contains blister packed in a sealed tri-laminated pouch.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Morningside Healthcare Ltd

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Leicester

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#### Manufacturer

Morningside Pharmaceuticals Ltd

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