

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Bimizza 150 microgram/ 20 microgram tablets

Desogestrel/ethinylestradiol

**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.

#### 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 tablets are a combined oral contraceptive, also called the pill. Each tablet contains a small amount of two types of female hormones, namely, a progestogen, desogestrel and an oestrogen, ethinylestradiol.

These help to stop you from getting pregnant, just as your natural hormones would stop you conceiving again when you are already pregnant.

The combined contraceptive pill protects you against getting pregnant in three ways. These hormones

1. stop the ovary from releasing an egg each month (ovulation).
2. also thicken the fluid (at the neck of the womb making it more difficult for the sperm to reach the egg).
3. alter the lining of the womb to make it less likely to accept a fertilised egg.

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

##### **General notes**

Before you can begin taking Bimizza tablets, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using Bimizza tablets, or where the reliability of the pill may be decreased. In such situations you should either not have sex, or you should take extra non-hormonal contraceptive precautions (e.g. use a condom or another barrier method). Do not use rhythm or temperature methods. These methods can be unreliable because Bimizza tablets alter the monthly changes of body temperature and of cervical mucus.

**Bimizza tablets, like other hormonal contraceptives, do not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

**Do not take Bimizza tablets**

- if you have (or have ever had) a blood clot in a blood vessel of the leg (thrombosis), lung (pulmonary embolism) or other organs,
- if you have (or have ever had) a heart attack or stroke
- if you have (or have ever had) a disease that can be an indicator of a heart attack in the future (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects).
- if you have a disease that may increase the risk of a clot in the arteries. This applies to the following diseases:
  - diabetes with damaged blood vessels
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
- if you have a disturbance of blood clotting (for example, protein C deficiency)
- if you have (or have ever had) a certain form of migraine (with so-called focal neurological symptoms).
- if you have (or have ever had) an inflammation of the pancreas (pancreatitis)
- if you have (or have ever had) a liver disease and your liver function is still not normal.
- if you have (or have ever had) a tumour in the liver.
- if you have (or have ever had) or if you are suspected to having breast cancer or cancer of the genital organs.
- if you have any unexplained bleeding from the vagina.
- if you are allergic to ethinylestradiol or desogestrel, or any of the other ingredients of this medicine (listed in section 6).

## **Warnings and precautions**

In some situations you need to take special care while using Bimizza tablets or any other combination pill, and your doctor may need to examine you regularly. If any of the following conditions applies to you, tell your doctor before starting to use Bimizza tablets. Also if any of the following applies or if any of the conditions develop or worsen while you are using Bimizza tablets consult your doctor:

- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you have depression
- if you have Crohn's disease or inflammatory bowel disease (ulcerative colitis)
- if you have a blood disease called HUS (haemolytic uraemic syndrome; which causes kidney damage)
- if you have a blood disease called sickle cell anaemia.
- if you have epilepsy (see "The pill and using other medicines")
- if you have a disease of the immune system called SLE (systemic lupus erythematosus)
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes) a nerve disease causing sudden movements of the body (Sydenham's chorea)
- if you have or have ever had chloasma (a discoloration of the skin especially of the face or neck known as "pregnancy patches".) If so, avoid direct sunlight or ultraviolet light.
- If you have hereditary angioedema, products containing oestrogens may cause or worsen symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing.

## **The pill and venous and arterial blood clots (thrombosis)**

### **Venous thrombosis**

The use of any combination pill, including Bimizza tablets, increases a woman's risk of developing a **venous blood clot (venous thrombosis)** compared with women who do not take any contraceptive pill.

If you take Bimizza tablets, you have a higher risk of developing a venous thrombosis than women using other combined pills containing the progestogen levonorgestrel.

The risk of venous blood clots in users of combined pills increases:

- with increasing age
  - if you are overweight,
  - if one of your close relatives ever had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age,
  - if you have to have surgery, if you have had a serious accident or if you are immobilized for a long time.
- It is important to tell your doctor that you are using Bimizza tablets as you may have to stop taking it. Your doctor will tell you when to start Bimizza tablets again. This is usually about two weeks after you are back on your feet.

Your chances of having a blood clot are increased by taking the Pill.

- Of 100,000 women who are not on the Pill and not pregnant, about 5-10 may have a blood clot in a year.
- Of 100,000 women taking a Pill like Bimizza tablets, 20-40 may have a blood clot in a year, the exact number is unknown.
- Of 100,000 women who are pregnant, around 60 may have a blood clot in a year.

A blood clot in the veins may travel to the lungs and may block blood vessels (called a lung embolus). Formation of blood clots in the veins may be fatal in 1-2% of cases.

The level of risk may vary according to the type of pill you take. Discuss with your doctor the available options.

### **Arterial thrombosis**

The use of combination pills has been connected with an increase of the risk of **arterial blood clot (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of arterial blood clot in users of combined pills increases:

- If you smoke. You are strongly advised to stop smoking when you use Bimizza tablets, especially if you are older than 35 years.
- if the fat content of your blood is increased (cholesterol or triglycerides)
- if you are overweight
- if one of your close relatives ever had a heart attack or stroke at young age
- if you have high blood pressure
- if you suffer from migraine
- if you have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm)

**Stop taking Bimizza tablets and contact your doctor immediately if you notice possible signs of blood clot, such as:**

- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache or worsening of migraine
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak
- giddiness or fainting
- weakness, strange feeling, or numbness in any part of the body

### **The pill and cancer**

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

### **Bleeding between periods**

During the first few months that you are taking Bimizza tablets, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

### **What you must do if no bleeding occurs in the gap week**

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

### **Other medicines and Bimizza tablets**

Always tell the doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Bimizza tablets. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

• Some medicines can make Bimizza tablets less effective in preventing pregnancy, or can cause unexpected bleeding. These include:

- Medicines used for the treatment of
    - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine)
    - tuberculosis (e.g. rifampicin),
    - HIV infections (ritonavir, nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
  - the herbal remedy St. John's wort.
- Bimizza tablets may influence the effect of other medicines, e.g.
- medicines containing cyclosporin,
  - the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

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**

If you are pregnant, do not take Bimizza tablets. If you become pregnant while taking Bimizza tablets stop immediately and contact your doctor. If you want to become pregnant, you can stop taking the pill at any time.

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

### **Breast-feeding**

Use of Bimizza tablets is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast feeding you should contact your doctor.

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

### **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.

### **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” usually starts on the 2<sup>nd</sup> or 3<sup>rd</sup> day of the gap week.

On the 8<sup>th</sup> day after the last tablet of 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 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 against pregnancy is not reduced, and you do not need to take extra precautions.

• **One tablet forgotten in week 3**

You can choose between two possibilities:

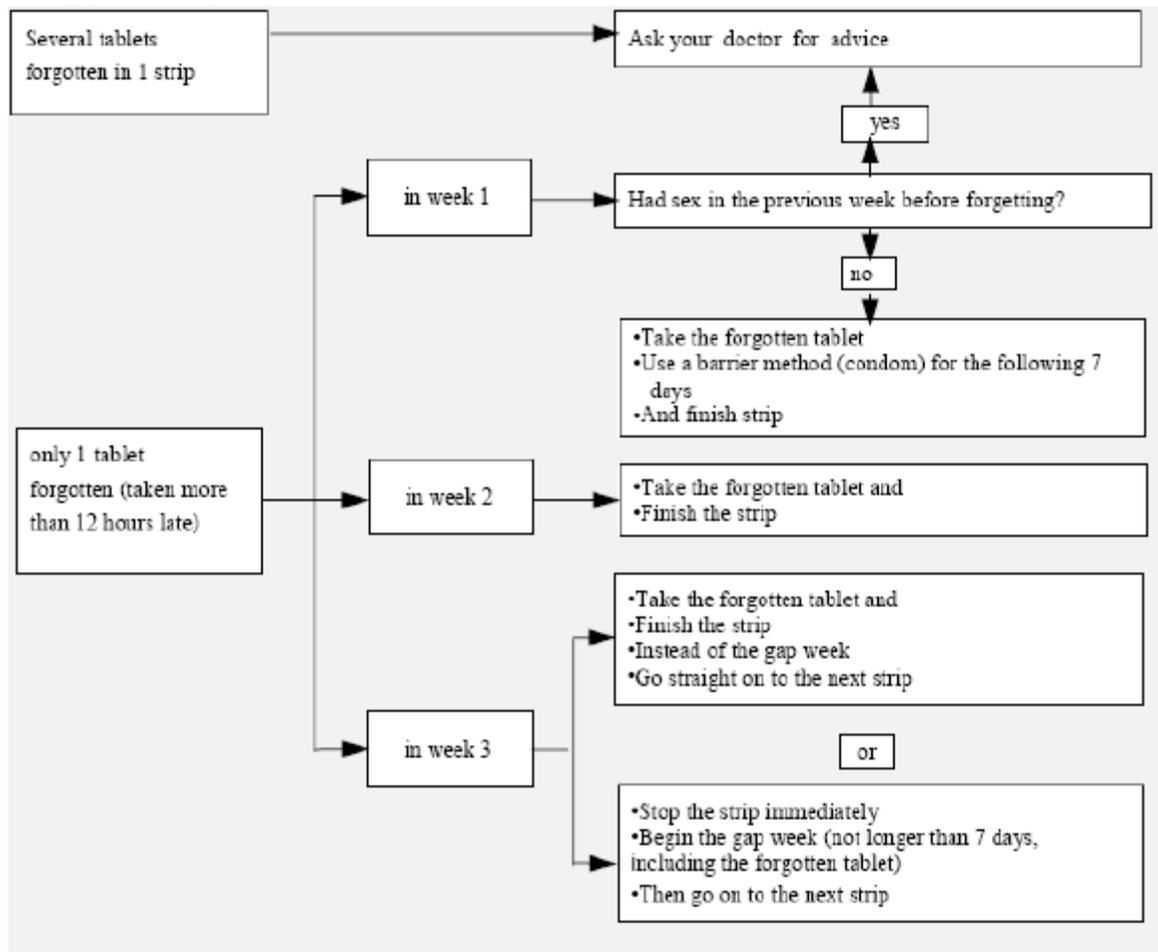
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the tablet-free period start next strip.

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

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

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

- If you have forgotten any of the tablets in a strip, and you do not have bleeding in the first tablet-free period, you may be pregnant. Contact your doctor before you start 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 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 begins 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.

##### **Serious reactions**

More serious reactions associated with combined hormonal contraceptive pills are detailed above in section 2 under “The pill and venous and arterial blood clots (thrombosis)” and “The pill and cancer”. Please read these subsections carefully, and if you have any questions, ask your doctor.

*The following serious side effects have been reported in women using the pill: Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases), systemic lupus erythematosus (SLE, a disease of the connective tissue), epilepsy, the rash known as herpes gestationis, chorea (a movement disease), a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail), brown patches on the face and body (chloasma), movement disorder called Sydenham's chorea, yellowing of the skin, gynaecological disorders (endometriosis, uterine myoma)*

##### **Other possible side effects**

The following side effects have been reported in women using the pill, which can occur in the first few months after starting Bimizza tablets, but they usually stop once your body has adjusted to the pill. The most commonly reported side effects (more than 1 in every 10 users may be affected) are irregular bleeding and weight gain.

*Common or uncommon (between 1 and 100 in every 1,000 users may be affected):* none or reduced bleeding, tender breasts, breast enlargement, breast pain, decreased sexual desire, depression, headache, nervousness, migraine, dizziness, nausea, vomiting, acne, rash, nettle-rash (urticaria), fluid retention, high blood pressure.

*Rare (between 1 and 10 in every 10,000 users may be affected):*, vaginal candidiasis (fungal infection), impaired hearing (otosclerosis), thromboembolism, hypersensitivity, increased sexual desire, eye irritation due to contact lens, loss of hair (alopecia), itching, skin disorders (erythema nodosum – a skin disease associated with joint pain, fever, hypersensitivity, or infection, and characterized by small, painful, pink to blue nodules under the skin and on the shins that tend to recur; erythema multiforme – a skin disease characterized by solid raised spots on the skin or fluid-filled blisters lesions and reddening or discoloration of the skin often in concentric zones about the lesions), vaginal discharge, breast discharge.

### **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](http://www.mhra.gov.uk/yellowcard)

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.

Version: V001/06/01/15/PL20117/0091  
Supersedes: None

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

Not all pack sizes may be marketed

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