

Bredicon®

Desogestrel 75 microgram

COMPOSITION:

Each tablet contains: Desogestrel BP 75 microgram

DESCRIPTION:

Bredicon contains a small amount of female sex hormone, the progestogen desogestrel. For this reason Bredicon is called a progestogen-only-pill (POP), or a minipill. Contrary the combined pill, Bredicon does not contain an oestrogen hormone next to the progestogen. Most minipills work primarily by preventing the sperm cells from entering the womb but do not always prevent the egg cell from ripening, which is the primary action of combined pills. Bredicon is distinct from other mini-pills in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, Bredicon provides high contraceptive efficacy. In contrast to the combined pill, Bredicon can be used by women who do not tolerate estrogens and by women who are breast-feeding. A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of Bredicon and also may not have any bleeding at all.

INDICATIONS:

Bredicon is used to provide contraceptive efficacy in women who want to prevent pregnancy. Bredicon has proved to be highly efficacious as a contraceptive pill and is an alternative for women who have a weak tolerance levels for the estrogen hormones or who are lactating or breast feeding.

CONTRAINDICATIONS:

Known or suspected pregnancy, active venous thromboembolic disorder, presence or history of severe hepatic disease with current abnormal liver function tests, progestogen dependent tumors, undiagnosed vaginal bleeding, hypersensitivity to ingredients

DOSAGE AND ADMINISTRATION:

One tablet at the same time each day, taken continuously without a break. Tablets should be taken within 3 hours of the same time each day.

When and how to take the tablets

Each strip of Bredicon contains 28 tablets. Arrows are printed on the front side of the strip, between the tablets. If you turn the strip over, next to each tablet is printed the day of the week each tablet should be taken. Take your tablet at about the same time each day. Swallow each tablet whole with water. Each time you start a new strip of Bredicon; take a tablet in the top row. For example if you start on Wednesday, you should take the tablet from the top row marked that particular day. You should continue to take one tablet a day until the strip is empty, always follow the direction indicated by the arrows. In this way you can easily check whether you have taken your daily tablet. You may have some bleeding during the use of Bredicon but you must continue to take your tablets as normal. When a strip is empty, you must start with a new pack of Bredicon on the next day without interruption and without waiting for a bleed. You can stop taking Bredicon whenever you want. From the day you stop, you are no longer protected against pregnancy.

Starting first pack of Bredicon

If you are not using hormonal contraception at present (or in the past month) wait for your period to begin. On the first day of your period take the first Bredicon tablet. If you take your first tablet on days 2 to 5 of your period use an additional barrier method of contraception for the first 7 days of tablet taking.

When change from a combined pill

Start Bredicon on the day after the last active tablet of the combined pill; in this case additional contraceptive precautions are not necessary.

When change from a mini-pill, injection, implant or hormonal IUD.

Switch on any day from another mini pill. Start Bredicon the day an implant or IUD is removed or the day your next injection would be due, additional contraceptive precautions are not necessary.

If you have a baby or abortion

Start immediately after first trimester abortion, additional contraceptive precautions are not necessary. After delivery or second trimester abortion, start before periods return. If

more than 21 days have elapsed, pregnancy must be ruled out and an additional barrier method of contraception should be used for the first 7 days.

If you forget to take one or more tablets

If you are more than 12 hours late:

Take a tablet as soon as you remember and take the next one at the usual time. This may mean taking two tablets in one day. This is not harmful. (If you have forgotten more than one tablet you don't need to take the earlier missed ones). You are not protected against pregnancy. Continue to take your tablets as usual but you must also use an extra method, such as a condom, for the next seven days. If you are more than 12 hours late taking your tablet and have had sex it is safe to use emergency contraception.

If you are less than 12 hours late:

Take the tablet as soon as you remember, and take the next tablet at the usual time. The contraceptive action of Bredicon is maintained. If you missed one or more tablets in the first week of tablet intake and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.

If you vomit or use medical charcoal

If you vomit or use medical charcoal within 3 - 4 hours after taking your Bredicon tablet, the active ingredient may not have been completely absorbed. Follow the advice for missed tablets.

PRECAUTIONS AND WARNINGS:

Epidemiological studies have associated the use of combined OCs with an increased incidence of venous thromboembolism (VTE, deep venous thrombosis and pulmonary embolism). It is unclear whether desogestrel used alone carries the same risk. Discontinue in the event of a thrombosis. Consider stopping prior to long term immobilization due to surgery or illness. Benefit/risk assessment should be made in women with liver cancer. Caution patients with a history of thromboembolic disorders. Patients with diabetes should be carefully monitored. Effects on bone density are unknown.

PREGNANCY AND LACTATION:

Not recommended for use during pregnancy. Bredicon does not affect the production or quality of breast milk. Small amounts of the metabolite etonogestrel are excreted with the milk. Long term follow-up data are not available, however 7 month data do not indicate a risk to the nursing infant.

INTERACTIONS:

Enzyme inducing drugs may result in increased clearance and lead to breakthrough bleeding and contraceptive failure. This may be seen with hydantoins, barbiturates, primidone, carbamazepine, rifampicin, oxcarbazepine, rifabutin, felbamate, ritonavir, griseofulvin and products containing St John's Wort. Reduced absorption of etonogestrel may be seen with medical charcoal.

ADVERSE REACTIONS:

Common: irregular bleeding, amenorrhoea, headache, weight gain, breast pain, nausea, acne, mood changes, decreased libido. Less common: Vaginitis, dysmenorrhoea, ovarian cysts, vomiting, alopecia, fatigue, difficulty wearing contact lenses. Rare: Rash, urticaria, erythema nodosum.

OVERDOSE:

No serious deleterious effects have been reported from overdose. Other symptoms may include nausea, vomiting and in young girls, slight vaginal bleeding. Treatment should be symptomatic.

PACKAGING:

Bredicon is presented in strips of 28 tablets packed in a ply carton.

STORAGE CONDITIONS:

Store at room temperature (below 30° c). Do not use after the expiry date stated on the package.

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Manufactured by :



RENATA LIMITED

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