

## Package leaflet: Information for the user

### Marvelon®

Desogestrel (150 micrograms)

Ethinyl estradiol (30 micrograms)

#### **Five important things to know about the Pill.**

- The Pill is a reliable contraceptive and may reduce your risk of cancer of the ovary and womb if used in the long term.
- The Pill will not protect you against sexually transmitted diseases.
- This medicine can increase your risk of problems such as blood clots and breast cancer.
- Some women should not take the Pill because of current medical problems or illnesses. Please read this leaflet to make sure Marvelon is right for you.
- To prevent pregnancy it is important to take Marvelon 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.**

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, family planning nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor, family planning nurse or pharmacist.

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#### **1 What Marvelon does**

Marvelon is a combined oral contraceptive pill ('the Pill'). **You take it to stop you getting pregnant.**

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

Marvelon 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.

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

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

## **2 Make sure Marvelon is OK for you**

It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn't suitable for everyone.

→**Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

### **Before you start taking the Pill**

- Your doctor will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a breast examination.

### **While you're on the Pill**

- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again.

## **2.1 The Pill and blood clots**

**The Pill may slightly increase your risk of having a blood clot (*called a thrombosis*) especially in the first year of taking it.**

A clot in a leg vein – a *deep vein thrombosis* (or DVT) – is not always serious. However, if it moves up the veins to the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called a *pulmonary embolism* and is very rare.

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

- Of 100,000 women who are **not on the Pill** and not pregnant, about **5** will have a blood clot in a year.
- Of 100,000 women **taking a Pill such as Marvelon**, about **25** will have a blood clot in a year.

- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year.

**You are more at risk of having a blood clot in your veins:**

- as you get **older**
- if you are **seriously overweight**
- if you or any of your close family have had **blood clots**
- if you have certain rare medical conditions such as **systemic lupus erythematosus (SLE)** or **Crohn's disease**
- if you're **off your feet for a long time** because of major surgery, injury or illness
- if you have **recently had a baby**.

→**Tell your doctor** if any of these apply to you.

Taking the Pill may add to this risk so Marvelon may not be suitable for you.

**Signs of a blood clot include:**

- **painful swelling in your leg**
- sudden **chest pain**
- sudden **coughing**
- **difficulty breathing**

→**See a doctor as soon as possible. Do not take any more Marvelon** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

**You are more at risk of having a heart attack or stroke:**

- as you get **older**
- if you are **seriously overweight**
- if you have **high blood pressure**
- if you **smoke cigarettes** (or other tobacco) – you are strongly advised to stop smoking when you use Marvelon, especially if you are older than 35
- if you have **migraines**
- if you have a **heart valve** problem
- if you have an **irregular heartbeat** (atrial fibrillation)
- if you had a problem with the **fat in your blood** (dyslipoproteinemia)
- if you or someone in your close family has had a **heart attack or stroke** at a young age
- if you have **diabetes**.

→**Tell your doctor** if any of these apply to you. Taking the Pill may add to this risk so Marvelon may not be suitable for you.

**Signs of a heart attack or stroke include:**

- sudden **sharp pains in your chest** which may reach your left arm or **sharp pains in your stomach**
- sudden **weakness or numbness** in one side or part of your body
- having a **migraine** for the first time or any migraine that is worse than normal
- **slurred speech** or any other difficulties affecting your speech

- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- dizziness, collapse or seizures.

→**See a doctor as soon as possible. Do not take any more Marvelon** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

## 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 Marvelon.

## 2.3 Marvelon should not be taken by some women

→**Tell your doctor or family planning nurse** if you have any medical problems or illnesses.

**Do not take Marvelon if any of the following apply to you.** Taking Marvelon would put your health at risk:

- If you have moderate or severe **high blood pressure** (*hypertension*)

- If you have ever had a **heart attack** or **stroke**
- If you have ever had a condition that may be a **first sign of a heart attack** (such as angina pectoris or chest pain) **or stroke** (such as transient ischaemic attack or small reversible stroke)
- If you have more than one **risk factor for a blood clot** (*thrombosis* - see section 2.1, *The Pill and blood clots*)
- If you have ever had a problem with your blood circulation. This includes a **blood clot** (*thrombosis*) in the legs (*deep vein thrombosis*), lungs (*pulmonary embolism*), or any other parts of the body
- If you have had a **migraine** with aura
- If you have **diabetes with blood vessel damage**
- If you have ever had the disease **systemic lupus erythematosus**
- If you have or have recently had a **severe liver disease**
- If you have ever had a **liver tumour**
- 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 Marvelon.

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

#### 2.4 Marvelon can make some illnesses worse

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

- If you have ever had problems with your **heart, circulation or blood clotting**
- If you or someone in your close family have **high fat levels in your blood** (high *triglyceride* levels)
- 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 angiodema*
- If you have **brown patches on your face or body** (*chloasma*) – if so avoid too much exposure to the sun or ultraviolet light.

→**Tell your doctor or family planning nurse if any of these apply to you**. Also tell them if you get any of these for the first time while taking the Pill, or if any get worse or come back, because you may need to stop taking Marvelon.

## 2.5 Taking other medicines

If you ever need to take another medicine at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you're taking Marvelon. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

**Some medicines can stop Marvelon from working properly** – for example:

- some medicines used to treat **epilepsy** (primidone, phenytoins, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
- medicine to treat **tuberculosis** (rifampicin)
- certain **HIV medicines** (ritonavir)
- certain **antibiotics** (penicillins, tetracyclines)
- **St. John's Wort** (a herbal remedy)
- Griseofulvin (an antifungal drug).

If you do need to take one of these medicines, Marvelon may not be suitable for you, or you may be able to take Marvelon and use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

**Marvelon can also affect how well other medicines work.** For example ciclosporin and lamotrigine. Remind your doctor if you are taking these in case your treatment needs to be adjusted.

## 2.6 Taking Marvelon with food and drink

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

## 2.7 Pregnancy and breast-feeding

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

Marvelon is not recommended for use during breast-feeding. Ask your doctor or family planning nurse about alternative contraception. Breast-feeding may not stop you getting pregnant.

## 2.8 Driving and using machines

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

## 2.9 Marvelon contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using Marvelon.

## 2.10 Use in adolescents

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

### **3 Taking Marvelon**

#### **3.1 How to take it**

To prevent pregnancy, always take Marvelon exactly as described below. Check with your doctor or family planning nurse if you are not sure.

#### **Take Marvelon every day for 21 days**

Marvelon 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 Marvelon after the seven pill-free days – even if you are still bleeding. Always start the new strip on time.

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

#### **3.2 Starting Marvelon**

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

**Either** take your first Marvelon 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 Marvelon 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 Marvelon from another contraceptive Pill**

- **If you are currently on a 21-day Pill:** start taking Marvelon 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 Marvelon.

- **If you are currently on a 28-day Pill:** start taking Marvelon 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 Marvelon.
- **Or if you are taking a progestogen-only Pill (mini-Pill or POP):** start Marvelon 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 Marvelon the next day. You will need to use extra contraception, such as a condom, for seven days.

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

Start taking Marvelon 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 Marvelon.

**Starting Marvelon after a miscarriage or abortion**

If you have had a miscarriage or an abortion, your doctor may tell you to start taking Marvelon 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.

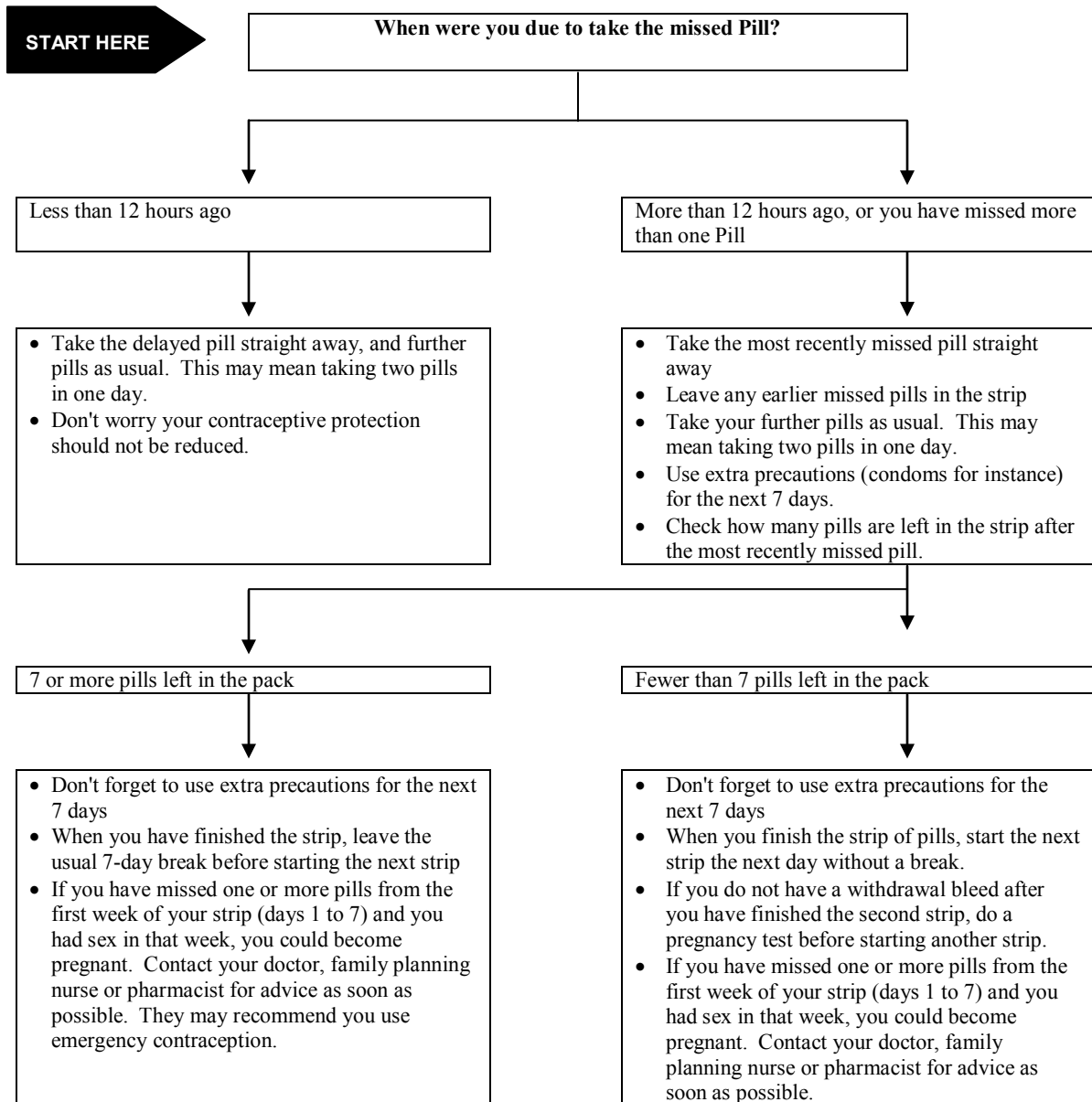
If you are not breast-feeding:

- you can start taking Marvelon three weeks after the birth or,
- you can start taking Marvelon 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 Marvelon 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 family planning clinic, 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, family planning nurse 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 Marvelon** 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 chemist or get a free test at your family planning clinic or doctors surgery. If you are pregnant, stop taking Marvelon 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 Marvelon until you have had a proper period. Your doctor or midwife 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, Marvelon can cause side effects, although not everybody gets them.

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Marvelon.

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

##### Signs of a blood clot include:

- **painful swelling in your leg**
- **sudden chest pain**
- **sudden coughing**
- **difficulty breathing.**

##### Signs of heart attack or stroke include:

- a **migraine** for the first time, or a migraine that is worse than normal
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- dizziness, fainting, collapse or seizures
- sudden **weakness** or **numbness** in one side or part of your body
- **slurred speech** or any other difficulties affecting your speech
- sudden **sharp pains in your chest** which may reach your left arm or **sharp pains in your stomach.**

##### Signs of a severe allergic reaction to Marvelon

- **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 Marvelon.

#### 4.2 Other possible side effects

**Common** (more than 1 in 100 people who take Marvelon are affected)

- **Migraine or headache** (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)
- **Putting on weight or losing weight**
- **Breast problems**, such as painful or tender breasts; producing a milky fluid from the nipples
- **Depression or mood changes**
- **Changes in sexual desire**
- **Heart or circulation problems**, such as increased blood pressure, swollen hands, ankles or feet– a sign of fluid retention
- **Changes in vaginal secretions**
- **Irregular vaginal bleeding** -see section 4.3, *Bleeding between periods should not last long*
- **Skin problems**, such as rash; bruise-like swelling to the shins (*erythema nodosum*)
- **Stomach problems**, such as nausea; vomiting
- **Discomfort of the eyes** if you wear contact lenses

**Rare** (less than 1 in 1000 people who take Marvelon are affected)

- **High blood pressure**
- **Gall stones**
- **Chorea** (a problem with the nervous system causing jerky movements that you can't control)
- Worsening of **systemic lupus erythematosus** (SLE; when your immune system attacks your body causing, for example, joint ache and tiredness)
- **Stomach and intestine problems** such as pancreatitis; Crohn's disease; ulcerative colitis
- Worsening of **otosclerosis** (a hearing problem)
- **Problems with blood sugar**
- Worsening of a rare condition called **porphyria**
- Worsening of **skin problems**, such as brown patches on your face or body (*chloasma*) blister-like rash, (*herpes gestationis*)

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

#### 4.3 Bleeding between periods should not last long

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

## **5 How to store Marvelon**

Keep all medicines out of the reach and sight of children.

Store Marvelon below 25°C but not in the fridge.

Store it in the original pack to protect it from light and moisture.

Do not use Marvelon after the expiry date shown on the packet. The expiry date refers to the last day of that month.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

## **6 What is in Marvelon and who makes it**

### **What is in Marvelon**

Each box of Marvelon contains three strips of 21 tablets.

Each strip of Marvelon contains 21 white tablets.

Each tablet is round, measures 6mm across, has TR5 marked on one side and ORGANON \* on the other side.

Each tablet contains: 150 micrograms of the progestogen desogestrel, and 30 micrograms of the oestrogen ethinyl estradiol.

Marvelon also contains the inactive ingredients: dl-alpha-tocopherol, potato starch, povidone, stearic acid, aerosol and lactose.

### **The company that holds the product licence for Marvelon is:**

Merck Sharp & Dohme Limited,  
Hertford Road,  
Hoddesdon,  
Hertfordshire, EN11 9BU, UK

### **Marvelon is made by:**

N.V. Organon, P.O. Box 20, 5340 BH Oss, The Netherlands., or  
Organon (Ireland) Ltd., Drynam Road, P.O. Box 2857, Swords, Co. Dublin, Ireland

**This leaflet was last updated in July 2013.**

In correspondence please quote packing number.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name: Marvelon

Reference Number: PL 00025/0596

This is a service provided by the Royal National Institute of Blind people.