

MARVELON®

Ethinylestradiol/Desogestrel (0.030mg/0.150mg)

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What MARVELON is used for

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 oral contraceptive. As all tablets in the pack combine the same hormones in the same dose, it is considered a monophasic combined oral contraceptive.

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

How MARVELON works

MARVELON releases two female sex hormones that prevents the release of an egg cell from the ovaries. If no egg is released you cannot become pregnant.

Before you take MARVELON

- When you must not use it

Do not use the MARVELON if you have any of the conditions listed below. If anything on this list applies to you, tell your doctor before starting to use MARVELON. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- If you have, or have had in the past a blood clot (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs.
- If you have or have had in the past a heart attack or stroke.

- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have a disturbance of blood clotting (for example, protein C deficiency).
- If you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see '**The Pill and Thrombosis**').
- If you have (had) a type of migraine called 'migraine with aura'.
- If you have diabetes mellitus with blood vessel damage.
- If you have a serious risk factor, or several risk factors for developing thrombosis, this may also be a reason why you cannot use MARVELON (See also '**The Pill and Thrombosis**').
- If you have or have had a pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- If you have jaundice (yellowing of the skin) 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 tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are allergic to any of the ingredients of MARVELON.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also "Things to be careful of".

Do not use Marvelon if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with

or without dasabuvir (see section "Taking other medicines").

-Before you start to take it

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 can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use MARVELON.

- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you have a heart valve disorder or a certain heart rhythm 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 liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE; a chronic connective tissue 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 '**The Pill and Thrombosis**');
- if 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 (see '**The Pill and Thrombosis**');

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- 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, a disease called porphyria, a skin disease called herpes gestationis, a disease called Sydenham's chorea); hereditary and acquired angioedema [*you should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives, potentially with difficulty breathing*]. Products containing estrogens may cause or worsen hereditary and acquired angioedema.
- 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 any of the above conditions appear for the first time, come back or get worse while using the Pill, you should contact your doctor.

The 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 Pill. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis is highest during the first year after you start using the 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 using Pills with desogestrel may be slightly higher than for women using Pills with levonorgestrel. The absolute numbers remain very small. If 10 000 women use a Pill with levonorgestrel for one year, 2 women would get a thrombosis. If 10 000 women use a 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 a thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Pills with desogestrel.

Blood clots can also occur very rarely in an artery (arterial thrombosis); for example 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 users of combined pills 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 using MARVELON as the treatment may have to be stopped. Your doctor will tell you when to start MARVELON again. This is usually about two weeks after you are able to move around. See also "When you must not use it".
- If you gave birth less than a few weeks ago.

The risk of arterial thrombosis in users of combined pills increases:

- **if you smoke. You are strongly advised to stop smoking when you use MARVELON, especially if**

you are older than 35 years.

- 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 you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately (See also '**When should you contact your doctor?**').

The 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 use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers 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 was noticed earlier.

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 had never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 women-years.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the 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

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virus. 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).

The Pill and Pregnancy

MARVELON must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using MARVELON, you should tell your doctor as soon as possible.

The Pill and Breast-feeding

MARVELON is not usually recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please ask your doctor.

The Pill and Driving and Using machines

There are no observed effects.

Important information about some of the ingredients of MARVELON

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

More about hormonal contraceptives

The combined Pill may also have non-contraceptive health benefits.

- Your period 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 Pills containing 50 µg of ethinylestradiol ('high-dose Pills'). These are benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease or PID), ectopic pregnancy (pregnancy in which the embryo implants outside of the uterus) and cancer of the endometrium (lining of the womb) and ovaries. This may

also be the case for low-dose Pills but this has not been confirmed.

- *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.

Some medicines may stop Marvelon 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 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 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 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.

Marvelon may also interfere with 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 if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir as this may cause increases in liver function blood

test results (increase in ALT liver enzyme). Marvelon can be restarted approximately 2 weeks after

completion of treatment with the combination drug regimen (See "Before you take MARVELON")

If you are taking other Hepatitis C drug combinations (such as glecaprevir/pibrentasvir) you may experience increased levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood.

Laboratory tests

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

How to take MARVELON

- How much to take, When to take it, How long to take it

The MARVELON pack contains 21 tablets. On the pack, 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 21 tablets have been taken. During the next 7 days you take no tablets. A period 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 pack on the 8th day 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.

Starting your first pack of MARVELON

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

Start taking MARVELON on the first day of your cycle, i.e. the first day of menstrual bleeding. Take a tablet 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 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 if you do, make sure

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you also use an additional contraceptive method (barrier method) 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 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 inactive tablets you can 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 present Pill (or the day after the last inactive tablet of your present Pill). In case you use a vaginal ring or transdermal patch, it is best to start using MARVELON on the day you remove the ring or 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 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 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) for the first 7 days that you are taking MARVELON.

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

Start using MARVELON when your next injection is due or on the day that your implant or IUD is removed. But

if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking MARVELON.

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. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding 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 forget to use it*

- 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. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning or at the end of the pack. 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 (barrier method) 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 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 the Pill 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 current pack is finished so that **no gap is left between packs**. You may not have a withdrawal bleed until the end of the second pack but you may have spotting or breakthrough bleeding on tablet taking days.

Or

2. Stop taking tablets from your current pack, have a tablet-free break of 7 days or less (**including the day you missed your tablet**) and then start the next pack.

- If you do this, you can always start your next pack on the same day of the week as you usually do.
- If you have forgotten tablets in a

- *If you use too much (overdose)*

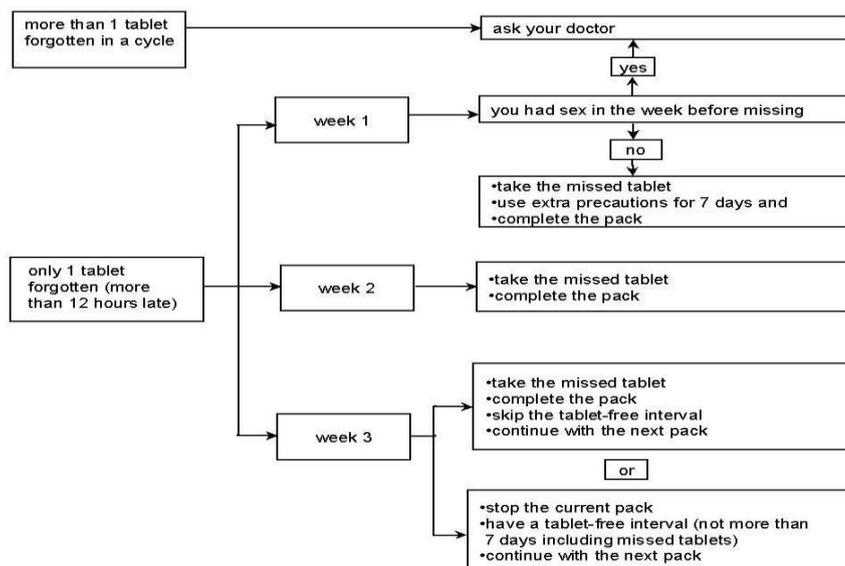
There have been no reports of serious harmful effects from taking too many MARVELON tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken MARVELON, ask your doctor for advice.

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 methods of birth control. If you stop taking MARVELON because you want to get pregnant, you should wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

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**What to do if...****... 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. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. You must follow the advice for missed tablets. If you have severe diarrhoea, please tell your doctor.

...you want to delay your period

You can delay your period if you start with your next pack of MARVELON immediately after finishing 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 tablet-taking days. Start with your next pack after the usual 7-day tablet-free break.

... you want to change the starting day of your period

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 tablet-free break. For example, if your period usually starts on a Friday and in 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 tablet-free break very short (e.g. 3 days or less), you may not bleed during the break. You may have some breakthrough bleeding or spotting while using the next pack.

... you 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 (usually after about 3 months). 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, or used other medicines then you are very unlikely to be pregnant. Keep taking MARVELON 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 until your doctor has checked you are not pregnant.

While you are using MARVELON - Things you must do**When should you contact your doctor?****Regular check-ups**

When you are using the Pill, your doctor will tell you to return for

regular check-ups. You should usually have a check-up every year.

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 also section '**When you must not use it**' and '**Before you start to take it**'); do not forget about changes in the health of your immediate family);
- 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 potentially with difficulty breathing (see also section '**Before you start to take it**');
- you are going to use other medicines (see also section '**Taking 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 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).

Stop taking tablets and see your doctor immediately if you notice possible signs of 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.

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'The Pill and Thrombosis'

- Things you must not do

MARVELON has been prescribed for you personally. Do not share it with others.

- Things to be careful of

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 temperature and cervical mucus that occur during the menstrual cycle.

MARVELON, like all contraceptive Pills, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Side effects

Like all medicines, MARVELON can have side effects, although not everybody gets them.

Tell your doctor 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.

Serious reactions seen with the Pill, as well as the related symptoms, are described in the sections 'The Pill and Thrombosis' and 'The Pill and Cancer'.

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
- erythema nodosum, erythema multiforme (these are skin conditions)
- breast secretion, vaginal secretion
- decrease in body weight.

Unknown (frequency cannot be estimated from the available data):

- angioedema, particularly in patients who already have a (family) history of angioedema.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of MARVELON

- Storage

- Do not use MARVELON after the expiry date stated on the package.
- Store your tablets below 30°C in the original package. Do not freeze.
- Store protected from light and moisture.
- Do not use the product if you notice, for example, color change in the tablet, crumbling of the tablet or any other visible signs of deterioration.
- **Keep MARVELON out of reach and sight of children!**

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

MARVELON comes in 1, 3 or 6 strips of 21 tablets packed in a ply carton. The tablets are biconvex, round and 6 mm in diameter. Each tablet is marked TR above 5 on one side and Organon on the reverse side.

Not all pack sizes are marketed.

- Ingredients

- Active ingredients
The active substances are: ethinylestradiol (0.030 mg) and desogestrel (0.150 mg)
- Inactive ingredients
The other ingredients are: silica colloidal anhydrous; lactose monohydrate; potato starch; povidone; stearic acid; all-*rac*- α -tocopherol.

- MAL number:

MAL19872093AZ

Manufacturer

N.V. Organon, Oss, The Netherlands

Product Registration Holder

Organon Malaysia Sdn. Bhd.
39W022, Mercu 2,
No.3, Jalan Bangsar,
KL Eco City,
59200 Kuala Lumpur,
Malaysia

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