

# Marvelon<sup>®</sup> 28

Desogestrel and ethinyloestradiol  
Tablets for oral use

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## What is in this leaflet

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**Please read this leaflet carefully before you start taking Marvelon 28.**

This leaflet answers some common questions about Marvelon 28. It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist, or professional health care provider.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Marvelon 28 against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor, pharmacist or health care provider.**

Keep this leaflet with the medicine. You may need to read it again.

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## What Marvelon 28 is taken for

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Marvelon 28 is a combined oral hormonal contraceptive, commonly known as a 'Birth Control Pill' or 'the Combined Pill' that has been prescribed to prevent you from getting pregnant.

Oral contraceptives are a very effective method of birth control. When taken correctly (without missing tablets) the chance of becoming pregnant is very low.

Marvelon 28 consists of 21 large white tablets, each containing 2 active ingredients: 30 micrograms of ethinyloestradiol (an oestrogen) and 150 micrograms of desogestrel (a progestogen) and 7 small white inactive tablets (first row of the strip).

Because of the small amounts of different female hormones in the active tablets, Marvelon 28 is considered a low-dose combined oral contraceptive.

Marvelon 28 prevents pregnancy in several ways:

- It inhibits the egg release by stopping it maturing;
- Changing the cervical mucus consistency making it difficult for sperm to reach the egg; and
- Changing the lining of the uterus making it less suitable for implantation.

The following non-contraceptive health benefits have been associated with the Combined Pill:

- Your periods may be lighter and shorter. As a result, the risk of anaemia may be lower. Your period pains may become less severe or may completely disappear.
- In addition, some serious disorders have been reported to occur less frequently in users of Combined Pills containing 50 micrograms of ethinyloestradiol ('high-dose Combined Pills'). These are: benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease), ectopic pregnancy (pregnancy in which the embryo implants

outside of the womb) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for low-dose Combined Pills but so far this has only been confirmed for endometrial and ovarian cancer.

Marvelon 28 is also used to treat mild to moderate acne.

Your doctor may have prescribed Marvelon 28 for another reason.

Ask your doctor if you have any questions about why Marvelon has been prescribed for you.

Marvelon 28 is available only with a doctor's prescription.

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## Before you take Marvelon 28

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### ***When you must not take it***

Do not take Marvelon 28 if:

#### **1. you are allergic to any of the ingredients found in Marvelon 28**

The ingredients found in Marvelon 28 are listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing, rash, itching or hives on the skin.

#### **2. you have or have had any of the conditions listed below:**

- a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), or other parts of the body. (See also the section later in this leaflet called '*The Combined Pill and Thrombosis*').
- a stroke (caused by a blood clot in or a rupture of a blood vessel in the brain).
- 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).
- a major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see section '*The Combined Pill and Thrombosis*')
- a history of migraine accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of your body.
- diabetes mellitus with blood vessel damage.
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- jaundice (yellowing of the skin) or severe liver disease and your liver is not working normally.
- a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- a benign or malignant liver tumour.
- any unexplained vaginal bleeding.
- a disturbance of blood clotting (for example, protein C deficiency).
- a serious risk factor, or several risk factors for developing thrombosis, this may also be a reason why you cannot use Marvelon 28 ( See also "The Combined Pill and Thrombosis" in the next section.

- a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a disease called porphyria, a skin disease called herpes gestationis, severe pruritus, a disease called Sydenham's chorea).
- Endometrial hyperplasia (a condition of excessive proliferation of the cells of the inner lining of the uterus).
- Hyperlipoproteinaemia (a condition of abnormal elevated levels of any or all lipids and/or lipoproteins in the blood).

Do not use Marvelon 28 if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin (see ***Taking other medicines***).

**3. you are pregnant or if you think you are pregnant.**

Pregnancy must be excluded before you start using Marvelon 28.

**If any of the above applies to you, or if you are not certain whether these may apply to you, tell your doctor before starting to take Marvelon 28. If any of the above appears for the first time while taking Marvelon 28, stop taking it at once and consult your doctor. Your doctor may advise you to use a different type of Combined Pill or an entirely different (non-hormonal) method of birth control. In the meantime, use non-hormonal contraceptive measures. See also 'General Notes' in the next section.**

**4. the expiry date (EXP) printed on the pack has passed.**

Marvelon 28 may have no effect at all, or worse, an entirely unexpected effect, if you take it after the expiry date.

**5. the packaging is torn or shows signs of tampering.**

If this is the case, take the tablets back to your pharmacist.

***Before you start to take it***

***General notes***

In this leaflet, several situations are described where you should stop taking Marvelon 28, or where the reliability of Marvelon 28 may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Marvelon 28 alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

**Marvelon 28, like all contraceptive Combined Pills, does not protect against HIV infection (AIDS) or any other sexually transmissible disease.**

If you are concerned about contracting a sexually transmissible disease, ask your doctor about adequate methods of protection.

**You should have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine check.**

**You must tell your doctor if:**

1. you are allergic to any foods, dyes, preservatives or any other medicines.
2. any of the following apply to you.

- you smoke;
- you are overweight;
- you have diabetes;
- you have or have had high blood pressure;
- you have a heart valve disorder or a certain rhythm disorder;
- heart or kidney function disorder;
- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you suffer from migraine;
- you suffer from epilepsy;
- you or someone in your immediate family have or have had high cholesterol or triglycerides (fats in the blood);
- anyone in your immediate family has had breast cancer;
- you have or have had depression;
- you have liver or gall bladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS; a disorder of blood clotting causing failure of the kidneys);
- you have sickle cell disease (a rare blood disease);
- you have an operation, or if your ability to move around is limited for a long period of time (see section 'The Combined Pill and Thrombosis');
- you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using Marvelon 28 (see section 'The Combined Pill and Thrombosis');
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly on the face) if so, avoid too much exposure to the sun or ultraviolet light;
- you have an intolerance to lactose.

**If any of the above applies to you, you may need to be kept under close observation.**

**Your doctor can explain this to you.** Tell your doctor if any of the above conditions appear for the first time, recur, or worsen while taking Marvelon 28.

### **The Combined Pill and Thrombosis**

A thrombosis is the formation of a blood clot which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Combined Pill. The risk is higher in Combined Pill-users than in non-users. The chance of getting a thrombosis is highest during the first year after you start using the Combined Pill for the very first time. The risk is also higher if you restart using the Pill (the same product or a different product) after a break of 4 weeks or more.

The risk is not as high as the risk of developing a thrombosis during pregnancy.

The risk of getting a deep venous thrombosis for women taking the Combined Pills with desogestrel may be slightly higher than for women taking the Combined Pill with levonorgestrel. The absolute numbers remain very small. If 10,000 women use a combined Pill with levonorgestrel for one year, 2 women would get a thrombosis. If 10,000 women take a Combined Pill with desogestrel for a year approximately 3 to 4 women would get a thrombosis. For comparison, if 10,000 women get pregnant, approximately 5-20 would get thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Combined Pills with desogestrel.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of venous thrombosis in people who take the Combined Pill increases:

- with increasing age;
- if you are overweight;
- if one of your close relatives has had a blood clot (thrombosis) in the leg, lung, or other organ at a young age;
- if you must have an operation, if your ability to move around is limited for long period of time, or if you have had a serious accident. It is important to tell your doctor in advance that you are taking Marvelon 28 as the treatment may have stopped. Your doctor will tell you when to start taking Marvelon 28 again. This is usually about two weeks after you are able to move around. See also section "When you must not take Marvelon 28".
- if you gave birth less than a few weeks ago.
- and possibly also with superficial thrombophlebitis (inflammation of a vein that occurs with blood clots).

The risk of arterial thrombosis in people who take the Combined Pill increases:

- with increasing age;
- **if you smoke; You are strongly advised to stop smoking when you take Marvelon 28, especially if you are older than 35 years of age;**
- if you have an increased fat content in your blood (cholesterol or triglycerides);
- if you have high blood pressure;
- if you have migraine;
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm);
- if one of your close relatives has had a blood clot (thrombosis) in an artery at a young age.

If you notice possible signs of a thrombosis, stop taking Marvelon 28 and consult your doctor immediately (see also 'While you are taking Marvelon 28?').

### **The Combined Pill and Cancer**

The information given below was obtained from studies of women who used combined oral hormonal contraceptives, such as the combined pill, and from an additional study that included both oral and non-oral hormonal contraceptive-users.

In studies with the combined Pill, breast cancer has been diagnosed slightly more often in women who take the Combined Pill than in women of the same age who do not take the Combined Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping taking the Pill.

In the additional study that included both oral and non-oral hormonal contraceptive-users, the occurrence of breast cancer was reported to increase the longer the women used the contraceptive. The difference in the reported risk of breast cancer between women who have never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 women-years.

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 was noticed earlier.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in people who take the Combined Pill. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer is caused by an infection with the Human Papilloma Virus. It has been reported to occur more often in women using the Combined 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).

### **The Combined Pill and Pregnancy**

Marvelon 28 must not be taken by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already taking Marvelon 28, you should consult your doctor as soon as possible.

### **The Combined Pill and Breastfeeding**

Marvelon 28 is generally not recommended during breastfeeding. If you wish to take Marvelon 28 while breastfeeding, please seek the advice of your doctor.

### **The Combined Pill and Driving and Using Machines**

There are no observed effects.

### ***Taking other medicines***

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use Marvelon 28. Some medicines may stop Marvelon 28 from working properly. These include medicines used for the treatment of:

- epilepsy (e.g. primidone, phenytoin, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate);
- tuberculosis (e.g. rifampicin)
- 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)

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 also affect how other medicines work, causing either an increase in effect (e.g., ciclosporin) or a decrease in effect (e.g., lamotrigine).

Do not use Marvelon 28 if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Marvelon 28 can be restarted approximately 2 weeks after completion of treatment with the combination drug regimen. (See **Before you take Marvelon 28 – When you must not take it**).

### Laboratory tests

If you are having any blood or urinary test, tell your health care professional that you are using Marvelon 28 as it may affect the results of some tests.

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## How to take Marvelon 28

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**For both contraception and treatment of acne, take Marvelon 28 exactly as your doctor has prescribed.**

**Follow all directions given to you by your doctor or pharmacist carefully.**

**They may differ from the information contained in this leaflet.**

**If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.**

### ***When and how to take the tablets***

The Marvelon 28 pack contains 28 white tablets: 21 large tablets with active substances and 7 small tablets that do not contain active substances. On a strip each tablet is marked with the day of the week on which it is to be taken. Take your tablet at about the same time each day, with some liquid if necessary. Follow the direction of the arrows until all 28 tablets have been taken. A period should begin during the 7 days that you take 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 small inactive 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.

This preparation has been prescribed for you personally and you should not pass it on to others. It may harm them.

If your doctor has prescribed Marvelon 28 for a purpose other than contraception, follow their directions closely, even if they are not the same as on the pack.

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

*When no hormonal contraceptive has been used in the past month.*

Start taking Marvelon 28 on the first day of your cycle, i.e. the first day of menstrual bleeding. Take a tablet from the green section marked with that day of the week. For example, if your period starts on a Friday, take a tablet marked Friday. Then follow the days in order. Marvelon 28 will work immediately, it is not necessary to use an additional contraceptive method.

You may also start on days 2–5 of your cycle, but in that case make sure you also use an additional contraceptive method (see *Additional Contraceptive Precautions* in this section) for the first 7 days of tablet-taking in the first cycle.

*When changing from another combined hormonal contraceptive (combined oral contraceptive pill (COC), vaginal ring, or transdermal patch)*

You can start taking Marvelon 28 the day after you take the last tablet from your present Combined Pill pack (this means no tablet-free break). If your present Combined Pill pack also contains inactive (placebo) tablets 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 or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Combined Pill (or the day after the last inactive tablet of your present Combined Pill). In case you use a vaginal ring or transdermal patch, you should start taking Marvelon 28 preferably on the day of removal, but at the latest when the next ring or patch would have been applied.

If you have used the Combined Pill, patch or ring consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the Combined 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 can stop taking the minipill any day and start taking Marvelon 28 the next day, at the same time. But make sure you also use an additional contraceptive method (see *Additional Contraceptive Precautions in this section*) for the first 7 days of tablet-taking,

*When changing from an injectable, an implant or a progestogen-releasing intrauterine device (IUD)*

Start taking Marvelon 28 when your next injection is due or on the day that your implant or your IUD is removed. But make sure you also use an additional contraceptive method (see *Additional Contraceptive Precautions* in this section) for the first 7 days of tablet-taking.

*After having a baby*

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking Marvelon 28. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take Marvelon 28, you should discuss this first with your doctor.

*After a miscarriage or an abortion*

Your doctor will advise you.



### *Additional contraceptive precautions*

When additional contraceptive precautions are required you should either abstain from vaginal sex, or use a barrier method of contraception, a condom or a cap (diaphragm) plus spermicide. Rhythm methods are not advised as the Combined Pill disrupts the cyclical changes associated with the natural menstrual cycle e.g. changes in temperature and cervical mucus.

### ***How long to take it***

**Your doctor will advise you on how long to take Marvelon 28.**

**If you are not sure how long you should be taking Marvelon 28, ask your doctor.**

### ***If you forget to take it***

- If you are **less than 12 hours late** in taking a tablet, the reliability of the Marvelon 28 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 Marvelon 28 may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss large (active) tablets at the beginning of the pack or in the third week (the week before you start taking the small tablets). Therefore you should follow the rules given below (see also the diagram below).

### **More than one tablet forgotten in a pack**

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 (see *Additional Contraceptive Precautions* in the previous section) for the next 7 days. If you had sexual intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. So tell your 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 Marvelon 28 is maintained. You need not use extra contraceptive precautions.

#### **1 tablet missed 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. Start the next pack as soon as the large (active) tablets in the current pack are finished, so **skip the smaller placebo**

**tablets.** You may not have a withdrawal bleed until you take the placebo tablets at the end of the second pack but you may have spotting or breakthrough bleeding on active tablet-taking days.

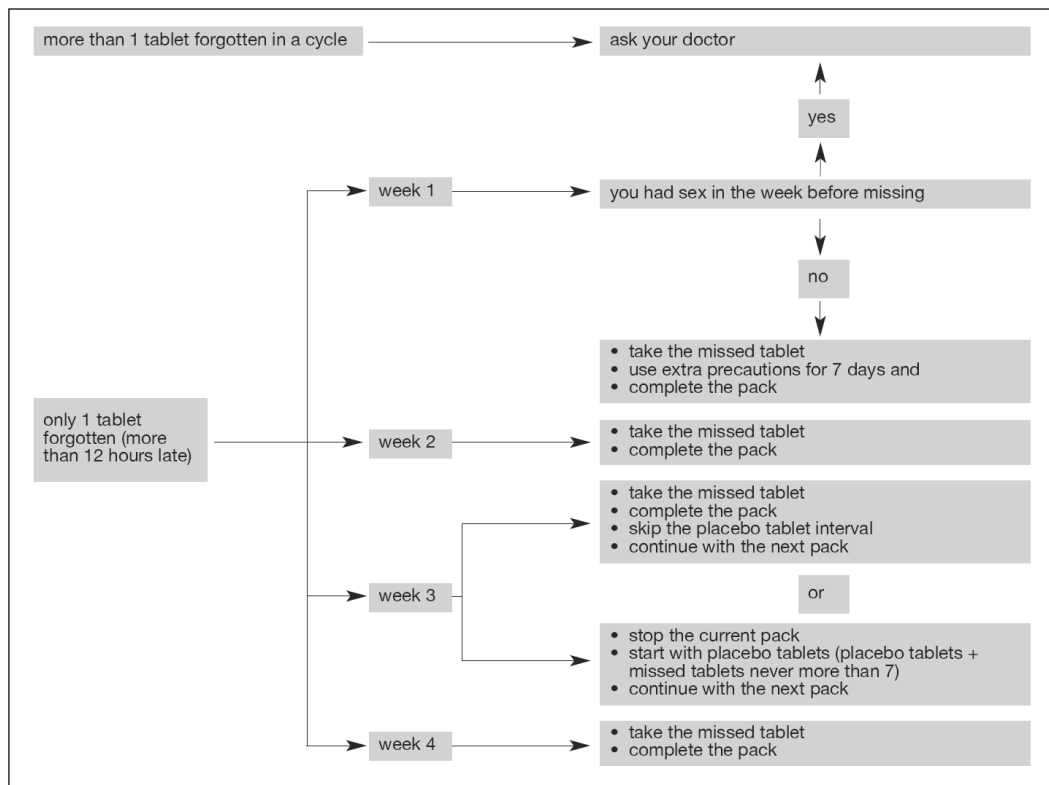
Or

2. Stop taking the large (active) tablets from your current pack and immediately continue with the smaller placebo tablets (**a maximum of 6 days, the total number of placebo plus missed tablets may not be more than 7**). Then continue with the next pack. When following this method, you can always start your next pack on the same day of the week as you usually do.

### 1 tablet missed in week 4

The reliability of Marvelon 28 is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.

If you have forgotten tablets in a pack and you do not have the expected period in the first normal placebo tablet interval, you may be pregnant. Consult your doctor before you start with the next pack.



### ***If you want to stop taking it***

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

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

**Ask your doctor or pharmacist for advice about taking folate if you plan to become pregnant.**

***If you want to delay your period***

You can delay your period if you continue with the large (active) tablets in your next pack of Marvelon 28 immediately after finishing the large tablets in your current pack. You can continue with this pack for as long as you wish, until this pack is empty. When you wish your period to begin, just stop tablet-taking. While using the second pack you may have some breakthrough bleeding or spotting on active tablet-taking days. Start with your next pack after the usual 7-day placebo tablet interval.

***If you want to change the starting day of your period***

If you take your tablets as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten, (never lengthen) the next placebo tablet interval. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should now 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 breakthrough bleeding or spotting during the use of the large tablets in the next pack.

***If you have unexpected bleeding***

With all Combined 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 continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Combined Pill (usually after about 3 tablet-taking cycles). Tell your doctor if it continues, becomes heavy or starts again.

***If you have missed a period***

If you have taken all of your tablets at the right time, and you have not vomited, or 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. Tell your doctor immediately. Do not start the next pack of Marvelon 28 until your doctor has checked you are not pregnant.

***If you suffer from gastro-intestinal disturbances, such as vomiting or severe diarrhoea***

If you vomit, or have severe diarrhoea, the active ingredients of your Marvelon 28 tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. Therefore, follow the advice for missed tablets. Tell your doctor if you have severe diarrhoea.

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**While you are taking Marvelon 28**

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***Things you must do***

**Tell all doctors, dentists and pharmacists who are treating you that you are taking Marvelon 28.**

**If you are about to start taking any new medicines, tell the doctor or pharmacist**

**If you become pregnant while taking Marvelon 28, see your doctor immediately.**

**Have regular check-ups from your doctor including a Pap smear. You should usually have a check-up once a year.**

**Perform regular breast self-examination**

**Contact your doctor as soon as possible if:**

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see *Before you use Marvelon 28*). Do not forget about changes in the health of your immediate family;
- you feel a lump in your breast;
- you experience symptoms of angioedema (swelling, similar to hives) 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;
- your ability to move around is limited for a long period of time or you are to have surgery (tell your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot tablets in the first week of the pack and had intercourse in the seven days before;
- you suffer from depression;
- you have severe diarrhoea;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until your doctor tells you to).

### ***Things you must not do***

**Do not give Marvelon 28 to anyone else, even if they have the same condition as you.**

**Do not take Marvelon 28 for any other purpose unless your doctor tells you to.**

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## **In case of overdose**

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### ***If you take too much (overdose)***

**Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Marvelon 28. Do this even if there are no signs of discomfort or poisoning.**

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.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Marvelon 28.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

### ***Serious side effects***

Serious reactions associated with the use of the Combined Pill, as well as the related symptoms, are described in the following sections: 'The Combined Pill and Thrombosis and The Combined Pill and Cancer'. Please read these sections for additional information and consult your doctor at once where appropriate.

Stop taking Marvelon 28 and tell your doctor immediately, or go to accident and emergency at your nearest hospital, if you notice signs of any of the following:

- thrombosis:
  - an unusual cough;
  - severe pain in the chest which may reach the left arm;
  - breathlessness;
  - any unusual, severe, or prolonged headache or migraine attack;
  - partial or complete loss of vision, or double vision;
  - slurring or speech disability;
  - sudden changes to your hearing, sense of smell, or taste;
  - dizziness or fainting;
  - weakness or numbness in any part of your body;
  - severe pain in your abdomen;
  - severe pain or swelling in either of your legs;
- liver disease including liver cancer (jaundice or a yellowing of the eyes or skin).

### ***Other possible side effects***

The following side effects have been reported by users of the Combined Pill, although they need not be caused by the Combined Pill. These side effects may occur in the first few months that you are taking Marvelon 28 and usually lessen with time. Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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

- depressed mood, mood changes;
- headache;

- nausea, abdominal pain;
- breast pain, breast tenderness;
- increase in body weight;

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

- fluid retention;
- decreased sexual drive;
- migraine;
- vomiting, diarrhoea;
- rash, hives;
- breast enlargement

Rare (occurring in less than one per 1000 users):

- hypersensitivity reactions;
- blood clot in a vein
- blood clot in an artery
- increased sexual drive;
- contact lens intolerance;
- breast secretion, vaginal secretion;
- decrease in body weight;
- erythema nodosum, erythema multiforme (these are skin conditions)

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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## After taking Marvelon 28

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### ***Storage***

**Do not use after the expiry date stated on the strip and outer box.**

**Store your tablets at or below 25°C in a dry place and protect them from light.**

**Do not store Marvelon 28 or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.**

Heat and dampness can destroy some medicines.

**Do not take the product if you notice, for example, colour change in the tablet, crumbling of the tablet or any other visible signs of deterioration.**

**Keep your tablets out of the reach of children.**

A locked cupboard at least 1.5 metres above the ground is a good place to store medicines.

### ***Disposal***

If your doctor tells you to stop taking Marvelon 28 or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

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## Product Description

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### ***What it looks like***

Marvelon 28 tablets are packed in push-through strips made of PVC/aluminium, which is packed in an aluminium laminated sachet. The sachet is packed in a printed cardboard box together with a package leaflet.

Each strip contains 28 tablets:

- 21 large white active tablets coded 'TR/5' and 'Organon' and a star on the other side;
- 7 smaller white inactive tablets coded 'KH/2' on one side and a square on the other side.

Each pack contains 1 or 3 strips of tablets.

### ***Ingredients***

#### Large tablets

##### *Active ingredients:*

- ethinyloestradiol 30 micrograms;
- desogestrel 150 micrograms

##### *Inactive ingredients:*

- silica colloidal anhydrous;
- lactose monohydrate;
- potato starch;
- povidone;
- stearic acid;
- alpha-tocopherol

#### Small tablets

No active ingredients

##### *Inactive ingredients*

- lactose monohydrate;
- potato starch;
- magnesium stearate

This medicine contains lactose. Tell your doctor if you have an intolerance to lactose.

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## **Sponsor Details**

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Marvelon 28 is supplied in New Zealand by:

Organon New Zealand Limited

P O Box 99 851

Newmarket

Auckland 1149

New Zealand

Tel: 0800 111 700

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## **Date of Preparation**

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This leaflet was last revised in 1 December 2020

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