

## **Package leaflet: Information for the user**

### **Freedonel & Placebo 0.02/3mg Film-coated tablets**

Ethinylestradiol/Drospirenone

**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.
- 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.

#### **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**

1. What Freedonel & Placebo is and what it is used for
2. What you need to know before you take Freedonel & Placebo
3. How to take Freedonel & Placebo
4. Possible side effects
5. How to store Freedonel & Placebo
6. Contents of the pack and other information

#### **1. What Freedonel & Placebo is and what it is used for**

Freedonel & Placebo is a contraceptive pill and is used to prevent pregnancy.

Each of the 21 pink tablets contains a small amount of two different female hormones, namely drospirenone and ethinylestradiol.

The 7 white tablets contain no active substances and are also called placebo tablets.

Contraceptive pills that contain two hormones are called “combination” pills.

#### **2. What you need to know before you take Freedonel & Placebo**

##### **General notes**

Before you start using Freedonel & Placebo 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 can begin taking Freedonel & Placebo, 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 Freedonel & Placebo, or where the reliability of Freedonel & Placebo 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 Freedonel & Placebo alters the monthly changes of body temperature and of the cervical mucus.

**Freedonel & Placebo, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

### **When you should not use Freedonel & Placebo**

You should not use Freedonel & Placebo 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 take Freedonel & Placebo**

- 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 (or 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:
  - 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) a liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of 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 drospirenone, or any of the other ingredients of this medicine (listed in section 6). This may cause itching, rash or swelling.
- if you have hepatitis C and are taking the medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section “Other medicines and Freedonel & Placebo”).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Freedonel & Placebo.

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.**

In some situations you need to take special care while using Freedonel & Placebo or any other combination pill, and your doctor may need to examine you regularly. If the condition develops, or gets worse while you are using Freedonel & Placebo, you should also tell 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 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 Freedonel & Placebo
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins
- if you have epilepsy (see "Freedonel & Placebo and using other medicines")
- 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 discolouration 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.

**BLOOD CLOTS**

Using a combined hormonal contraceptive such as Freedonel & Placebo 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 a harmful blood clot due to Freedonel & Placebo is small.**

## HOW TO RECOGNISE A BLOOD CLOT

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

| Are you experiencing any of these signs?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | What are you possibly suffering from?           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <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> <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> | Pulmonary embolism                              |
| <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> <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,</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Stroke                                          |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                          |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| especially on one side of the body <ul style="list-style-type: none"> <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> 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. |                                          |
| <ul style="list-style-type: none"> <li>• swelling and slight blue discolouration 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 Freedonel & Placebo 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 Freedonel & Placebo 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 drospirenone, such as Freedonel & Placebo, 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).

|                                                                                                                     | <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 Freedomel & Placebo                                                                                     | 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 Freedomel & Placebo 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 Freedomel & Placebo may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Freedomel & Placebo 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 Freedomel & Placebo needs to be stopped.

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

- with increasing age (beyond about 35 years)
- **if you smoke.** When using a combined hormonal contraceptive like Freedomel & Placebo 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 Freedonel & Placebo, 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.

### **Freedonel & Placebo and cancer**

Cervical cancer has been found more often in women taking combined hormonal contraceptives. However, this may be due to other causes including sexually-transmitted disease.

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 Freedonel & Placebo, you may have unexpected bleeding (bleeding outside the week when you are taking the white tablets). 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 to do if no bleeding occurs during the placebo days**

If you have taken all the pink active 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 Freedonel & Placebo**

Tell your doctor if you are taking, have recently taken or might take any other medicines. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Freedonel & Placebo. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Some medicines can have an influence on the blood levels of Freedonel & Placebo and can make it **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, oxcarbazepine, felbamate, topiramate)
  - tuberculosis (e.g. rifampicin)
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz)
  - fungal infections (e.g. griseofulvin, ketoconazole)
  - arthritis, arthrosis (etoricoxib)
  - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St John's wort

Freedonel & Placebo may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

Do not use Freedonel & Placebo if you have Hepatitis C and are taking the medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir 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 medicines.

Freedonel & Placebo can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use Freedonel & Placebo”.

### **Freedonel & Placebo with food and drink**

Freedonel & Placebo 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**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### Pregnancy

If you are pregnant, you must not take Freedonel & Placebo. If you become pregnant while taking Freedonel & Placebo you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Freedonel & Placebo at any time (see also “If you stop taking Freedonel & Placebo”).

#### Breast-feeding

Use of Freedonel & Placebo 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.

### **Driving and using machines**

There is no information suggesting that use of Freedonel & Placebo affects driving or use of machines.

**Freedonel & Placebo contains lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Freedonel & Placebo**

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

Each blister contains 21 active pink tablets and 7 white placebo tablets.

The two differently coloured tablets of Freedonel & Placebo are arranged in order. A strip contains 28 tablets.

Take one tablet of Freedonel & Placebo, 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.

**Do not confuse the tablets:** take a pink tablet once per day for the first 21 days, and then one white tablet per day for the last 7 days. Then you should start a new strip (21 pink tablets and 7 white tablets). Consequently there is no drug-free interval between strips.

Due to the different composition of the tablets, your first tablet must be the one in the upper left hand corner, continuing to take a tablet every day. To keep the right order, follow the direction of the arrows on the strip.

**Preparation of the strip**

To help you remember to take the contraceptive, every strip (blister) of Freedonel & Placebo tablets comes with seven adhesive stickers which have the days of the week printed on them. You must know the day of the week you are going to start taking the tablets.

According to the day of the week you are going to start taking the tablets, you should choose the corresponding adhesive week sticker. For example, if you begin on Wednesday, use the sticker which says "WED". Then stick the corresponding sticker in the upper left hand corner of the strip, on the "Start" position. Now you have a day of the week above every tablet and you can see if you have taken a tablet. The arrows show the order you should take the tablets in.

During the 7 days when you are taking the white placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2<sup>nd</sup> or 3<sup>rd</sup> day after the last pink active tablet of Freedonel & Placebo. Once you have taken the last white tablet, 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 Freedonel & Placebo in this manner, you are protected against pregnancy also during the 7 days when you are taking a placebo tablet.

**When can you start with the first strip?**

- *If you have not used a contraceptive with hormones in the previous month*  
Begin with Freedonel & Placebo on the first day of the cycle (that is the first day of your period). If you start Freedonel & Placebo 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 Freedomel & Placebo 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 Freedomel & Placebo 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 Freedomel & Placebo use.  
If, after having a baby, you have had sex before starting Freedomel & Placebo (again), be sure that you are not pregnant or wait until your next period.
- *If you are breast-feeding and want to start Freedomel & Placebo (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 Freedomel & Placebo than you should**

There are no reports of serious harmful results of taking too many Freedomel & Placebo 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 Freedomel & Placebo tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

### **If you forget to take Freedomel & Placebo**

The tablets in the 4<sup>th</sup> row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Freedomel & Placebo. Throw away the forgotten placebo tablet.

If you miss a pink active tablet from the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> row do as follows:

- 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 pink tablet at the beginning or at 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 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:

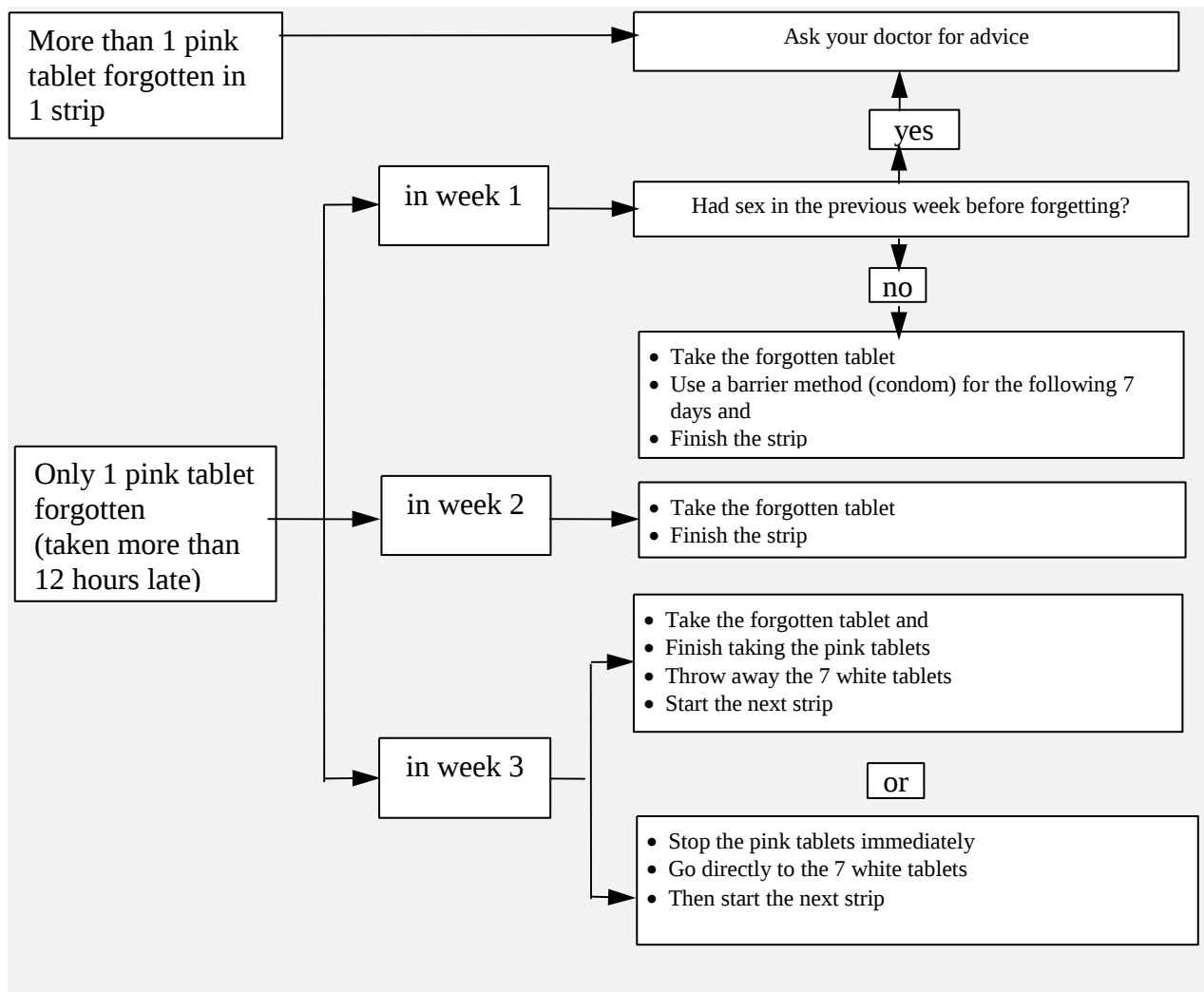
1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the white placebo tablets on this strip, throw them away and start the next strip.

Most likely, you will have a period at the end of the second strip - while taking the white placebo tablets - but you may have light or menstruation-like bleeding during the second strip.

2. You can also stop the active pink tablets and go directly to the 7 white placebo tablets (**before taking the placebo tablets, record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, take the placebo tablets for *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 a bleeding during the normal placebo days, you may be pregnant. Contact your doctor before you start the next strip.



### What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours after taking an active pink 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 pink 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 “If you forget to take Freedonel & Placebo”.

### Delaying your period: what you need to know

Even though it is not recommended, you can delay your period by not taking the white placebo tablets from the 4<sup>th</sup> row and going straight to a new strip of Freedonel & Placebo and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 7 white tablets from the 4<sup>th</sup> row. Then start your next strip.

*You might ask your doctor for advice before deciding to delay your menstrual period.*

### Changing the first day of your period: what you need to know

If you take the tablets according to the instructions, then your period will begin during *the placebo week*. If you have to change this day, reduce the number of placebo days – when you take the white placebo tablets – (*but never increase them - 7 is the maximum!*). For example, if you normally start taking the placebo tablets 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 placebo 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 stop taking Freedomel & Placebo**

You can stop taking Freedomel & Placebo 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 Freedomel & Placebo 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 medicine, ask your doctor or pharmacist.*

#### **4. Possible side effects**

Like all medicines, this medicine 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 Freedomel & Placebo, 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 Freedomel & Placebo”.

The following is a list of the side effects that have been linked with the use of Freedomel & Placebo.

**Common:** may affect up to 1 in 10 people

- mood swings
- headache
- abdominal pain (stomach ache)
- acne
- breast pain, breast enlargement, breast tenderness, painful or irregular periods
- weight gain.

**Uncommon:** may affect up to 1 in 100 people

- Candida (fungal infection)
- cold sores (herpes simplex)
- allergic reactions
- increased appetite
- depression, nervousness, sleep disorder,
- feeling of “pins and needles”, giddiness (vertigo)
- problems with vision
- irregular heartbeat or unusually fast heart rate
- a blood clot (thrombosis) in the lungs (pulmonary embolism), high blood pressure, low blood pressure, migraine, varicose veins

- sore throat
- nausea, vomiting, inflammation of stomach and/or intestine, diarrhoea, constipation
- sudden swelling of the skin and/or mucous membranes (e.g. tongue or throat), and/or difficulty swallowing or hives together with difficulty breathing (angioedema), hair loss (alopecia), eczema, itching, rashes, dry skin, oily skin disorders (seborrheic dermatitis)
- neck pain, limb pain, muscle cramps
- bladder infection
- breast lump (benign and cancer), milk production while not pregnant (galactorrhea), ovarian cysts, hot flushes, absence of periods, very heavy periods, vaginal discharge, vaginal dryness, lower abdominal (pelvic) pain, abnormal cervical smear (Papanicolaou or Pap smear), decreased interest in sex
- fluid retention, lack of energy, excessive thirst, increased sweating
- weight loss.

**Rare:** may affect up to 1 in 1,000 people

- asthma
- hearing impairment
- erythema nodosum (characterized by painful reddish skin nodules)
- erythema multiforme (rash with target-shaped reddening or sores)
- harmful blood clots in a vein or artery for example:
  - o in a leg or foot (i.e. DVT)
  - o in a lung (i.e. PE)
  - o heart attack
  - o stroke
  - o mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - o blood clots in the liver, stomach/intestine, kidneys or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Freedomel & Placebo**

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

Do not use this medicine after the expiry date which is stated on the carton or blister after "Do not use after:" or "EXP:" The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Freedonel & Placebo contains:

A strip of **Freedonel & Placebo** contains 21 pink active tablets in the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> rows of the strip and 7 white placebo tablets in row 4.

### Active tablets:

The active ingredients are ethinylestradiol 0.02 mg and drospirenone 3 mg.

The other ingredients are:

Tablet core: lactose monohydrate, pregelatinised starch (maize), povidone, croscarmellose sodium, polysorbate 80, magnesium stearate.

Coating: Polyvinyl alcohol partial hydrolyzed, titanium dioxide (E171), macrogol 3350, talc, yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).

### Placebo tablets:

Tablet core: lactose anhydrous, povidone, magnesium stearate.

Coating: Polyvinyl alcohol partial hydrolyzed, titanium dioxide (E171), macrogol 3350, talc.

### What Freedonel & Placebo looks like and contents of the pack

Active tablets are pink, round film-coated tablets.

Placebo tablets are white, round film-coated tablets.

- Freedonel & Placebo is available in boxes of 1, 2, 3, 6 and 13 blisters, each one containing 28 tablets (21 active plus 7 placebo tablets)

Not all package sizes may be marketed.

### Marketing Authorisation Holder and Manufacturers

#### Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

#### Manufacturers

Laboratorios León Farma S.A., Pol. Ind. Navatejera, C/ La Vallina s/n, 24008 - Villaquilambre, León, Spain.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

### This medicinal product is authorised in the Member States of the EEA under the following names:

|           |                                                      |
|-----------|------------------------------------------------------|
| Austria:  | Drosiane mite 0,02 mg/3 mg - Filmtabletten           |
| Denmark:  | Rubira                                               |
| Estonia:  | Marionelle                                           |
| Finland:  | Rubira 0,02 mg/3 mg tabletti, kalvopäällysteinen     |
| Hungary:  | Deciora Daily 3 mg/0,02 mg filmtablett               |
| Ireland:  | Freedonel & Placebo 0.02 mg/3 mg Film-Coated Tablets |
| Norway:   | Rubira                                               |
| Poland:   | Indrona                                              |
| Portugal: | Drospirenona+Ethinylestradiol Sandoz                 |
| Romania:  | FELICITY PLUS 3 mg / 20 µg comprimate filmate        |
| Slovenia: | DROSPIRENON/ETINILESTRADIOL Lek 3mg/0.02mg tablete   |
| Slovakia: | PHAENYELA 28                                         |

Spain: Drosianelle Diaro 0,02 mg / 3 mg comprimidos recubiertos con película

**This leaflet was last revised in: 08/2017.**