

Hepuri F.C. Tablets 0.5mg[®]

Consumer Medication Information Leaflet (RiMUP)

Entecavir 0.5mg

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What *Hepuri* is used for Entecavir is used to treat chronic hepatitis B virus (HBV) infection in adults with compensated or decompensated liver disease or with HIV/HBV co-infection who have received prior lamivudine therapy.

How *Hepuri* works

Entecavir is an antiviral medication. Entecavir prevents certain virus cells from multiplying in your body

Before you use *Hepuri*

- When you must not use it

You should not take this medication if you are allergic to entecavir, or any other ingredients of *Hepuri*.

Pregnancy and lactation

Do not take *Hepuri* if you are pregnant, trying to get pregnant or think you may be pregnant.

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

- Before you start to use it

Before you take entecavir, tell your doctor if:

- You have liver disease
- You have kidney disease
- You are suffered from HIV or AIDS
- You have liver transplant
- You are infected with hepatitis C or D
- You are lactose intolerance

- Taking other medicines

Tell your doctor if you use any other medicines, including medicines purchased without a prescription from a

pharmacy, supermarket, or health food store.

Before taking entecavir, tell your doctor if you are using any of the following drugs:

- Lamivudine
- Adefovir dipivoxil
- Enofovir disoproxil

How to use *Hepuri*

- How much to use

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.

Compensated liver disease

Nucleoside naive patients: 0.5mg once daily

Lamivudine-refractory patients: 1mg once daily on empty stomach.

Decompensated liver disease

1mg once daily on empty stomach.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Hepuri* 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 the missed dose.

- 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 are no signs of discomfort or

poisoning. You may need urgent medical attention.

Symptoms of overdose is not known yet.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Hepuri*.

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.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *Hepuri* can cause side effects, although not everybody gets them.

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

Common side effects include insomnia, headache, dizziness, sleepiness, vomiting, diarrhea, nausea, indigestion, increased liver enzyme, and fatigue.

Other side effects include rash, hair loss, and anaphylactoid reaction.

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

Storage and Disposal of Hepuri

- Storage

Keep out of the reach and sight of children.

Store below 30 °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 tablet; film coated, triangular-shaped tablet, branded “948” on one side and “STD” on the other surface.

- Ingredients

- Active ingredient
Entecavir 0.5mg

- Inactive ingredients Lactose (Spray dried), Microcrystalline cellulose, Crospovidone, Magnesium stearate, Hydroxypropyl Methylcellulose, Polyethylene glycol 4000, Talc, Titanium dioxide

- MAL number:

MAL18116080AZ

Manufacturer

Standard Chem. & Pharm. Co., Ltd., 2nd plant
No. 154, Kaiyuan Road, Sinying District
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Product Registration Holder

Medispec (M) Sdn Bhd.
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16/12/2021