

AVORIX 0.5MG FILM COATED TABLETS

Entecavir 0.5mg

What is in this leaflet

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

What Avorix is used for

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

How Avorix works

Avorix 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 Avorix

– When you must not use it

Do not take Avorix if:

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

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

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

Avorix 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 Avorix 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 Avorix together with any other medicines.

How to use Avorix

– 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 based on your condition.

– When to use it

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

– How long to use it

Continue taking Avorix for as long as your doctor recommends.

– 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 the missed dose.

– 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 Avorix with food unless advised by your doctor or pharmacist.

Do not breastfeed if you are taking Avorix.

Do not take any new medicines without consulting your doctor.

– Things to be careful of

Therapy with Avorix 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, Avorix 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.

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

AVORIX 0.5MG FILM COATED TABLETS

Entecavir 0.5mg

Storage and Disposal of Avorix

– Storage

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package.

– 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, round film-coated tablet debossed with “C21” on one side and plain on the other side.

The tablets are available in 1 x 10's, 3 x 10's, 6 x 10's, 10 x 10's, 50 x 10's, 100 x 10's in blister form packed in the outer carton. Not all pack sizes will be marketed

– Ingredients

– Active ingredient

The active substance of Avorix is Entecavir Monohydrate 0.532mg equivalent to Entecavir 0.5mg.

– Inactive ingredient

Tablet core:

- Lactose Monohydrate
- Microcrystalline Cellulose
- Crospovidone
- Povidone
- Magnesium Stearate

Film coat

- Opadry Complete Film Coating System YS-1-18027-A White

Component: Titanium Dioxide, Hypromellose (6mPas), Hypromellose (3mPas), Macrogol, Polysorbate 80

– MAL numbers

MAL22126046AZ

Manufacturers

Novugen Pharma Sdn. Bhd.
No. 27, Jalan Lengku Teknologi
2, Taman Teknologi Enstek Fasa
1, 71760 Bandar Baru Enstek,
Negeri Sembilan, Malaysia.

Product Registration Holder

Novugen Pharma Sdn. Bhd.
No. 3, Jalan Jururancang U1/21,
Hicom Glenmarie Industrial
Park, 40150, Shah Alam,
Selangor, Malaysia.

Date of revision

08/08/2024

Serial Number

NPRA (R2) 22/076