# Hepavir®

Lamivudine

***Antiviral***

## COMPOSITION

Hepavir® tablet : Each film coated tablet contains Lamivudine 100 mg.

## PHARMACOLOGY

Lamivudine is a synthetic nucleoside analogue. Lamivudine is phosphorylated intracellularly to lamivudine triphosphate. Incorporation of the monophosphate form into viral DNA occurs by hepatitis B virus (HBV) polymerase. As a result DNA chain is terminated. Lamivudine triphosphate also inhibits the RNA and DNA-dependent DNA polymerase activities of HIV-1 reverse transcriptase (RT). Lamivudine triphosphate is a very weak inhibitor of mammalian alpha, beta, and gamma-DNA polymerases.

## INDICATION

Hepavir® (Lamivudine) is indicated for the treatment of chronic hepatitis B associated with evidence of hepatitis B viral replication and active liver inflammation.

## DOSAGE AND ADMINISTRATION

The recommended oral dose of Hepavir® for the treatment of chronic hepatitis B in adults is 100 mg once daily.

It is recommended that doses of Hepavir® should be adjusted in accordance with renal function. Dosage adjustment of Hepavir® in accordance with creatinine clearance is as follows:

| Creatinine clearance (ml/min) | Recommended dosage of Hepavir® |
|---|---|
| 50 | 100 mg once daily |
| 30-49 | 100 mg first dose, then 50 mg once daily |
| 15-29 | 100 mg first dose, then 25 mg once daily |
| 5-14 | 35 mg first dose, then 15 mg once daily |
| <5 | 35 mg first dose, then 10 mg once daily |

## CONTRAINDICATION AND PRECAUTION

Hepavir® (Lamivudine) is contraindicated in patients hypersensitive to any of the components of the product.

Patients should be assessed before beginning treatment and during treatment with lamivudine by a physician experienced in the management of chronic hepatitis B.

Safety and efficacy of lamivudine for the treatment of chronic hepatitis B in children have not been established.

**SIDE EFFECT**

Several serious adverse events reported with lamivudine (lactic acidosis and severe hepatomegaly with steatosis, post treatment exacerbations of hepatitis B, pancreatitis, and emergence of viral mutants associated with reduced drug susceptibility and diminished treatment response).

Malaise, fatigue, fever, ENT infections, sore throat, nausea, vomiting, abdominal discomfort, pain, diarrhea, myalgia, arthralgia, headache, skin rashes may occur. Lactic acidosis and severe hepatomegaly with steatosis, have been reported.

**DRUG INTERACTION**

Trimethoprim 160 mg/Sulfamethoxazole 800 mg once daily has been shown to increase lamivudine exposure (AUC). The effect of higher doses of trimethoprim /sulfamethoxazole on lamivudine pharmacokinetics has not been investigated.

**USE IN PREGNANCY AND LACTATION**

There is no adequate and well-controlled study in pregnant women. Lamivudine should be used during pregnancy only if the potential benefits outweigh the risks. Although it is not known if lamivudine is excreted in human milk, there is the potential for adverse effects from lamivudine in nursing infants. Mothers should be instructed not to breast feed if they are receiving lamivudine.

**STORAGE CONDITION**

Store below 30˚C. Protect from light. Keep out of the reach of children.

**HOW SUPPLIED**

Hepavir® : Box containing 5 x 4 tablets in blister pack.