

# Gestop 28<sup>®</sup>

Gestodene 0.075 mg & Ethinylestradiol 0.030 mg

## Presentation

Gestop 28<sup>®</sup>: Each Gestop 28 pack contains 28 tablets. Among these 21 tablets are white in color and each contains Gestodene BP 0.075 mg & Ethinylestradiol BP 0.030 mg. Each of 7 light red colored tablets of the bottom row of the pack is placebo or inactive tablet.

## Description

Gestop 28 contains two active ingredients, Gestodene and Ethinylestradiol. Ethinylestradiol is a synthetic version of oestrogen and Gestodene is a synthetic form of progesterone. If Gestop 28 is taken according to instructions the egg cells (normally released by the ovary each month) are prevented from maturing to the point where they can be fertilized. Secondary mechanisms, which may contribute to the effectiveness of Gestop 28 as a contraceptive, include changes in the cervical mucus (which increase the difficulty of sperm penetration) and changes in the endometrium (which reduce the likelihood of implantation).

## Indications and Uses

Gestop 28 is indicated for:  
Prevention of pregnancy

## Dosage and Administration

### How to Take Gestop 28

To achieve maximum contraceptive effectiveness, Gestop 28 must be taken in the order directed on the package and at intervals not exceeding 24 hours. Women should be instructed to take the tablets at about the same time every day, preferably after the evening meal or at bedtime. One tablet is to be taken daily for 28 consecutive days. Each subsequent pack is started on the day after the current pack is completed.

1. If you have decided to take Gestop 28 for contraception, wait for your next menstruation begins.
2. From the first day of your menstruation, start taking the first white tablet from the left corner of the top row (with arrow mark indicating begin) of your Gestop 28 tablet pack.
3. Continue taking one white tablet each day along the arrow mark.
4. After taking 21 white tablets for 21 days, then continue taking the light red placebo tablet every day from the last row in the pack for next 7 days.
5. It is most likely that your menstruation will start while taking the light red inactive tablets. Do not discontinue taking the light red inactive tablets. Taking of the light red tablets for 7 days will help you keep your tablet taking routine. If your menstruation does not start during this time, check with your doctor to make sure you are not pregnant.
6. After completing the seven light red inactive tablets, start taking white active tablets from another Gestop 28 pack and continue taking the tablet as long as you don't want to be pregnant.

### Management of Missed Tablets

If you forgot to take a tablet one day, take the missed tablet as soon as you remember. This may mean taking two tablets the very next day. Additionally you should use some other method of contraception while you are taking the tablets & until your next menstruation.

If you forget to take the tablets for two continuous days, then it is likely that you will no longer be protected against pregnancy. You should therefore discontinue taking the tablet and adopt some other temporary methods (condom/foam tablet) till your next menstruation. Discard the unfinished pack of tablets and start taking tablets from the very first white tablet of the top row from a fresh pack from the first day of next menstruation.

### How to Delay a Period

To delay a period you should continue with another new pack of Gestop 28 just after finishing the white active tablet of the present pack (that is no need to take light red placebo tablet of present pack). The extension can be carried on for as long as wished until the end of the second pack. When you wish your period to begin, just stop tablet taking. While using the second pack woman may have some breakthrough bleeding or spotting. Start with your next pack after the usual 7 day light red inactive tablet interval.

### Advice in Case of Vomiting

If vomiting occurs within 3-4 hours after white active tablet taking, absorption may not be complete. In such an event, the advice concerning Management of Missed Tablets is applicable. The woman must take the extra active tablet(s) needed from a back up pack after vomiting.

### Side-effects

At the initial stage some women may experience side-effects like dizziness, headache, nausea, diarrhea, abdominal pain, weight gain, fluid retention, depression, mood changes, breast pain, breast tenderness, rash, vaginal discharge, erythema etc. If taken regularly, such types of side-effects normally lessen with time. If she continues to have the side effects beyond 2-3 months, she could consult with a doctor.

### Precautions

Some medications may interfere with the efficacy of the tablet. Contact your doctor if you are taking any drugs, such as antibiotics, rifampicin or medicines for seizures. You may have to use another method of contraception during this time.

### Pregnancy & Lactation

*Use during pregnancy:* The administration of Gestop 28 is contraindicated during pregnancy.

*Use during lactation:* The use of Gestop 28 during breast-feeding is not recommended.

### Contraindications

Gestop 28 should not be used:

- If you are pregnant or think to become pregnant
- If you had stroke or thrombosis in blood vessels of heart, legs, lungs or other parts of body
- If you are a heavy smoker
- If you suffer from liver disease or jaundice
- If you are suffer from high blood pressure, migraine, feel something hard in your breast, diabetes with vascular involvement, experience excessive bleeding for which no reason has yet been ascertained
- If you have or had a benign or malignant liver tumor
- Hypersensitivity to any of the components of Gestop 28

### Drug interactions

Interactions between ethinylestradiol and other drugs may lead to decreased or increased ethinylestradiol concentrations, respectively. Decreased ethinylestradiol serum concentrations may cause an increased incidence of breakthrough bleeding and menstrual irregularities and may possibly reduce efficacy of the oral contraceptive. Example of substances that may decrease serum ethinylestradiol concentrations include rifampicin, phenytoin, primidone, rifabutin, dexamethasone, griseofulvin, topiramate, some protease inhibitors, modafinil, ritonavir and barbiturates.

Certain antibiotics including ampicillin, other penicillins and tetracyclines may reduce the efficacy of oral contraceptives.

During concomitant use of Gestop 28 & other drugs that may lead to decreased ethinylestradiol serum concentrations, it is recommended that a non-hormonal back-up method of contraception to be used in addition to the regular intake of Gestop 28.

### Overdose

Symptoms of oral contraceptive overdosage in adults and children may include nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue; withdrawal bleeding may occur in females. There is no specific antidote and further treatment of overdose, if necessary, is directed to the symptoms.

### Storage

- Store in a cool, dry place.
- Keep away from light & out of reach of children

### Commercial Pack

Gestop 28<sup>®</sup>: Each blister contains 21 white active tablets (each containing Gestodene 0.075 mg & Ethinylestradiol 0.030 mg) and 7 light red placebo tablets.

Manufactured by  
 **Incepta Pharmaceuticals Ltd**  
Dhamrai Unit, Dhaka, Bangladesh

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