desogestrel, ethinylestradio

Important things to know about combined hormonal contraceptives: They are one of the most reliable reversible methods

of contraception if used correctly They slightly increase the risk of having a blood clot (thrombosis) in the veins and arteries, especially in the first year that you use a combined hormonal

contraceptive or when you restart 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 (thrombosis)').

#### Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again,

If you have any further questions, ask your doctor or pharmacist.

 This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet?

What Marvelon is and what it is used for? When should you not take this medicine or should

you be extra careful?

How to use this drug? Possible side effects

How to store this drug? Contents of the pack and other information

1. What Marvelon is and what it is used for?

# Composition and type of Pill

Marvelon is a combined oral contraceptive ('the combined Pill'). Each tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amounts of hormones, Marvelon is considered a low-dose contraceptive. As the two hormones in all tablets in the strip are used in the same quantity, it is called a one-phasic oral contraceptive.

## Why use this medicine?

General notes

Marvelon is used to prevent pregnancy. When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

# 2. When should you not take this medicine or should you be extra careful?

Before you start using Marvelon you should read the information on blood clots (thrombosis) in section 2. It is particularly important to read the symptoms of a blood clot see section 2 'Blood clots (thrombosis)'

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sexual intercourse 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 the Pill alters the usual changes in body temperature and cervical mucus that occur during the menstrual cycle.

### Marvelon, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease (STDs).

When should you not use this medicine? You should not use Marvelon 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 'When do you have to take special care with Marvelon' • 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 'Blood clots (thrombosis)')

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

sk of a clot in the art 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 had pancreatitis (inflammation

of the pancreas) associated with high levels of fatty substances in your blood if you have jaundice (yellowing of the skin or eyes) or

severe liver disease and the results of the liverfunction tests are not normal yet

if you have or have had a cancer that may grow under the influence of sex hormones (e.g. cancer of the breast

or the genital organs)

if you have or have had a liver tumour if you have any unexplained vaginal bleeding

if you have endometrial hyperplasia (abnormal growth of the lining of the womb) if you are allergic to any of the ingredients of this

medicine (listed in section 6). If any of these conditions appear for the first time while

using Marvelon, stop taking it at once and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also 'General Notes' above Do not use Marvelon if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir

and dasabuvir (see also section 'Are you using any other medicines?').

# When do you have to take special care with this drug?

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 (thrombosis)' section below). For a description of the symptoms of these serious side

effects please go to 'How to recognise a blood clot'. Tell your doctor if any of the following conditions apply

to you. If the condition develops, or gets worse while you are using Marvelon, you should also tell your doctor.

if you smoke

if you have diabetes if you are overweight

if you have high blood pressure if you have a heart valve disorder or a certain heart

rhythm disorder if you have an inflammation in the veins under the skin

(superficial thrombophlebitis):

if you have varicose veins if anyone in your immediate family has had a thrombosis,

a heart attack or a stroke

if you suffer from migraine if you suffer from epilepsy

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 (thrombosis)') 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 Marvelon. if anyone in your immediate family has had breast cancer

if you have liver or gallbladder disease 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 a condition that occurred for the first time or got worse during pregnancy or previous use of sex hormones, e.g., hearing loss, porphyria (a disorder

affecting the blood), pemphigoid gestationis (a rash with blisters during pregnancy), Sydenham's chorea (a nerve disorder involving sudden body movements), hereditary angioedema (a sudden swelling of body tissues, especially in the face and throat) if you have or have had chloasma (yellowish-brown pigmentation

patches on the skin, particularly of the face); if so, it is advisable

to avoid direct exposure to the sun or ultraviolet light The Pill and blood clots (thrombosis)

**BLOOD CLOTS (THROMBOSIS)** Using a combined hormonal contraceptive such as Marvelon 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, blood clots may be fatal. It is important to remember that the overall risk of a harmful

### HOW TO RECOGNISE A BLOOD CLOT

blood clot due to Marvelon is small

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?
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	Deep vein thrombosis
<ul> <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 lightheadedness 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').	
Symptoms most commonly occur in one eye:     immediate loss of vision or     painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clo- in the eye)
chest pain, discomfort, pressure or heaviness;     sensation of squeezing or fullness in the chest, arm or below the breastbone;     fullness, indigestion or choking feeling;	Heart attack

back, iaw, throat, arm and stomach: sweating, nausea, vomiting or dizziness: extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats sudden weakness or numbness of the Stroke face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both sudden trouble walking, dizziness, loss of balance or coordination; sudden, severe or prolonged headache

upper body discomfort radiating to the

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

with no known cause;

medical attention as you may be at risk of another stroke. swelling and slight blue discolouration Blood clots blocking of an arm or leg;

other blood vessels severe pain in your stomach (acute abdomen

### **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 is). 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 Marvelon your risk of a blood clot returns to normal

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

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 Marvelon, The risk of having a blood clot will vary according to your

between about 9 and 12 women will develop a blood clot in a year. personal medical history (see the sections 'Factors that increase your risk of a blood clot in a vein/artery' below).

	Risk of developing a blood clot in a year
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 levonorgestrel, norethisterone or norgestimate	About 5-7 out of 10,000 women
Women using Marvelon	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 Marvelon 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/m²) if someone in 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 Marvelon may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Marvelon ask your doctor when you can start using it again. as you get older (particularly above about 35 years of age) if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions vou 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 larvelon needs to be stopped

If any of the above conditions change while you are using Marvelon, 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 Marvelon is very small but can increase: with increasing age (beyond about 35 years of age) if you smoke. When using a combined hormonal contraceptive like Marvelon 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 (under the age of 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 Marvelon, for example you start smoking, a close family member experiences a blood clot (thrombosis) for no known reason, or you gain a lot of

## The Pill and Cancer

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. No difference is observed 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that Pill users are examined more thoroughly and more often, so that the breast cancer is noticed earlier.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours have occasionally led to life-threatening internal bleeding. Contact your doctor immediately if you suddenly experience severe pain in your abdomen

The main risk factor for cervical cancer is chronic infection with the human papilloma virus. The risk of cervical cancer is slightly higher in women using the Pill for a long time. It is unknown if this finding is due to the use of hormonal contraceptives or to sexual behaviour and other factors (such as better cervical screening).

Are you using any other medicines?

Tell your doctor/midwife or pharmacist if you are taking, have recently taken or might take any other medicines or herbal products, including those obtained without a prescription. Also tell any other doctor or dentist who prescribes another medicine for you that you use Marvelon. They can tell you if you need to take additional contraceptive precautions, e.g. condom,

and if so, for how long. Do not use Marvelon if you have Hepatitis C and are taking medicinal products 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 medicinal products. Marvelon can be restarted approximately 2 weeks after completion of this treatment. See section 'When should you not use Marvelon'.

• can have an influence on the blood levels of Marvelon

can make it less effective in preventing pregnancy can cause unexpected bleeding

These include medicines used for the treatment of: epilepsy (e.g. primidone, phenytoin, phenobarbital,

carbamazepine, oxcarbazepine, topiramate, felbamate tuberculosis (e.g. rifampicin, rifabutin)

hiv infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz)

hepatitis C virus infection (e.g. boceprevir, telaprevir) other infectious diseases (e.g. griseofulvin) high blood pressure in the blood vessels of the lungs (bosentan)

depressive moods (the herbal remedy St. John's wort)

Marvelon may also interfere with how other medicines work like for instance cyclosporin (a drug used against transplant rejection reactions) or the anti-epileptic drug lamotrigine (can lead to an increase in number of attacks).

Marvelon less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Marvelon may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

If you are taking medicines or herbal products that might make

Marvelon may also interfere with howinfluence the effect of other medicines e.g.work, causing either an increase in effect (e.g. cyclosporine) or a decrease in effect (e.g. and

lamotrigine) medicines containing ciclosporine the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)

e results of some tests

Pregnancy and breastfeeding

Laboratory tests If you need blood tests, tell the doctor or the laboratory staff that you are on the Pill, because hormonal contraceptives can influence

### **Pregnancy** Marvelon must not be used by women who are pregnant, or who

think they may while you are already using Marvelon, you should tell your doctor as soon as possible Breastfeeding

If you wish to take the Pill while breastfeeding, please ask your doctor. The Pill and driving and using machines There is no indication that Marvelon affects the ability to drive or

Marvelon is not usually recommended for use during breastfeeding.

Marvelon contains lactose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before starting with Marvelon.

No clinical data on efficacy and safety are available in adolescents below 18 years of age. When should you contact your doctor while using Marvelon?

Your doctor may advise you to return for regular check-ups. The frequency and nature of the check-ups will depend on your personal situation.

Use in children and adolescents till 18 year.

Contact your doctor as soon as possible 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 'The pill and blood clots (thrombosis)' above). For a description of the symptoms of these serious side effects please go to the section 'How to recognise a blood clot'. you notice any changes in your own health (or that of members of your immediate family) involving any of the items mentioned in this leaflet (see section 'When should you not use Marvelon?' and section 'When do you have to take special

care with Marvelon?' you feel a lump in your breast; you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing

you are going to use other medicines, especially antibiotics (see also section 'Are you using any other medicines?'); you are to have surgery or when you are confined to bed or off your feet for some time (tell your doctor at least four weeks

in advance); you have persistent or worsening irregular vaginal bleeding; you forgot tablets in the first week of the strip and had sex in the seven days before;

you have severe diarrhoea; you miss your period twice in a row (do not start the next strip until your doctor tells you).

### 3. How to use this drug? When and how to take the tablets

The Marvelon strip contains 21 tablets. At every tablet it is indicated on which day it should be taken. Take your tablet at about the same time each day, with some water if necessary. Follow the direction of the arrow that is indicated on the strip until you have taken all 21 tablets. During the next 7 days you take no tablets. Your vaginal bleed should begin during these 7 days (the withdrawal bleed). Usually it will start on day 2-3 after the last Marvelon tablet. Start taking your next strip on the 8th day even if your vaginal bleed hasn't finished. This means that you will always start new strips on the same day of the week, and also that you have your vaginal bleed on roughly the same days each month When to start your first pack of Marvelon

When no oral hormonal contraceptive has been used in the past

Start taking Marvelon on the first day of your cycle, i.e. the first day of menstrual bleeding. Marvelon will work immediately. You do not need to use an additional contraceptive method. You may also start on days 2-5 of your cycle, but if you do, make sure you also use an additional contraceptive method (e.g. condom)

for the first 7 days of tablet-taking. When changing from another combined oral contraceptive pill,

vaginal ring or contraceptive patch) You can start taking Marvelon the day after you take the last tablet from your previous Pill strip (this means no tablet-free break). If your previous Pill pack also contains inactive tablets you must start Marvelon on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your previous Pill (or the day after the last inactive tablet of your previous Pill

If you are changing from a vaginal ring or contraceptive patch, you can start using Marvelon on the day you remove the ring or the last patch. You can also start Marvelon later, but at the latest 7 days after removing the ring or the last patch.

If you have used the Pill, patch or ring consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the Pill on any day and start using Marvelon immediately. If you follow these instructions, it is not necessary to use an additional contraceptive method (e.g. a condom)

• When changing from a progesterone-only pill (minipill). You can switch to Marvelon from one day to the next, but you must also use an additional contraceptive method (e.g. a condom) for the first 7 days that you are taking Marvelon.

• When changing from a progestogen-only injectable, implant or a hormonal intrauterine device (IUD).

Start using Marvelon when your next injection is due or on the day that your implant or hormonal IUD is removed. However, you must also use an additional contraceptive method (e.g. a condom) for the first 7 days that you are taking Marvelon.

• After having a baby.

If you have just had a baby, your doctor will probably advise you to wait until after your first normal period before you start taking Marvelon. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breastfeeding and want to take Marvelon, you should talk to your doctor first.

• After a miscarriage or an abortion.

### Your doctor will advise you.

If you take too many Marvelon tablets (overdose) There have been no reports of serious harmful effects from taking too many Marvelon tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken Marvelon, ask your

### doctor for advice What to do if...

... you forget tablets If you are less than 12 hours late in taking a tablet, the reliability of the Pill is maintained. Take the tablet as soon as

you remember and take the next tablets at the usual times If you are more than 12 hours late in taking any tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. The risk of becoming pregnant is highest if tablets are missed at the beginning or

Therefore you should follow the rules given below (see also the diagram below) More than one tablet forgotten in a strip

Ask your doctor for advice 1 tablet missed in week 1

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Use extra contraceptive precautions for the next 7 days. If you had sexual intercourse in the week before missing the tablets, it's possible that you could be pregnant. So tell vour doctor immediately

#### 1 tablet missed in week 2 Take the missed tablet as soon as you remember (even if this

means taking two tablets at the same time) and take the next tablets at the usual time. The reliability of the Pill is maintained. You need not use extra contraceptive precautions. 1 tablet missed in week 3

You may choose either of the following two options, without the

need for extra contraceptive precautions. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Also skip the tablet-free break, starting the next strip as soon as the current strip is finished. You will probably not have a withdrawal bleed until the end of the second strip but you may have spotting or breakthrough bleeding on tablet-taking days.

Stop taking tablets from your current strip, have a tablet-free break of 7 days or less (always include the day you missed your tablet) and then start the next strip. If you do this, you can always start your next strip on the same day of the week as you usually do. If you have forgotten tablets in a strip and you do not have

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 'When should you not take this medicine or should you be extra careful?

If you are allergic to one of the ingredients of Marvelon, you may get one of the following symptoms: angio-oedema (swollen face, tongue and/or throat and/or difficulty swallowing) or hives in combination with difficulty breathing. If you experience these symptoms, stop using Marvelon and contact your doctor immediately.

As with all combined oral contraceptives, changes in vaginal bleeding patterns may occur, especially during the first months of use. These may include changes in bleeding frequency (absent, less frequent, more frequent or continuous), intensity or duration.

Common (occurring in more than one per 100 women):

depressed mood, mood changes headache

breast tenderness, breast pain increase in body weight

nausea, abdominal pain

Uncommon (occurring in less than one per 100 women):

fluid retention

decreased sexual drive migraine

vomiting, diarrhoea

rash, hives breast enlargement

Rare (occurring in less than one per 1000 women): • harmful blood clots in a vein or artery, for example:

in a leg or foot (i.e. DVT) in a lung (i.e. PÈ) heart attack

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.) hypersensitivity reactions

increased sexual drive

contact lens intolerance erythema nodosum (painful bluish-red bumps in the skin), erythema multiforme (rash with irregular red blotches or sores) breast secretion, changes in vaginal secretion

#### 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.

order to protect from light and moisture.

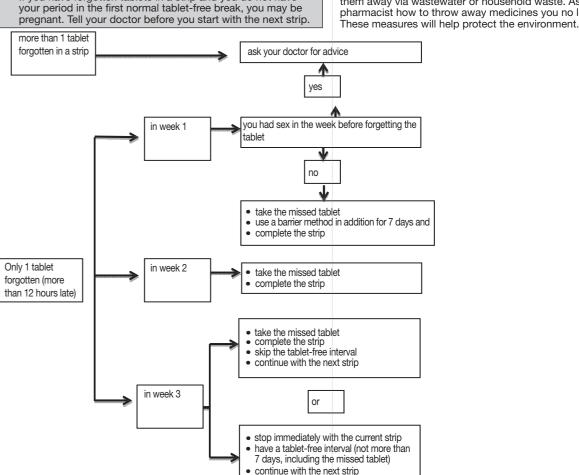
decrease in body weight

5. How to store this drug? Keep this medicine out of the sight and reach of children. Do not use this medicine after the date which is stated on the carton and blister strip after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30 °C, Store in the original blister strip in

Do not use this medicine if you notice, for example, a colour change in the tablet, crumbling of the tablet or any other visible signs of deterioration. Do not flush medicines down the toilet or do not throw them away via wastewater or household waste. Ask your

pharmacist how to throw away medicines you no longer use.



# ... you suffer from gastro-intestinal disturbances (e.g., vomiting, severe diarrhoea)

If you vomit, or have severe diarrhoea, the active ingredients of your Marvelon tablet may not have been completely absorbed into your body. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet, and you must follow the above advice for nissed tablets. If you have severe diarrhoea, please tell your doctor. you want to delay your period

It is possible to delay your period, although this is not advised.

new Marvelon strip without having a tablet-free interval. You can

In exceptional cases, you can delay your period by starting a

continue with this strip until you have taken all of the tablets, or you can stop earlier if you wish. While using the second strip, you may have breakthrough bleeding or spotting. After the usual 7-day tablet-free interval, start with the next strip you want to change the starting day of your period you take your tablets correctly, your period will start on about the same day each time. If you want to change this day, you can shorten (but never lengthen) the next tablet-free interval between the two strips. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier),

bleeding or spotting while using the next strip. vou have unexpected bleeding

With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (after about 3 strips). If bleeding continues, becomes heavy or starts again, tell your doctor. . you have missed a period

If you have taken all of your tablets at the right time, and you have

not vomited and/or had diarrhoea or used other medicines, then it

is very unlikely that you are pregnant. Carry on with the next strip.

However, if you miss your period twice in a row, you may be

start your next strip 3 days earlier than you usually do. If you

nake your tablet-free break very short (e.g. 3 days or less), you

may not bleed during the break. You may have some breakthrough

pregnant. Tell your doctor immediately. Do not start the next strip of Marvelon until your doctor has confirmed that you are not pregnant.

If you want to stop taking Marvelon You can stop taking Marvelon at any time you want. If you do not want to become pregnant, ask your doctor about other reliable

If you stop taking Marvelon because you want to get pregnant it is generally advisable to wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

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 Marvelon, please talk to your doctor.

6. Contents of the pack and other information

What Marvelon contains

Batch Releaser

ethinylestradiol (30 microgram).

Marketing Authorisation Holder:

N.V. Organon, Oss, The Netherlands

The other ingredients are: all-rac-alpha-tocopherol, lactose monohydrate, potato starch, povidone silica colloidal anhydrous, stearic acid.

What Marvelon looks like and contents of the pack

Marvelon comes in 1, 3 or 6 blisterstrips of 21 tablets.

Not all pack sizes are marketed The tablets are white, round, biconvex and 6 mm in diameter. The tablets are marked on one side with 'TR' above '5' and 'Organon\*' on the reverse side

Marketing Authorisation Holder, Bulk Manufacturer and

The active substances are desogestrel (150 microgram) and

N.V. Organon, Oss, The Netherlands **Bulk Manufacturer and Batch Releaser:** 

This package leaflet was last revised in June2017. (THIS IS A MEDICAMENT) Medicament is a product which affects your health,

and its consumption contrary to instructions is dangerous

for you.
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the The doctor and the pharmacist are experts in medicine, its benefits and risks.

Do not by yourself interrupt the period of treatment prescribed for you. Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists

