

ZINNIA TABLETS

Levonorgestrel /Ethinylestradiol (30mcg/150mcg)

What is in this leaflet

1. What Zinnia is used for
2. How Zinnia works
3. Before you use Zinnia
4. How to use Zinnia
5. While you are using it
6. Side effects
7. Storage and Disposal of Zinnia suspension
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Zinnia is used for

Zinnia is a contraceptive pill and it is used to prevent pregnancy. Each tablet contains a small amount of two different female hormones, namely ethinylestradiol and levonorgestrel. Contraceptive pills that contain two hormones are called “combination” pills.

How Zinnia works

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones stop you getting pregnant by working in three ways: by preventing an egg being released from your ovaries; by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; and by preventing the lining of your womb thickening enough for an egg to grow in it.

Before you use Zinnia

- When you must not use it

Do not take Zinnia if you:

- are pregnant
- have (or have ever had) a severe disturbance of liver function, including jaundice or continuous itching during previous pregnancy, Dubin-Johnson syndrome, Rotor Syndrome, previous and existing liver tumors.
- or your family have (or have ever had) blood clot in blood vessel (thromboembolism ,VTE) and other known risk factors for VTE.
- have (or have ever had) a disease of arterial condition and heart disease.
- have blood disease called sickle-cell anemia, porphyria, HUS (haemolytic

uraemic syndrome which causes kidney damage).

- or your family have (or have ever had) or if you are suspected of having breast cancer or cancer of the womb lining.
- have diabetes.
- have disorder of fat breakdown.
- have or ever had skin rash disease during pregnancy (gestational herpes).
- have abnormal growth of bone near middle ear (otosclerosis) during pregnancy.
- have unexplained bleeding from the vagina.
- are allergic to ethinylestradiol, levonorgestrel or any of other ingredients of this medicine. An allergic reaction may cause itching, rash or swelling.
- have gall stones
- have depression or fits
- have disease of immune system called SLE (Systemic Lupus Erythematosus or multiple sclerosis).
- have Crohn’s disease or inflammatory bowel disease (ulcerative colitis).
- have nerve disease causing sudden movements of body (Sydenham’s Chorea).
- have or ever had Chloasma (a discoloration of the skin especially of the face or neck known as “pregnancy patches”). If so, avoid direct exposure to sunlight or ultraviolet light.
- have high blood pressure
- have enlarge veins and history of vein inflammation.
- have migraine
- have involuntary muscle spasm
- have kidney dysfunction
- have obesity
- have asthma
- have an intolerance of contact lenses
- have any disease that likely to cause worsen during pregnancy.

- Before you start use it

Pregnancy and lactation

Do not take Zinnia if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while

taking Zinnia, stop taking it immediately and contact your doctor.

Do not take Zinnia if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without prescription especially the following:

Barbiturates, Primidone, Phenobarbitone, Phenytoin and Carbamazepine: to control fits.

Phenylbutazone: short-term treatment of pain and fever.

Griseofulvin: antifungal

Rifampicin, Ampicillin and other antibiotics: used to treat bacterial infections.

Women receiving short courses of enzyme inducers or broad spectrum antibiotics should take additional, non-hormonal (except rhythm or temperature method) contraceptive precautions during the time of concurrent medication and for 7 days afterwards.

With Rifampicin, additional contraceptive precautions should be continued for 4 weeks after treatment stops, even if only a short course was administered. The requirement for oral anti-diabetics or insulin can change as a result of the effect on glucose tolerance.

How to use Zinnia

- How much to use

Each strip contains 21 tablets.

Take one Zinnia if necessary with a small amount of water.

You should take the tablets every day around the same time.

Next to each tablet is printed the day of the week when it should be taken.

ZINNIA TABLETS

Levonorgestrel /Ethinylestradiol (30mcg/150mcg)

Start by taking a tablet from the first row marked with the correct day of the week. If, for example, you start on a Wednesday, take a tablet with “WED” next to it. Follow the direction of the arrows on the strip until you have taken all 21 tablets. Then take no tablets for 7 days.

In the course of these 7 tablets-free days bleeding should begin. This so-called “withdrawal bleeding” usually starts on the 2nd or 3rd day of the gap week. On the 8th day after the last Zinnia tablet (that is, after the 7 day gap week), you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week and that the withdrawal bleed should occur on the same days each month. If you use Zinnia in this manner, you are also protected against pregnancy during the 7 days when you are not taking tablets.

First Time User:

Tablet taking has to start on day 1 of the woman’s natural cycle.

Changing from combined oral contraceptive/COC:

The woman should start with Zinnia on day after the last tablet containing active substances of her previous COC, but at the latest on the day following the usual tablet-free interval of her previous COC.

Change from Progestogen-only-method:

The woman may switch any day from the contraceptive pill, but is advised to additionally use a barrier method of contraceptive for the first 7 days of tablet taking.

Your doctor will advise you when to start if you:

- are taking Zinnia after having baby.
- have had a miscarriage or an abortion.

Tablet- taking must never be discontinued more than 7 days. Advice in case of severe gastrointestinal disturbance, absorption may not be complete and additional contraceptive measures should be taken. If vomiting occurs within 3-4 hours after active tablet-taking, the advice concerning missed tablets is applicable. If

the woman does not want to change her normal tablet taking schedule, she has to take an extra tablets(s) needed from another pack.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Zinnia 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 a forgotten dose.

If you are less than 12 hours late taking a tablet, the protection from pregnancy is not reduced. In this case you do not need to use any additional method of contraception.

If you are more than 12 hours late taking a tablet, the protection from pregnancy may be reduced. The greater the number of tablets you have forgotten, the greater is the risk of becoming pregnant.

- 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 is no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdosage include nausea, vomiting and in females, withdrawal bleeding.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors and pharmacists treating you that you are taking Zinnia.

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 or pharmacist.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Some women may experience no or infrequent menstrual period after discontinuation of oral contraceptives, especially when these conditions existed prior to use.

The pill will not protect you against sexually transmitted diseases.

Side effects

Like all medicines, Zinnia can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- headaches
- gastric upsets
- nausea
- vomiting
- breast tenderness
- change in body weight
- changes in sexual desire
- depressive moods
- Chloasma (skin inflame after exposure to sunlight)
- reduction in menstrual flow
- missed menstruation
- intermenstrual bleeding
- effect on blood results including liver, thyroid, adrenal and kidney function, proteins and lipid/lipoprotein fractions, carbohydrate breakdown, clotting factors.)

ZINNIA TABLETS

Levonorgestrel /Ethinylestradiol (30mcg/150mcg)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems/ Sides Effects / AEFI / Vaccine Safety).

Storage and Disposal of Zinnia

- Storage

Keep this medicine out of the sight and reach of children.

Store in a dry place at a temperature below 25°C

- 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

White, circular and biconvex tablets

- Ingredients

- Active ingredient

Levonorgestrel (150 mcg),
Ethinylestradiol (30 mcg)

- Inactive ingredients

Lactose granules, Talc, Magnesium Stearate, Povidone K-90, Glycerol, Sucrose, Calcium Carbonate, Macrogol 6000, Titanium dioxide, Carnuba Wax, and Purified Water.

- MAL number(s):

MAL10043680AZ

Manufacturer

Jai Pharma Limited

Plot No. 1606 to 1609, G.I.D.C,

Sarigam, Tal- Umergam, Sarigam-396155, Dist. Valsad, Gujarat, India.

Product Registration Holder

Unimed Sdn Bhd

53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200, Kuala Lumpur, Malaysia.

Date of revision

27/05/2017

Serial Number:

BPFK(R4/1)240517/00114