

Levorest 28 Sugar Coated Tablet

Ethinylestradiol / Levonorgestrel (0.03mg/0.15 mg)

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What Levorest 28 is used for

Levorest 28 is a contraceptive pill and is used to prevent pregnancy.

How Levorest 28 works

Levorest 28 is a contraceptive pill that contains of the female hormones ethinylestradiol and levonorgestrel. The two hormones are called 'combined oral contraceptive' that work together to stop ovulation and make it harder for sperm to reach the egg.

Before you use Levorest 28

- When you must not use it

Do not use Levorest 28 if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use Levorest 28.

Your doctor may advise you to use a different type of contraceptive pills or an entirely different (including non-hormonal) method of birth control.

- if you are allergic (hypersensitive) to ethinylestradiol, levonorgestrel or any other ingredients of this medicine (listed in Product Description).
- have (or have ever had) a blood clot (e.g. in the legs or lungs), heart attack or stroke.
- have very high risk of getting blood clots (e.g. strong family history, some genetic conditions or certain medical illness).
- have or had migraines with warning signs (aura) like seeing flashes or zigzag lines.
- have diabetes mellitus with damaged blood vessels
- have (or have ever had) serious liver disease or liver tumor.

- are taking medicines for hepatitis C (e.g., ombitasvir, paritaprevir, ritonavir, dasabuvir).
- have or had breast or genital cancers affected by hormone.
- if you have any unexplained bleeding from the vagina

- Before you start to use it

Consult your doctor before starting to use Levorest 28 if any of the following conditions apply to you or if any of them develop or worsen while you are taking Levorest 28.

- if you smoke (especially if over 35 years old).
- if you have diabetes, high blood pressure, or high cholesterol.
- if you are overweight
- if you have a heart valve disorder or a certain heart rhythm disorder
- if you have personal or family history of blood clots, stroke, or heart disease.
- if you suffer from migraine
- if you have epilepsy
- if there is a history of cancer in your family.
- if you have liver or kidney problems
- if you have inflammatory bowel disease (e.g., Crohn's disease, ulcerative colitis)
- if you have any immune system disorder.
- if you have sickle cell disease or angioedema
- Some medical conditions may appear or worsen while taking Levorest 28, although it's not certain that the medication is the cause. These include liver-related problems like jaundice, gallstones, rare blood or immune system disorders (like porphyria, lupus, or hemolytic uremic syndrome), movement disorders (Sydenham's chorea), a rare pregnancy-related skin rash (herpes gestationis), and

certain types of hearing loss (linked to otosclerosis).

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

Pregnancy and lactation

If you become pregnant while taking Levorest 28, stop taking it immediately and contact your doctor.

If you want to become pregnant, stop taking Levorest 28 at any time.

The medicine may reduce the amount and quality of your breast milk; therefore, it is generally not recommended for use during breastfeeding. Discuss with your doctor if you want to take Levorest 28 while you are breast-feeding.

- 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.

Tell your doctor if you are taking: Medicines that can reduce the effectiveness of the medication (higher chance of pregnancy):

- Phenytoin, carbamazepine, phenobarbital, primidone, topiramate, oxcarbazepine, felbamate (epilepsy/seizure medications)
- Rifampicin (antibiotic for tuberculosis)
- Griseofulvin (antifungal medication for skin infections)
- John's Wort (Hypericum perforatum) (herbal remedy for depression/mood).

Medicines that can increase hormone levels (higher chance of side effects).

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- Itraconazole, fluconazole, voriconazole (antifungal medications)
- Erythromycin, clarithromycin (antibiotics for bacterial infections)
- Verapamil, diltiazem (heart and blood pressure medication)
- Etoricoxib (pain and inflammation medication)
- Grapefruit juice (fruit juice that affects drug breakdown)

Medicines that can be affected by Levorest 28:

- Lamotrigine (for epilepsy or bipolar disorder)
- Cyclosporine (used after organ transplant)
- Melatonin (for sleep)
- Tizanidine (muscle relaxant)
- Theophylline (for asthma or lung conditions)

How to use Levorest 28

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.

- How much to use

One tablet is to be taken everyday starting with the active tablets taken for 21 days followed by inactive (placebo film coated tablet) tablets for 7 days. The next pack of Levorest 28 Tablet should be started without a break.

You will usually get your period when taking the inactive tablets.

- When to use it

If you've never used any hormonal contraception before : Start on the first day of your period.

If you're switching from another birth control pill : Start Levorest 28 the day

after you finish the last active pill of your old pack (no break in between).

After giving birth or a miscarriage : Ask your doctor, but usually you can start 21–28 days after delivery.

Ask your doctor what to do if you not sure when to start

- How long to use it

Use this medicine for the duration that your doctor recommends.

You can stop taking Levorest 28 at any time. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control.

If you want to become pregnant, stop taking Levorest 28 and wait for a menstrual period before starting to try to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

- If you are less than 12 hours late taking your active pill, take it as soon as you remember. Then continue taking the rest of the pills at your usual time, even if that means taking two pills in one day. You are still protected from pregnancy, and there is no need to use extra contraception like condoms.
- If you are more than 12 hours late, the pill may not work as well to prevent pregnancy. Take the last missed pill as soon as you remember, even if it means taking two pills on the same day. Then continue taking the rest of the pack as normal. You must also use extra protection (such as condoms) for the next 7 days.

Do not take more than 2 tablets on a given day, to make up for missed Levorest 28.

- If you missed one or more pills and had unprotected sex during that time or in the 7 days before, you could be at risk of pregnancy. Take the last missed pill immediately, continue the pack as usual, and use extra contraception (example condoms) for the next 7 days. You may also need emergency contraception, so speak to a doctor or pharmacist as soon as possible.
- Depending on how many pills were missed, you may need to skip the 7-day placebo tablets and start the next pack immediately. If you're unsure what to do, see your doctor immediately.

- If you use too much (overdose)

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

If someone takes too many Levorest 28 at once, it's usually not dangerous, but mild symptoms like feeling sick (nausea), vomiting, or unexpected vaginal bleeding may occur especially in young girls who haven't started their periods yet if they took it by accident.

While you are using Levorest 28

- Things you must do

Use your medicine exactly as your doctor has told you.

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

Take Levorest 28 only with a doctor's prescription.

- Things you must not do

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

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Things to be careful of

If you experience symptoms like severe headaches, chest pain, breathing difficulty, leg swelling, or vision changes — stop the pill and seek medical help right away, as these could be signs of a blood clot or stroke. Also, if you get migraines for the first time or your migraines worsen, see your doctor.

If your period doesn't come during the break week and you missed some pills, do a pregnancy test and see your doctor as soon as possible.

If you vomit or have severe diarrhoea, the pill may not work as well. Use extra protection (like condoms).

The medication does not protect against HIV or other sexually transmitted infections (STIs), so you may still need to use condoms.

Side effects

Like all medicines, Levorest 28 can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Please read these sections carefully and consult your doctor at once where appropriate.

The following side effects were reported in Levorest 28 users:

Common: may affect up to 1 in 10 people

- Nausea
- abdominal pain
- weight gain
- headache
- depressed or altered mood
- breast pain including breast tenderness

Uncommon: may affect up to 1 in 100 people

- Vomiting
- Diarrhea
- fluid retention

- migraine
- reduced interest in sex
- breast enlargement
- rash
- urticaria (hives)

Other possible side effects (rare or serious):

- blood clots in the leg, lungs, brain, or heart can cause pain, swelling, chest pain, breathlessness, or stroke
- allergic reactions (like swelling or itching)
- problems wearing contact lenses
- dark patches on the skin (chloasma), especially on the face
- liver problems or tumors (very rare)
- slightly increased risk of breast cancer
- increased blood pressure

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

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 Levorest 28

Storage

Do not store above 30°C. Avoid excursions above 30°C. Protect from moisture.

Keep out of reach of children.

Do not use Levorest 28 after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

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

Active tablets

Yellow, round, sugar-coated tablets. They are biconvex (rounded on top and bottom) with a round edge. The tablets are plain on both sides.

Placebo tablets

6 mm, round, white film-coated tablet, one side debossed logo PO and other side debossed logo RO.

Ingredients

Active ingredients

Each active tablet contains 0.030 mg ethinylestradiol and 0.15 mg levonorgestrel.

Inactive ingredients

Active Tablets

- Maize starch
- Pre-gelatinised starch
- Povidone
- Lactose monohydrate
- Magnesium stearate
- Colloidal anhydrous silicon
- Ethanol
- Dichloromethane
- Polyvinyl alcohol-partially hydrolysed
- Titanium dioxide
- Talc
- Macrogol/ PEG
- Lecithin(soya)
- Sucrose
- Acacia gum
- Calcium carbonate
- Polysorbate-80
- Ferric oxide yellow
- Carnauba wax

Placebo Tablets

- Microcrystalline cellulose
- Lactose monohydrate
- Colloidal anhydrous silica

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- Magnesium stearate
- Polyvinyl alcohol-partially hydrolysed
- Titanium dioxide
- Talc
- Macrogol/ PEG
- Lecithin(soya)

- MAL number:
MAL*****

Manufacturer

Renata PLC
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Noyapara, Bhawal, Mirzapur,
Rajendrapur, Gazipur, Bangladesh

Product Registration Holder

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