

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS  
(PREPARATIONS) 1986**

**This medicine can be sold under doctor's prescription only**

## **MICRODIOL<sup>®</sup>**

Tablets

### **Composition:**

#### **Each Tablet contains:**

Desogestrel           0.15 mg  
Ethinyl estradiol    0.03 mg

For a list of inactive ingredients see section 6.1, "**What MICRODIOL contains**".

### **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 **MICRODIOL** is right for you.
- To prevent pregnancy it is important to take **MICRODIOL** 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.**

- This leaflet contains concise information about **MICRODIOL**. If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their medical condition seems similar to yours.
- Keep this leaflet. You may need to read it again.
- 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.

## **1. WHAT MICRODIOL IS AND WHAT IT IS USED FOR?**

### **1.1 What is MICRODIOL?**

**Therapeutic group:** Estrogen-progestogen combination.

### **1.2 What is MICRODIOL used for?**

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

**MICRODIOL** 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.

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

**MICRODIOL needs to be taken as directed to prevent pregnancy.**

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE MICRODIOL

### General notes

Before you start using **MICRODIOL** 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, 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 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1, “**When you should not use MICRODIOL**”). Your doctor will tell you when you can start taking the Pill again.

### 2.1 When you should not use MICRODIOL

You should not use **MICRODIOL** 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 2.2, “**Special warnings concerning use of MICRODIOL**”.

#### Do not use MICRODIOL:

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section 2, “**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:
  - 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 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;
- 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** (*hypersensitive*) to any of the ingredients in **MICRODIOL** (listed in section 6);
- If you are **pregnant** or suspect you may be **pregnant**. See section 2.5.

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

## 2.2 Special warnings concerning use of MICRODIOL

### 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 section 2 below, “**Blood clots**”).

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 **MICRODIOL**, you should also tell your doctor.

Before using **MICRODIOL**, tell your doctor:

- 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:
  - itching of the whole body (*pruritus*)
  - jaundice which was not caused by infection
  - gall stones
  - systemic lupus erythematosus (SLE)
  - a blister-like rash, called *herpes gestationis*
  - a hearing problem called *otosclerosis*
  - 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 defense 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 section 2 below, “**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 **MICRODIOL** (see section 2.2.1, “**The Pill and Thrombosis**”).
- If you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- If you have varicose veins.

### 2.2.1 The Pill and Thrombosis

#### Blood clots

Using a combined hormonal contraceptive such as **MICRODIOL**, 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 MICRODIOL 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>	Pulmonary embolism
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>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>	<p>Retinal vein thrombosis (blood clot in the eye)</p>
<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>	<p>Heart attack</p>
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li> <li>• sudden confusion, trouble speaking or understanding;</li> <li>• sudden trouble seeing in one or both eyes;</li> <li>• sudden trouble walking, dizziness, loss of balance or coordination;</li> <li>• sudden, severe or prolonged headache with no known cause;</li> <li>• loss of consciousness or fainting with or without seizure.</li> </ul> <p>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.</p>	<p>Stroke</p>
<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>	<p>Blood clots blocking other blood vessels</p>

### **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 **MICRODIOL** 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 **MICRODIOL** 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 **MICRODIOL** 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 <b>MICRODIOL</b>	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 **MICRODIOL** is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/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 **MICRODIOL** may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop **MICRODIOL** 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 **MICRODIOL** needs to be stopped.

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

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

### **2.2.2 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 **MICRODIOL**.

### 2.3 Other medicines and MICRODIOL

**If you are taking or have recently taken other medicines, including non-prescription medicines, herbal products and nutritional supplements, you should tell the attending doctor or pharmacist.**

Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use **MICRODIOL**. This is because **MICRODIOL** 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 MICRODIOL from working properly.** These include medicines used for the treatment of:

- **epilepsy** (primidone, phenytoins, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate, modafinil);
- **tuberculosis** (rifampicin);
- **HIV infection** (ritonavir, nelfinavir, nevirapine, efavirenz);
- **Hepatitis C virus infection** (e.g., boceprevir, telaprevir);
- **other infectious disease** (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 **MICRODIOL** less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on **MICRODIOL** may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

#### Laboratory tests

If you are having any blood or urinary test, tell your health care professional that you are using **MICRODIOL** as it may affect the results of some tests.

### 2.4 Taking MICRODIOL with food and drink

There are no special instructions about food and drink while on **MICRODIOL**.

### 2.5 Pregnancy and breast-feeding

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

**MICRODIOL** is not recommended for use during breast-feeding. Ask your doctor about alternative contraception. Breast-feeding may not stop you getting pregnant.

### 2.6 Driving and using machines

**MICRODIOL** has no known effect on the ability to drive or use machines.



## 2.7 Important information about some of the ingredients of MICRODIOL

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using **MICRODIOL** (see also section 6.1, “**What MICRODIOL contains**”).

## 2.8 Use in adolescents

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

## 3. HOW TO USE MICRODIOL

Always use **MICRODIOL** as instructed by the doctor. You should check with your doctor or pharmacist if you are unsure.

### 3.1 How to take MICRODIOL

To prevent pregnancy, always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

#### Take MICRODIOL every day for 21 days

**MICRODIOL** comes in strips of 21 pills, each marked with a day of the week.

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

#### Then have seven pill-free days

After you have taken all 21 pills in the strip, you have seven days when you take no pills. So if you take the last pill of one pack on a Friday, you will take the first pill of your next pack on the Saturday of the following week.

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

You don't need to use extra contraception during these seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time.

#### Then start your next strip

Start taking your next strip of **MICRODIOL** after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

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

### 3.2 Starting MICRODIOL

#### As a new user or starting the Pill again after a break

**Either** take your first **MICRODIOL** pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

**Or** if your period has already begun start taking **MICRODIOL** on day 5 (counting the first day of your period as day 1) whether or not your bleeding has stopped. You must also use extra contraception, such as condoms, until you have taken the first seven pills correctly.

#### Changing to MICRODIOL from another contraceptive Pill

- **If you are currently on a 21-day Pill:** start taking **MICRODIOL** the next day after the end of the previous strip. You will have contraceptive protection with your first pill but you will not have a bleed until after you finish your first strip of **MICRODIOL**.
- **If you are currently on a 28-day Pill:** start taking **MICRODIOL** the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after you finish your first strip of **MICRODIOL**.

- **Or if you are taking a progestogen-only Pill** (mini-Pill or POP): start **MICRODIOL** on the first day of bleeding, even if you have already taken the POP for that day. You will have contraceptive cover straight away. If you don't usually have any bleeding while you are taking a progestogen-only Pill, you can stop taking it any day and start **MICRODIOL** the next day. You will need to use extra contraception, such as a condom, for seven days.

### **Changing to MICRODIOL from a progestogen-only injection, implant or progestogen releasing intrauterine device (IUD)**

Start taking **MICRODIOL** when your next injection is due or on the day that your implant or IUD is removed. Make sure you also use an additional contraceptive method, such as a condom, for the first 7 days that you are taking **MICRODIOL**.

### **Starting MICRODIOL after a miscarriage or abortion**

If you have had a miscarriage or an abortion, your doctor may tell you to start taking **MICRODIOL** straight away. This means that you will have contraceptive protection with your first pill.

### **Contraception after having a baby**

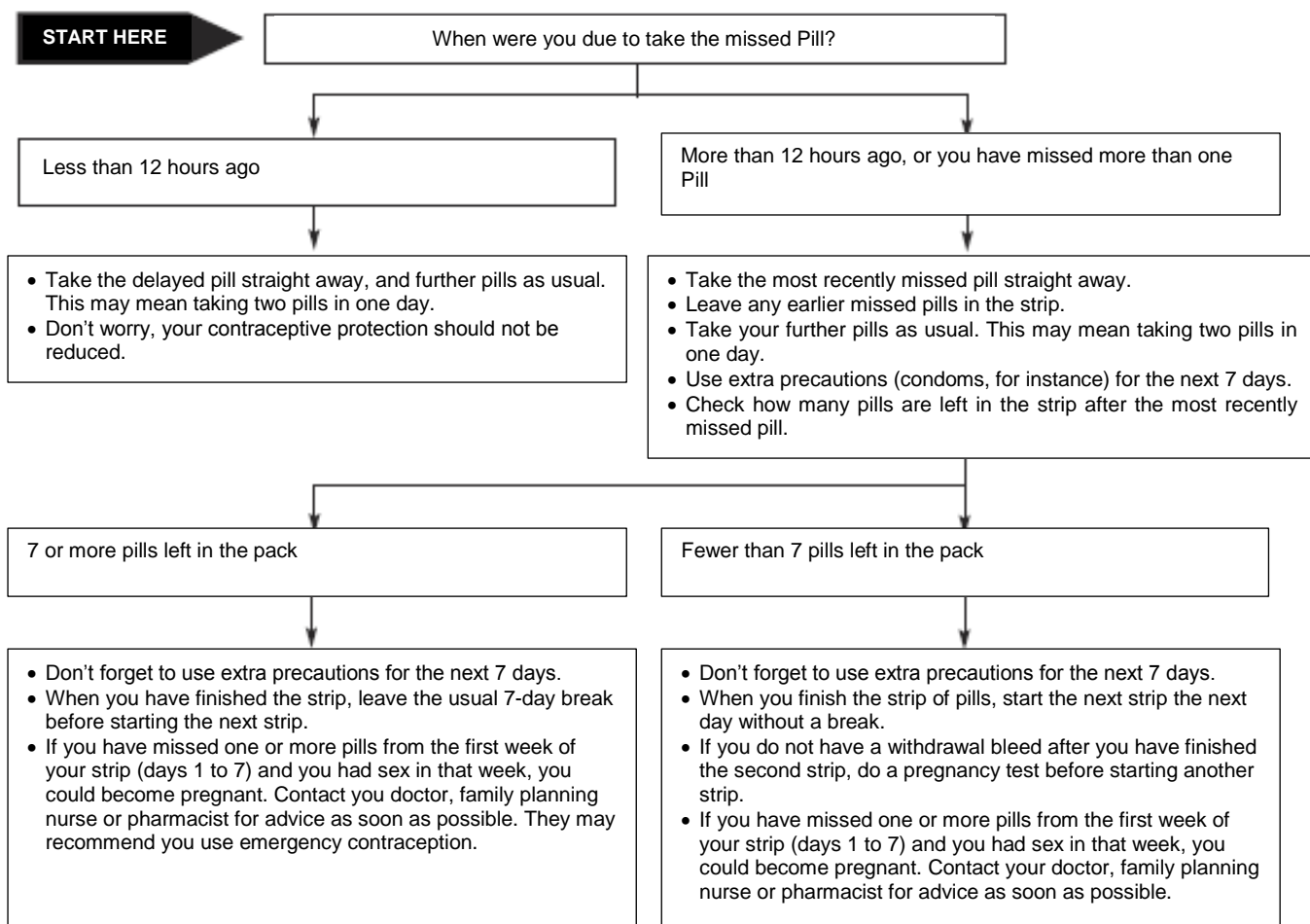
If you have just had a baby, ask your doctor for advice about contraception.

If you are not breast-feeding:

- you can start taking **MICRODIOL** three weeks after the birth or,
- you can start taking **MICRODIOL** more than three weeks after the birth but you need to use extra contraception, such as a condom until you have taken the first seven pills correctly.
- If you have had sex since the birth there is a chance that you could be pregnant, you should therefore use another form of contraception, such as a condom. In this case, take your first **MICRODIOL** pill on the first day of your next period.

### 3.3 A missed pill

If you miss a pill, follow these instructions:



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

If you start a new strip of pills late, or make your “week off” longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

### 3.4 A lost pill

If you lose a pill,

**Either** take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

**Or** if you do not want to change the starting day of your cycle, take a pill from a spare strip. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

### 3.5 If you are sick or have diarrhoea

If you are sick (*vomit*) or have very bad diarrhoea your body may not get its usual dose of hormones from that pill.

If you vomit within **3 to 4 hours** after taking your pill, this is like missing a pill. You must follow the advice for missed pills – see section 3.3, “**A missed pill**”.

If you have severe diarrhoea for **more than 12 hours after taking MICRODIOL** follow the instructions for if you are more than 12 hours late – see section 3.3, “**A missed pill**”.

→**Talk to your doctor if your stomach upset carries on or gets worse. He or she may recommend another form of contraception.**

### 3.6 Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the pharmacist. If you are pregnant, stop taking **MICRODIOL** and see your doctor.

### 3.7 Taking more than one pill should not cause harm

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

### 3.8 You can delay a period

If you want to delay having a period, finish the strip of pills you are taking. Start the next strip the next day without a break. Take this strip the usual way. After the second strip, leave seven pill-free days as usual, then start your next strip of pills in the normal way. When you use the second strip, you may have some unexpected bleeding or spotting on the days that you take the pill, but don't worry.

### 3.9 When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping **MICRODIOL** until you have had a proper period. Your doctor relies on the date of your last natural period before you get pregnant to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, **MICRODIOL** can cause side effects, although not everybody gets them.

Do not be alarmed by reading the list of side effects, you may not suffer from any of 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 **MICRODIOL** 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 **MICRODIOL**”.

### 4.1 Serious side effects – see a doctor straight away

**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 MICRODIOL**

- 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 **MICRODIOL**.

**4.2 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):

- **Breast enlargement**;
- **Vomiting**;
- **Diarrhea**;
- **Fluid retention** (swollen hands, ankles or feet – a sign of fluid retention);
- **Decreased sexual desire**;
- **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);
- **Skin problems, such as rash or hives**;

**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 **MICRODIOL**
- **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 or pharmacist** if you are worried about any side effects which you think may be due to **MICRODIOL**. Also tell them if any existing conditions get worse while you are taking **MICRODIOL**.

### 4.3 Bleeding between periods should not last long

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

If a side effect appears, if any of the side effects gets serious or if you notice a side effect not mentioned in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site ([www.health.gov.il](http://www.health.gov.il)) which refers to the online side effects reporting form, or by using the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@mo.h.gov.il>

## 5. HOW TO STORE MICRODIOL?

- Avoid Poisoning! This medicine, as all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use **MICRODIOL** after the expiry date (exp. date) which is stated on pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Store at 2°C-30°C. Protect from light and moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### 6.1 What MICRODIOL contains?

- The active substances are: desogestrel 0.15 mg, and ethinyl estradiol 0.03 mg.
- In addition to the active ingredients, **MICRODIOL** also contains: Lactose monohydrate, potato starch, povidone, stearic acid, silica, colloidal anhydrous, all-rac- $\alpha$ -Tocopherol.

Each **MICRODIOL** tablet contains up to 80 mg lactose monohydrate.

## **6.2 What MICRODIOL looks like and contents of the pack**

**MICRODIOL** tablet is white, round biconvex, measures 6 mm across, has TR above 5 marked on one side and ORGANON\* on the other side.

Each box of **MICRODIOL** contains one or three strips of 21 tablets.

Each strip of **MICRODIOL** contains 21 white tablets.

Not all pack sizes may be marketed.

### **Manufacturer:**

N.V. Organon, Oss, The Netherlands.

### **License holder:**

Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

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