

BENAVIR FILM-COATED TABLET 0.5MG

Entecavir 0.5mg

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What Benavir Tablet is used for

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

How Benavir Tablet works

Benavir Tablet 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 Benavir Tablet

- When you must not use it

Do not take Benavir Tablet if:

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

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

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

Benavir Tablet 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 Benavir Tablet 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 Benavir Tablet together with any other medicines.

How to use Benavir Tablet

- 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. Benavir Tablet should be taken on an empty stomach unless otherwise advised by your doctor or pharmacist.

- How long to use it

Continue taking Benavir Tablet 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 Benavir Tablet with food unless advised by your doctor or pharmacist.

Do not breastfeed if you are taking Benavir Tablet.

Do not take any new medicines without consulting your doctor.

- Things to be careful of

Therapy with Benavir Tablet 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, Benavir Tablet may cause side effect although not everyone may get it. Below are some of the recorded and reported.

- sleeping difficulty
- headache
- dizziness
- extreme sleepiness
- nausea
- diarrhoea
- 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

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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 Benavir Tablet

- Storage

Benavir Tablet should be stored in the original package at temperatures not above 30°C. Keep out of the reach and sight of children.

- 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

Benavir Tablet is a white, triangular shaped film-coated tablet with Pharmaniaga icon on one side and plain on the other.

- Pack Size

In boxes of 30 tablets (3 blister x 10 tablets).

- Ingredients

Active ingredient:
Entecavir 0.5mg

Inactive ingredients:
Lactose monohydrate
Microcrystalline cellulose
Crospovidone
Povidone
Magnesium stearate
Purified water
Opadry white

- MAL Number

MALxxxx

Manufacturer

Pharmaniaga Manufacturing Berhad
(198001006232)
No.11A, Jalan P/1, Kawasan
Perusahaan Bangi,
43650 Bandar Baru Bangi, Selangor
Darul Ehsan,
Malaysia.

Product Registration Holder

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18 April 2023

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