

Zentair 0.5 mg & 1 mg USP Film Coated Tablets

Entecavir (0.5mg & 1mg)

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What Zentair is used for

Zentair is indicated for the treatment of long term (chronic) hepatitis B virus infection in adults with evidence of active viral replication.

How Zentair works

Zentair contains an active ingredient, Entecavir, which has potent and selective activity against hepatitis B virus (HBV). By this way, it helps to reduce the amount of hepatitis B virus in your body.

Before you use Zentair

-When you must not use it

Do not take Zentair if:

- You have hypersensitivity to entecavir or any component of Zentair.
- You are HIV/HBV co-infected patient and also not receiving highly active antiretroviral therapy (HAART).

Do not take Zentair if you are pregnant, trying to get pregnant or think you may be pregnant, unless considered essential by the physician.

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

Zentair is not recommended for children below the age of 16 years.

-Before you start to use it

Inform and discuss with your doctor or pharmacist, if:

- you have kidney problem
- you have a transplanted liver
- your liver does not function properly (decompensated liver disease)
- you have any other allergies or health problem

Your doctor will decide whether Zentair is suitable for you or not.

-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. Your doctor or pharmacist will advise whether you should take Zentair together with any other medicines.

How to use Zentair

-How much to use

Always take this medicine exactly as your doctor or pharmacist has told to you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the dose that suits you base on your condition.

-When to use it

Use as directed by your doctor or pharmacist. Zentair should be taken on an empty stomach unless otherwise advised by your doctor or pharmacist.

-How long to use it

Continue taking Zentair for as long as your doctor recommends.

-If you forget to use it

If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you use too much (overdose)

If overdose occurs, 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.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

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

-Things you must not do

Do not take Zentair with food unless advised by your doctor or pharmacist.

Do not breastfeed if you are taking Zentair.

Do not take any new medicines without consulting your doctor.

-Things to be careful of

Therapy with Zentair has not been proven to reduce the risk of transmission of HBV and, therefore, appropriate precautions should still be taken.

Side Effects

Like any other medicines, Zentair may cause side effects although not everyone may get it. Below are some of the recorded and reported side effects:

- sleeping difficulty
- headache
- dizziness
- extreme sleepiness
- nausea
- diarrhea
- indigestion
- vomiting
- fatigue
- worsening of liver inflammation
- liver not functioning properly
- hair loss
- rash

Visit your doctor or pharmacist immediately if you experience any side effects listed or not listed above after taking this medicine.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Zentair

-Storage

Store below 30°C. Preserve in tight containers.

-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

Zentair 0.5 mg

White to off-white triangular shaped biconvex, film coated tablet debossed with 'E' on one side and plain on other side.

Zentair 1 mg

Pink coloured, triangular shaped biconvex film coated tablet debossed with "E" on one side and "1" on other side.

-Ingredients

Active ingredient:

Zentair 0.5 mg

Each film coated tablet contains Entecavir 0.5 mg.

Zentair 1 mg

Each film coated tablet contains Entecavir 1 mg.

Inactive ingredients:

Lactose monohydrate
Microcrystalline Cellulose
Crospovidone
Hydroxypropyl cellulose
Magnesium stearate

Excipients (coating):

Zentair 0.5 mg

Opadry 04F58804 White:

HPMC 2910 / Hypromellose 15 m Pas
Titanium dioxide
Macrogol / PEG MW6000

Zentair 1 mg

Opadry 03B14899 Pink:

HPMC 2910 / Hypromellose 15 m Pas
Titanium dioxide
Macrogol / PEG
Iron oxide red

-MAL Number

Zentair 0.5 mg: MALXXXXXAZ

Zentair 1 mg: MALXXXXXAZ

-Pack Size

3 x 10's tablets

Manufacturer and Product Registration Holder

Manufacturer

Cipla Ltd.
Unit IV
Plot No. 9 & 10
Indore Special Economic Zone,
Phase-II Pithampur, Dist, Dhar (M.P)
In-454775 India.

Product Registration Holder

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