

Desolon®

Composition : Each Tablet contains 0.15mg desogestrel BP & 0.03mg ethinyl estradiol BP.
USER PACKAGE LEAFLET

Please read this leaflet carefully before you start using Desolon®. This leaflet will provide information about the benefits and risks of using oral contraceptives. It will also advise you about how to take Desolon® properly and when to tell your doctor about health-related conditions.

WHAT IS DESOLON®?

Composition and type of Pill

Desolon® is a combined oral contraceptive. 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, Desolon® is considered a low-dose oral contraceptive.

Why to use Desolon®?

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

WHEN SHOULD YOU NOT USE DESOLON®

Do not use the combined Pill if you have any of the conditions listed below. If any of these apply to you tell your doctor before starting to use Desolon®. 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 ever had a disorder affecting the blood circulation. In particular, those conditions relating to thrombosis. Thrombosis is the formation of a blood clot. This may occur in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), the brain (stroke), or other parts of the body.
- 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 diabetes mellitus with blood vessel damage.
- If you have jaundice (yellowing of the skin) or severe liver disease.
- If you have or have had cancer of the breast or the genital organs.
- If you have or have had a benign or malignant tumour in the liver.
- 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 Desolon®.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures. See also General Notes

WHAT DO YOU NEED TO KNOW BEFORE USING DESOLON®

General Note

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 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 the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

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

Before you start to use Desolon®

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

- 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.
 - anyone in your immediate family have or had high blood levels of cholesterol or triglycerides (fatty substances);
 - 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 disease affecting the skin all over the body);
 - you have hemolytic uraemic syndrome (HUS); a disorder of blood coagulation causing failure of the kidneys);
 - you have sickle cell disease;
 - you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face);
- If so, avoid to much exposure to the sun or ultraviolet radiation.

If any of the above conditions appear for the first time recur or worsen while using the Pill, you should contact your doctor.

The Pill and other Medicines

Some medicines may stop the Pill from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenyto, barbiturates), and tuberculosis (eg. rifampicin); and antibiotics (e.g. ampicillin, tetracyclines griseofulvin); for some other infectious diseases. Always tell the doctor, who prescribes the Pill, which medicines you are already using. Also tell other doctor dentist who prescribes another medicines (or the dispensing pharmacist) that you use Desolon®. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

The Pill and Breastfeeding

Desolon® is generally not recommended for use during breast feeding. If you wish to take the Pill while breastfeeding, please seek the advice of your doctor.

The Pill and Pregnancy

Desolon® must not be used by women who are pregnant, or who think they may be pregnant.

The Pill and Ability to Drive

There are no observed effects.

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. In general, you should have a check-up every year. Contact your doctor as soon as possible if:

- you notice any change in your own health, especially involving any of the items mentioned in this leaflet (see also when should you not use Desolon®; do not forget about the items related to your immediate family).
- you feel a lump in your breast;
- you are going to use other medications (see also The Pill and Other Medicines).

- you are to be immobilised or are to have surgery (consult 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 miss your period twice in a row or suspect you are pregnant (do not start the next pack until told by your doctor).

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.

The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.

HOW DO YOU USE DESOLON®?

When and how to take the tablets?

The Desolon® 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 water 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 Desolon® 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 Desolon®

- When no hormonal contraceptive has been used in the past month. Start taking Desolon® 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. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.

- When changing form another combined Pill.

You can start taking Desolon® the day after you have 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 Desolon® on the day after taking the fast 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).

- When changing from progestogen-only Pill (minipill).

You can stop taking the minipill any day and start taking Desolon® the next day, at the same time. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking when having intercourse.

- When changing from an injectable or implant.

Start using Desolon® when your next injection is due or on the day that your implant is removed. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking when having intercourse.

- 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 Desolon®. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take Desolon® you should discuss this first with your doctor.

- After a miscarriage or an abortion.

Your doctor will advise you.

If too many Desolon® tablets are taken (overdose)

There have been no reports of serious harmful effects from taking too many Desolon® 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 Desolon® ask your doctor for advice.

When you want to stop taking Desolon®

You can stop taking Desolon® 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 Desolon® 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.

WHAT TO DO IF

.....you forget tablets

- If you are less than 12 hours late in taking a tablet, the reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.
- If you are more than 12 hours late in taking any tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. 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

As 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, there is a possibility of becoming pregnant. So tell your doctor immediately.

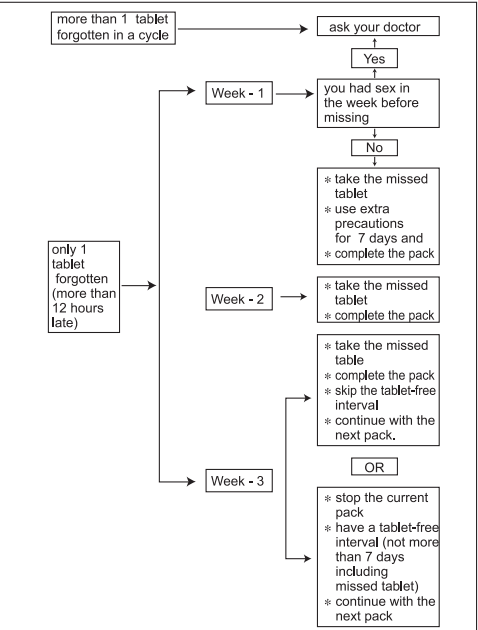
1 tablet missed in week 2

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 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 (also count the day you missed your tablet) and 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.
- If you have forgotten tablets in a pack and you do not have the expected period in the first normal tablet-free break, you may be pregnant. Consult your doctor before you start with the next pack.



..... you vomit

If you vomit within 3 to 4 hours after taking your Desolon® tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Therefore, follow the advice for missed tablets.

.....you want to delay your period

You can delay your period if you start with your next pack of Desolon® 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 days tablet free break.

..... 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 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) you should now start your next pack 3 days sooner than you usually do. If you make your table - free break very short (e.g. 3 days or less) you may not have bleeding during the break. You may have some breakthrough bleeding or spotting during the use of 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 continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 tablet-taking cycles). If it 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. Continue to take Desolon® as usual.

If you miss your period twice in row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of Desolon® until your doctor has checked you are not pregnant.

WHAT SIDE EFFECTS MIGHT YOU HAVE WHILE TAKING DESOLON®?

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.

Possible side effects

The following side effects have been reported by users of the Pill, although they need not be caused by the Pill. These side effects may occur in the first few months that you are using the Pill and usually lessen with time.

- breast tenderness, pain and secretion;
- headache;
- changes in sexual drive; depressive moods;
- contact lens intolerance;
- nausea, vomiting and feeling sick;
- changes in vaginal secretion;
- various skin reactions;
- fluid retention;
- changes in body weight,
- hypersensitivity reactions.

MORE ABOUT THE PILL

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 50µgm 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.

Packs and Tablets

Desolon® is presented in strips of 21 tablets packed in a ply carton.

Storage Conditions:

Do not use after the expiry date stated on the package. Store your tablets at 2°C to 25°C in a dry place and protect them from light. Do not use product if you notice, for example, color change in the tablet, crumbling of the tablet or any other visible signs of deterioration.

Keep Desolon® pack out of the reach of children!

IF YOU HAVE ANY FURTHER QUESTIONS OR REQUIRE THE FULL PRESCRIBING INFORMATION FOR DESOLON®, PLEASE CONSULT YOUR DOCTOR OR PHARMACIST

®Trade Mark

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