

DESOLON TABLET

Desogestrel/ Ethinylestradiol (0.15mg/0.03mg)

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What *Desolon* is used for

Desolon is an estrogen and progestin combination pill used for the prevention of pregnancy.

How *Desolon* works

Combined oral contraceptives like *Desolon* Tablet work mainly by tricking your body into thinking that ovulation has already happened. This prevents an egg from ripening and being released from the ovaries each month.

The hormones also increase the thickness of the natural mucus at the neck of the womb, which makes it more difficult for sperm to cross from the vagina into the womb and reach an egg. They also change the quality of the womb lining (endometrium), making it less likely that a fertilised egg can implant there.

Before you use *Desolon*

- When you must not use it

Do not use this medication if you are allergic to any of the ingredients of *Desolon* Tablet or are pregnant. Tell your doctor right away if you become pregnant during treatment. You should not use this medicine if you have:

- Unexplained vaginal bleeding
- History or suspected cancer that may grow under the influence of sex hormones (breast, endometrium)
- Liver disease or tumor
- History of disorder affecting the blood circulation.
- Severe high blood pressure
- Diabetes with blood vessel damage
- Severe headache with impairments of nerve, spinal cord, or brain function
- Major surgery with prolonged inability to move around

- Heavy smoking (15 cigarettes/day) in individuals >35 years of age
- History of blood clots or blood clotting problems (such as stroke, heart attack).

Do not use *Desolon* if you have Hepatitis C and are taking the medicinal products containing ombitasvir/ paritaprevir/ ritonavir and dasabuvir.

Pregnancy and lactation

Do not take *Desolon* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Desolon* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor or pharmacist if you have any of these other conditions, you may need a dose adjustment or special tests to safely take *Desolon* Tablet:

- blood clot events
- Liver function test is abnormal
- Varicose veins (swollen and enlarged veins)
- Chloasma (facial pigmentation)
- Depression
- You are taking any steroids
- Heart failure
- Kidney problem
- High Blood Pressure
- Epilepsy
- Migraine
- Gynaecological problem that is sensitive to estrogen (eg: tumor in uterus, cells growth outside the uterus)
- Abdominal mass and/or with abdominal pain
- Infection

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

- Acetaminophen (for pain killer or fever)
- Acitretin (for psoriasis)
- Aminoglutethimide (antisteroid medicine)
- Antibiotics (eg: ampicillin, tetracycline, rifampin)

- Anticoagulants (to prevent blood clot)
- Anticonvulsants (eg: carbamazepine, felbamate, phenobarbital, phenytoin, topiramate)
- Vitamin C
- Atorvastatin (for cholesterol)
- Benzodiazepine (eg: alprazolam, chlordiazeposide, diazepam, lorazepam, oxazepam, temazepam which used as sleeping pill)
- Clofibric acid (for cholesterol)
- Cyclosporine (used in organ transplant rejection)
- Griseofulvin (antifungal)
- Morphine (pain killer)
- Antiviral medicines (eg: nevirapine, amprenavir, lopinavir, nelfinavir, ritonavir)
- Prednisolone (steroid)
- Repaglinide, troglitazone (for diabetes)
- Salicylic acid (for pain killer)
- Selegiline (for Parkinson disease)
- Theophylline (for respiratory disorder)
- Tricyclic antidepressant (eg: amitriptyline, imipramine, nortriptyline)
- Certain food (eg: caffeine, grapefruit juice)
- Herbs/supplements (eg: St John's wort, dong quai, black cohosh, saw palmetto, red clover, ginseng)

Do not use *Desolon* if you have Hepatitis C and are taking the medicinal products containing ombitasvir/ paritaprevir/ ritonavir and dasabuvir. Your doctor will prescribe another type of contraceptive before starting the treatment with these medicinal products.

How to use *Desolon*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

One tablet is taken every day for 21 days followed by a seven day break from pill-taking. Each subsequent pack is started

after the 7-day tablet-free period has elapsed.

- When to use it

The first tablet of the first pack is taken on the first day of menstruation. This also applies when changing over from another brand of oral contraceptive.

After delivery administration can be started on the first day of the first spontaneous menstruation. If it is necessary to start earlier, eg. immediately after delivery, additional contraceptive precautions are necessary for the first 14 days of tablet intake.

After a miscarriage or abortion administration should start immediately. In this way no additional contraceptive precautions are required.

- How long to use it

Continue taking *Desolon* for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are: nausea, vomiting and possible slight vaginal bleeding in young girls.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Desolon*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give *Desolon* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Driving and using machines

If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *Desolon* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Desolon may cause:

- blood clot, stroke, high blood pressure, heart attack, edema (swelling)
- depression, dizziness, headache, migraine, nervousness, premenstrual syndrome
- acne
- brown, blotchy spots on exposed skin
- rash
- gain of body hair or loss of facial hair
- No menstrual, breakthrough bleeding, spotting or change in menstrual flow.
- breast enlargement, tenderness, or secretion
- increased or decreased interest in sexual intercourse
- decrease milk supply
- Increase sex hormones
- temporary infertility
- intolerance to carbohydrate
- Increase triglycerides
- abdominal cramping or bloating, change in appetite, nausea, vomiting

- weight gain or loss
- yellowing of the skin and white of the eyes
- infection in vaginal
- benign liver tumours
- cataract, intolerance to contact lens
- impaired kidney function

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 *Desolon*

- Storage

Keep out of the reach and sight of children.

Store in a cool place (below 30°C), protected from light.

- 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

Each tablet is smooth well-formed white round biconcave with upper punch logo and lower punch plain, free from chips, spots and foreign particles

- Ingredients

- Active ingredients
Desogestrel 0.15mg and
Ethinylestradiol 0.03mg.

- Inactive ingredients
Colloidal silicon dioxide,
pregelatinised maize starch, Maize starch, lactose monohydrate, polyvinyl pyrrolidone, stearic acid, DL- α -Tocopherol, acetone, dichloromethane

- MAL number:

MAL10070585AZ

Manufacturer

Renata Limited
Section 7,
Milk Vita Road, Mirpur,
Dhaka, Bangladesh

Product Registration Holder

Vitamode Sdn Bhd
55, Lorong Sempadan 2,
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