

PACKAGE LEAFLET: INFORMATION FOR THE USER

MORNINGSIDE
HEALTHCARE

Bimizza

150 microgram/ 20 microgram tablets
Desogestrel/ethinylestradiol

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 Bimizza is right for you.
- To prevent pregnancy it is important to take Bimizza 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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bimizza tablets are and what they are used for
2. What you need to know before you take Bimizza tablets
3. How to take Bimizza tablets
4. Possible side effects
5. How to store Bimizza tablets
6. Contents of the pack and other information

1. What Bimizza tablets are and what they are used for

Bimizza 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. Bimizza also makes the fluid (mucus) in your cervix thicker which makes it more difficult for sperm to enter the womb.

Bimizza 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.

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

Bimizza needs to be taken as directed to prevent pregnancy.

2. What you need to know before you take Bimizza tablets

General notes

Before you start taking Bimizza 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 2-4 weeks before the operation. This is to reduce the risk of a blood clot (see section "Do not take Bimizza tablets"). Your doctor will tell you when you can start taking the Pill again.

Do not take Bimizza tablets

You should not use Bimizza 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 "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 embolism, 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 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 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 are **allergic** to any of the ingredients in Bimizza.
- if you have hepatitis C and are taking medicinal products containing ombitasvir/ paritaprevir/ ritonavir and dasabuvir or glecaprevir/pibrentasvir (see also section "Other medicines and Bimizza").

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

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" section below).
- For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

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

- If the condition develops, or gets worse while you are using Bimizza, 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 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 gall stones,
 - o systemic lupus erythematosus (SLE),
 - o a blister-like rash, called *herpes gestationis*,
 - o a hearing problem called *ototoxicosis*,
 - o other rare conditions called *porphyria* and *hereditary angioedema*.

- 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 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 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 Bimizza (see section The Pill and Thrombosis).
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- If you have varicose veins.

The Pill and Thrombosis

Blood Clots

Using a combined hormonal contraceptive such as Bimizza, 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 Bimizza is small.

How to recognise a blood clot

Are you experiencing any of these signs?

swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none">• 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.	What are you possibly suffering from? Deep vein thrombosis
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<ul style="list-style-type: none">• 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.	Pulmonary embolism
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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').

Symptoms most commonly occur in one eye: <ul style="list-style-type: none">• immediate loss of vision or• painless blurring of vision which can progress to loss of vision.	Retinal vein thrombosis (Blood clot in the eye)
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<ul style="list-style-type: none">• chest pain, discomfort, pressure, heaviness;• sensation of squeezing or choking in the chest, arm or below the breastbone;• numbness, tingling, indigestion or feeling faint;• 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;	Heart attack
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<ul style="list-style-type: none">• 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.	Stroke
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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.

swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen);	
	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 it always slightly higher than if you were not using a combined hormonal contraceptive.

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

What is the risk of developing a blood clot?

- The overall risk of a blood clot in the leg or lung (DVT or PE) with Bimizza 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 Bimizza between about 9 and 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 not using 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 levonorgestrel, norethisterone or norgestimate	About 5-7 out of 10,000 women
Women using Bimizza	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 Bimizza 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/m²);
 - 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 if you have your leg in a cast. The use of Bimizza may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Bimizza 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 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 Bimizza needs to be stopped.

If any of the above conditions change while you are using Bimizza, 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?

- **If you smoke.** When using a combined hormonal contraceptive like Bimizza 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.

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 Bimizza is very small but can increase:

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

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 Bimizza.

Psychiatric disorders

Some women using hormonal contraceptives including Bimizza 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.

Other medicines and Bimizza 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 Bimizza. This is because Bimizza 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 Bimizza from working properly. These include medicines used for the treatment of:

- **epilepsy** (primidone, phenytoins, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate, modafinil);
- **tuberculosis** (rifampicin);
- **HIV infections** (ritonavir, nelfinavir, nevirapine, efavirenz);
- **Hepatitis C virus infection** (e.g. bocepruvir, telaprevir);
- **other infectious diseases** (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 Bimizza less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Bimizza 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 Bimizza tablets if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir/pibrentasvir as this 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. Bimizza tablets can be restarted approximately 2 weeks after completion of this treatment. See the section on "Do not take Bimizza tablets"

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

Bimizza tablets with food and drink

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

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.

Pregnancy and breast-feeding

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

Bimizza 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.

Driving and using machines

There is no information suggesting that use of Bimizza tablets affects driving or use of machines.

Bimizza 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.

Use in adolescents

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

3. How to take Bimizza tablets

Take one Bimizza tablet every day, if necessary with a small amount of water. 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" and it usually starts on the 2nd or 3rd day of the gap week.

On the 8th day after the last tablet of Bimizza (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 and that the withdrawal bleed should occur on the same days each month.

If you use Bimizza 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 Bimizza on the first day of the cycle (that is the first day of your period). If you start Bimizza on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

- **Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch**
You can start Bimizza 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.

- **Changing from a progestogen-only method (progestogen-only pill, injection, implant or a progestogen-releasing IUD)**
You may switch any day from the progestogen-only pill (from an implant or an IUD) on the day of its removal, 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**
Follow the advice of your doctor.

- **After having a baby**
You can start Bimizza 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 Bimizza use. If, after having a baby, you have had sex before starting Bimizza (again), be sure that you are not pregnant or wait until your next period.

- **If you are breastfeeding and want to start Bimizza 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.

If you take more Bimizza tablets than you should

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

What to do if you forget to take Bimizza 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. The greater the number of tablets that 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 the end of the strip. Therefore, you should keep to the following rules (see the diagram below):

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 that you have to take 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 that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection

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 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 "If you forget to take Bimizza tablets".

Delay of menstrual period: what you need to know

Even though it is not recommended, you can delay your menstrual period by going straight to a new strip of Bimizza Tablets instead of the tablet-free period, and finishing it. You may experience light or menstruation-like bleeding while using this second strip. 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 Bimizza Tablets

You can stop taking Bimizza 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 Bimizza tablets and wait for a period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

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

4. Possible side effects

Like all medicines, Bimizza 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 Bimizza, 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 Bimizza"

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 Bimizza

- 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 Bimizza.

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:
 - 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 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot.)

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

Bleeding between periods should not last long

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

Before you have any blood tests

Tell your doctor or the laboratory staff that you are taking the pill, because oral contraceptives can affect the results of some tests.

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 Bimizza tablets

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

Do not store above 25°C. Store in 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 Bimizza tablets contains

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 Bimizza tablets look like and contents of the pack

Each tablet is round, white to off-white, uncoated, biconvex, debossed with '141' on one side and other side plain.

Each strip of Bimizza tablets contains 21 white tablets.

Each box of Bimizza tablets contains 1, 3 or 6 strips of 21 tablets provided with or without a desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in July 2021