

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

### **Marvelon® 28 tablets** desogestrel/ethinylestradiol

#### **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”).

#### **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/midwife or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor/midwife, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Marvelon 28 is and what it is used for
2. What you need to know before you use Marvelon 28
3. How to use Marvelon 28
4. Possible side effects
5. How to store Marvelon 28
6. Contents of the pack and other information

### **1. What Marvelon 28 is and what it is used for**

#### **Composition and type of pill**

Marvelon 28 is a combined oral contraceptive. Each large tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). The small tablets do not contain hormones and are called placebo tablets. Because of the small amounts of hormones, Marvelon 28 is considered a low-dose oral contraceptive. As all active tablets in the pack combine the same hormones in the same dose, it is considered a monophasic combined oral contraceptive.

#### **Why use Marvelon 28?**

Marvelon 28 is used to prevent unwanted pregnancy.

When taken correctly, the chance of becoming pregnant is very low.

Marvelon 28 prevents the egg from ripening and influences the lining of the womb so that the growth of a fertilised egg is prevented. The passage of the sperms to the womb is also influenced. The effect remains during the 7 day placebo tablet interval. The ovaries regain their normal function after stopping treatment and it is possible to become pregnant again.

The Desogestrel/Ethinylestradiol in Marvelon 28 may also be approved for treatment of other conditions not mentioned in this product information. Ask your doctor, pharmacy or other health care professional if you have further questions and always follow their instructions.

## 2. What you need to know before you use Marvelon 28

### *General notes*

Before you start using Marvelon 28 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”.

In this leaflet several situations are described when you should stop using Marvelon 28, or when the reliability of the Pill may be lowered. In these situations you should not have intercourse or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use safe periods or temperature methods. These are unreliable because Marvelon 28 influences the normal changes in temperature and in the vaginal secrete during the menstruation cycle.

**Please note that Marvelon 28, like other oral contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.**

When you are using the Pill, your doctor/midwife will tell you to return for regular check-ups. You should usually have a check-up every year.

### **Do not use Marvelon 28:**

You should not use Marvelon 28 if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor/midwife. Your doctor/midwife will discuss with you what other form of birth control would be more appropriate.

- if you have (or have ever had) a blood clot in blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus) or any 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 a surgery or if you are off your feet for a long time (see section ‘Blood clots’).
- if you have ever had a heart attack or a 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 had pancreatitis (inflammation of the pancreas) in combination with high levels of lipids in the blood.
- if you have or have had severe liver disease and your liver is not yet working normally.
- if you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- if you have or have had a liver tumor.
- if you have unexplained vaginal bleeding.
- if you have endometrial hyperplasia (abnormal growth of the lining of the womb).
- if you are allergic (hypersensitive) to desogestrel, ethinylestradiol or any of the other ingredients of Marvelon 28.
- if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir / pibrentasvir (see also section “Other medicines and Marvelon 28”).

If you have any of the conditions above, or if any of them should appear for the first time while you are using Marvelon 28, the treatment should be stopped and you should contact your doctor/midwife.

In the meanwhile you should use a non-hormonal contraceptive, e.g. condom. See also the section "General notes".

### Warnings and precautions

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 clot' (thrombosis) section below).

For a description of the symptoms of these serious side effects please go to "How to recognize a blood clot".

Marvelon 28 should normally not be used to delay a period. However, if in exceptional cases you need to delay a period, contact your doctor/midwife.

#### *What you need to know before using Marvelon 28*

If the combined Pill is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor/midwife can explain this to you. Therefore, if any of these apply to you, tell your doctor/midwife before starting to use Marvelon 28.

#### **Tell your doctor/midwife if any of the following conditions apply to you.**

If the condition develops, or gets worse while you are using Marvelon 28, you should also tell your doctor/midwife.

- if you smoke
- if you have diabetes
- if you are overweight
- if you have high blood pressure
- if you have heart valve disorder or a certain heart rhythm disorder
- if anyone in your closest family have had thrombosis, myocardial infarction or stroke
- if you suffer from migraine
- if you suffer from epilepsy
- if you or someone in your closest family have or have had high lipid levels in the blood (cholesterol or triglycerides)
- if someone in your closest family have or have had breast cancer
- if you have a liver disease (e.g. jaundice) or gall bladder disease (e.g. gall stones)
- 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 uremic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys)
- if you have sickle cell anaemia (an inherited disease of the red blood cells)
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas)
- if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots')
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking Marvelon 28
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis)
- if you have varicose veins

- if you have a condition that appeared for the first time or got worse during pregnancy or previous use of sex hormones (e.g. hearing disturbance, a metabolic disease called porphyria, a skin disease called herpes gestationis or a neurological disease called Sydenham's chorea)
- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- if you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet light
- if you have had angioedema with symptoms of swelling of the face, tongue or throat, or difficulties to swallow or rash together with breathing difficulties.

### Blood clots

Using a combined hormonal contraceptive such as Marvelon 28 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 Marvelon 28 is small.**

### How to recognize a blood clot

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

Are you experiencing any of these signs?	What are you possibly suffering from?
<ul style="list-style-type: none"> <li>• swelling of one leg or along a vein in the leg or foot especially when accompanied by:                             <ul style="list-style-type: none"> <li>○ pain or tenderness in the leg which may be felt only when standing or walking</li> <li>○ increased warmth in the affected leg</li> <li>○ change in colour of the skin on the leg e.g. turning pale, red or blue</li> </ul> </li> </ul>	Deep vein thrombosis
<ul style="list-style-type: none"> <li>• sudden unexplained breathlessness or rapid breathing;</li> <li>• sudden cough without an obvious cause, which may bring up blood;</li> <li>• sharp chest pain which may increase with deep breathing;</li> <li>• severe light headedness or dizziness;</li> <li>• rapid or irregular heartbeat;</li> <li>• severe pain in your stomach;</li> </ul> <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> <li>• immediate loss of vision or</li> </ul>	Retinal vein thrombosis (blood clot in the eye)

<ul style="list-style-type: none"> <li>• painless blurring of vision which can progress to loss of vision</li> </ul>	
<ul style="list-style-type: none"> <li>• chest pain, discomfort, pressure, heaviness</li> <li>• sensation of squeezing or fullness in the chest, arm or below the breastbone;</li> <li>• fullness, indigestion or choking feeling;</li> <li>• upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li> <li>• sweating, nausea, vomiting or dizziness;</li> <li>• extreme weakness, anxiety, or shortness of breath;</li> <li>• rapid or irregular heartbeats</li> </ul>	Heart attack
<ul style="list-style-type: none"> <li>• sudden weakness or numbness of the face, arm or leg, 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>	Stroke
<ul style="list-style-type: none"> <li>• swelling and slight blue discolouration of an arm or a leg;</li> <li>• severe pain in your stomach (acute abdomen)</li> </ul>	Blood clots blocking other blood vessels

## Blood clots in a vein

### What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

### When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more

After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop Marvelon 28 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 Marvelon 28 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 Marvelon 28, 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 Marvelon 28	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 28 is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m<sup>2</sup>);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have a surgery, 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 28 may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Marvelon 28 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 Marvelon 28 needs to be stopped.

If any of the above conditions change while you are using Marvelon 28, 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 28 is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like Marvelon 28 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 Marvelon 28, 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.

### **The Pill and cancer**

Breast cancer has been found slightly more often in women who take oral contraceptives than in women of the same age who do not take oral contraceptives. This slight increase in the number of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

In rare cases benign liver tumours, and in even more rare cases malignant liver tumours, have been reported in users of the Pill. These tumours can lead to inner bleedings. Contact your doctor/midwife immediately if you get severe stomach pains.

Cervical cancer is caused by an infection with the human papilloma virus (HPV). It has been reported to occur more often 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).

### **Psychiatric disorders**

Some women using hormonal contraceptives including Marvelon 28 have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### **Children and adolescents**

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

### **Other medicines and Marvelon 28**

Always tell your doctor/midwife which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine or the pharmacist that you take Marvelon 28. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

Do not use Marvelon 28 if you have Hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir / pibrentasvir 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 28 can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Marvelon 28".

Some medicines

- can have an influence on the blood levels of Marvelon 28
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding

These include medicines for the treatment of:

- epilepsy (e.g. primidone, phenytoin, phenobarbital, carbamazepine, oxcarbamazepine, topiramate, felbamate)
- tuberculosis (e.g. rifampicin, rifabutin)
- HIV-infection (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 in the lungs (bosentan)
- depressive moods (the herbal remedy St. John's wort)

If you are taking medicines or herbal products that might make Marvelon 28 less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Marvelon 28 may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

Marvelon 28 may influence the effect of other medicines e.g.

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

#### *Laboratory tests*

If you are having any blood or urinary test you should inform your doctor or the laboratory personnel that you use an oral contraceptive since they may affect the results on certain tests.

### **Pregnancy and breast-feeding**

#### *Pregnancy*

Marvelon 28 must not be used by women who are pregnant or think they might be pregnant. If you suspect that you are pregnant while you are already using Marvelon 28 you should stop treatment and contact your doctor/midwife as soon as possible.

*Breast-feeding* Marvelon 28 is not usually recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please ask your doctor/midwife.

### **Driving and using machines**

There are no reasons to suspect that Marvelon 28 would influence the ability to drive a car.

### **Marvelon 28 contains lactose**

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

## **3. How to use Marvelon 28**

Always use Marvelon 28 according to the instructions from the doctor/midwife. Ask your doctor/midwife or pharmacist if you are uncertain.

Each pack contains 28 white tablets: 21 large tablets with the active substances (number 1-21) and 7 small tablets without active substances (number 22-28). Take your tablet at about the same time each day, with some liquid if necessary. Start on the first day of the cycle with the number 1 tablet in the left-hand top corner (marked "start"). Follow the direction of the arrow until all 28 tablets have been taken. Doing this, you use all the large tablets first, and then continue with the smaller placebo tablets.



A period should begin during the 7 days that you use the placebo tablets (the withdrawal bleed). Usually it will start on day 2-3 after the last large tablet. Start taking your next pack immediately after the last placebo tablet, even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days, each month. Sometimes, the withdrawal bleed can be absent. If you have taken the tablets according to the instructions, this does not necessarily mean that you are pregnant. Therefore, you should start with a new pack as usual.

It is important to take the Pill regularly as directed to get full protection.

### **Starting your first pack of Marvelon 28**

- *When no hormonal method has been used in the past month*  
Start with Marvelon 28 on the first day of your menstruation cycle, i.e. the first day of menstrual bleeding. Marvelon 28 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 to use an additional contraceptive method (barrier method, e.g. condom) for the first 7 days.
- *When changing from another combined hormonal contraceptive (combined oral contraceptives, vaginal ring, or transdermal patch)*  
You can start taking Marvelon 28 the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present Pill pack also contains hormone-free tablets (placebo) you can start Marvelon 28 on the day after taking the last **active** tablet (if you are not sure which this is, ask your doctor/midwife or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last inactive tablet of your present Pill). If you have used a vaginal ring or a patch you should preferably start with Marvelon 28 the day you take out the ring or remove the patch. You can also start, at the latest, on the day you would have started using the next ring or 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 or remove the ring or patch on any day and start using Marvelon 28 immediately. If you follow these instructions, it is not necessary to use an additional contraceptive method.
- *When changing from a progestogen-only pill (minipill)*  
You may stop taking the minipill any day and start taking Marvelon 28 the next day, at the same time. But if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method, e.g. condom) for the first 7 days that you are taking Marvelon 28.
- *When changing from injection, implant or progestogen releasing intrauterine device (IUD)*  
Start with Marvelon 28 the same day as the next injection should have been given or the day your implant or IUD is removed. But if you are having intercourse, make sure you also use an additional contraceptive method (barrier method, e.g. condom) for the first 7 days that you are taking Marvelon 28.
- *After having a baby*  
If you just have had a baby, your doctor/midwife will most likely tell you to wait until your first normal period before you start taking Marvelon 28. Sometimes it is possible to start sooner. Your doctor/midwife will give you advice. If you are breast-feeding and want to take Marvelon 28, you should talk to your doctor/midwife first.
- *After miscarriage or abortion*  
Your doctor/midwife will inform you about when you can start.

### **If you use more Marvelon 28 than you should**

If you have taken too much medicine, or if a child has taken the medicine by mistake, contact a doctor, hospital or Swedish Poison Institute (tel. 112) for judgment of the risks and advice.

There have been no reports of serious harmful effects from taking too many Marvelon 28 tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding.

### **If you forget to take Marvelon 28**

- If **less than 12 hours** have passed since you should have taken your tablet, you are still protected against pregnancy. Take the tablet as soon as you remember and take the next tablet on the usual time.
- If **more than 12 hours** have passed since you should have taken your tablet the effect against pregnancy may be reduced. The more tablets in a row you have missed, the higher the risk that the contraceptive efficacy is decreased. The risk of getting pregnant is especially high if you forget to take tablets in the beginning of the pack or in the third week (the week before you start taking the small tablets). Therefore you should always follow the instructions below (see also the diagram):

- **More than 1 tablet forgotten in a pack:**

Contact your doctor/midwife 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. Do not forget to use extra contraception (barrier method, e.g. condom) for the next seven days. If you have had intercourse the week before missing the tablets there is a risk that you have become pregnant. Therefore you should contact your doctor/midwife 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. Provided that you have taken the tablets correctly for the 7 days just before the forgotten tablet, the reliability of the Pill is maintained and you need not use any extra contraceptive precautions.

- **1 tablet forgotten in week 3:**

You may choose either of the following options, without the need for extra contraceptive precautions:

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. Take the following white active tablets at the usual time but skip the small white hormone-free tablets and start the next pack immediately. Most likely you will not have a withdrawal bleed until the end of the second pack but you may have irregular bleeding (spotting and breakthrough bleeding) on active tablet-taking days.

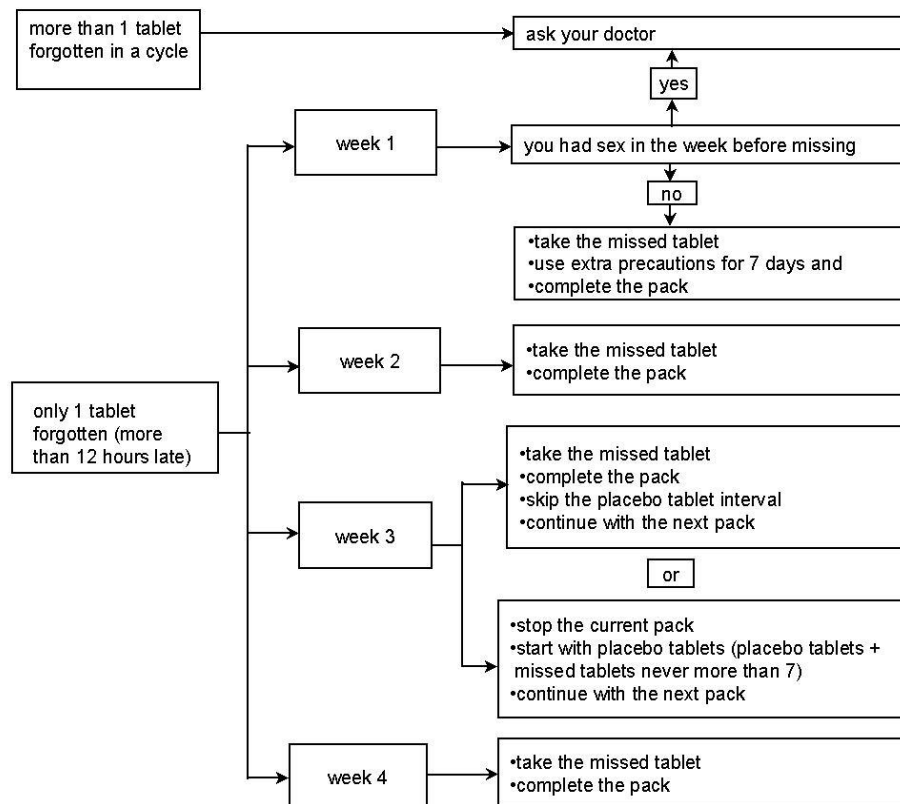
Or:

2. Stop taking the large (active) tablets from your current pack and immediately continue with the small placebo tablets for a maximum of 6 days (7 days including the day when you forgot to take the tablet). Then continue with the next pack as usual. When following this method, you can always start your next pack on the same day of the week as you usually do.

- **1 tablet forgotten in week 4:**

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 have missed taking tablets in a pack and you do not have the expected period in the first normal placebo tablet interval, you may be pregnant. If so you should contact your doctor/midwife before you start with the next pack.



### If you suffer from gastro-intestinal disturbances (vomiting and diarrhoea)

If you vomit or have severe diarrhoea the absorption of the hormones in the tablets may decrease and the protection against pregnancy may be reduced. In such situations you should take extra contraceptive precautions (non-hormonal, e.g. condom) for seven days. If you vomit within 3 - 4 hours after taking your tablet you must follow the advice for missed tablets.

### If you want to change the starting day

If you take your tablets correctly, you will have your period on about the same day every 4 weeks. If you want to change this day, just shorten (never lengthen) the next placebo tablet interval. For example, if your period usually starts on a Friday and in the future you want it to start on Tuesday (3 days earlier) start your next pack 3 days sooner than you usually do. If you make your placebo tablet interval very short (e.g. 3 days or less), you may not have a bleeding during the interval. You may have some irregular bleeding (spotting or breakthrough bleeding) during the use of the large tablets in the next pack.

### If you get an unexpected bleeding

During the first months you use oral contraceptives you can have irregular bleedings (breakthrough bleedings or spotting). You may need to use sanitary pads, but keep taking your tablets as usual. The irregular bleedings usually stops once your body has adjusted to the Pill (usually after about three months). Talk to your doctor/midwife if the irregular bleedings persist after three months, get worse or if irregular bleedings suddenly starts after three months.

### If you have missed a period

If you have taken all of your tablets at the right time, and you have not vomited or had severe diarrhoea and not used other medicines then you are very unlikely to be pregnant. Keep taking

Marvelon 28 as usual.

If you miss your period twice in a row, you may be pregnant. Contact your doctor/midwife immediately. Do not start with the next pack until a pregnancy has been ruled out.

#### **If you want to stop using Marvelon 28**

You can stop using Marvelon 28 at any time. If you do not want to become pregnant, ask your doctor/midwife about other methods for birth control.

If you stop taking Marvelon 28 because you want to get pregnant, you should wait until you have had a natural period before trying to conceive. This will make it easier for you to calculate the expected date of birth.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any side effects, particularly if severe and persistent, or have any change to your health that you think may be due to Marvelon 28, 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 Marvelon 28".

During the first months of treatment a large amount of the women (10-30 %) may experience side effects, for example breast tenderness, nausea or spotting. These side effects are often mild and usually disappear within 2-4 months. If the bleedings are troublesome you should contact your doctor/midwife. Tell your doctor/midwife if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the Pill.

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section 2 "What you need to know before you use Marvelon 28").

Serious reactions and symptoms seen with the Pill are described in the sections: "Blood clots/The Pill and cancer".

*Common (occurring in more than 1 per 100 users):*

- depressed mood, mood changes
- headache
- nausea, abdominal pain
- breast pain, breast tenderness
- increase in body weight
- vaginal bleedings

*Uncommon (occurring in more than 1 per 1000 users but not more than 1 per 100 users):*

- fluid retention
- decreased sexual drive
- migraine
- vomiting, diarrhoea
- skin redness, rash, hives
- breast enlargement
- absent withdrawal bleeding

- increase in blood pressure

*Rare (occurring in less than 1 per 1000 users):*

- hypersensitivity reactions
- increased sexual drive
- difficulties in wearing contact lenses, decreased tear flow
- erythema nodosum, erythema multiformae (a form of skin redness), chloasma (brown pigmentation of the skin), itching
- breast secretion, vaginal discharge
- decrease in body weight
- changes in liver function values, jaundice, gall stones, benign liver adenoma
- elevated blood glucose, decreased ability for the body to take care of glucose, increased insulin demand
- harmful blood clots in a vein or artery for example:
  - o in a leg or foot (i.e. DVT)
  - o in a lung (i.e. PE)
  - o heart attack
  - o stroke
  - o mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - o blood clots in the liver, stomach/intestine, kidneys or eye.

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

### **Reporting of side effects**

If you get any side effects, talk to your doctor/mid-wife or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the website [www.lakemedelsverket.se](http://www.lakemedelsverket.se). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Marvelon 28**

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

Do not store above 30°C.

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

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

## **6. Contents of the pack and other information**

### **What Marvelon 28 contains**

The active substances are:

in the large tablets: ethinylestradiol 30 µg and desogestrel 150 µg

in the smaller tablets: no active ingredients

The other ingredients are

in the large tablets: potato starch, silica anhydrous colloidal, lactose monohydrate, povidone, stearic acid, alpha-tocopherol

in the smaller tablets: lactose monohydrate, magnesium stearate, potato starch

**What the medicine looks like and content of the pack**

Marvelon 28 is available in packages of 1 and 3 blisters. Each blister contains 28 tablets (21 large and 7 smaller tablets).

The large (active) tablets are round, biconvex and 6 mm in diameter. On one side the tablet is marked TR5 and Organon and a five-pointed star on the reverse side.

The smaller hormone-free tablets are round, white and marked with KH2 on one side and a small square on the reverse side.

**Marketing Authorisation Holder**

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