

Part VI: Summary of the risk management plan

Summary of risk management plan for Entecavir Medical Valley (entecavir monohydrate)

This is a summary of the Risk Management Plan (RMP) for Entecavir Medical Valley. The RMP details important risks of Entecavir Medical Valley and how more information will be obtained about Entecavir Medical Valley's risks and uncertainties (missing information).

Entecavir Medical Valley's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Entecavir Medical Valley should be used.

Important new concerns or changes to the current ones will be included in updates of Entecavir Medical Valley's RMP.

I. The medicine and what it is used for

Entecavir Medical Valley is authorised for the treatment of chronic hepatitis B virus infection in adults with compensated or decompensated liver disease, and for treatment of chronic hepatitis B virus infection in nucleoside naive paediatric patients 2 to < 18 years of age with compensated liver disease (see SmPC for the full indication).

It contains entecavir monohydrate as the active substance and it is given by oral route.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Entecavir Medical Valley, together with measures to minimise such risks are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Entecavir Medical Valley is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Entecavir Medical Valley are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Entecavir Medical Valley. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Summary of safety concerns	
Important identified risks	<ul style="list-style-type: none">• Entecavir resistance• Exacerbation of hepatitis (alanine aminotransferase (ALT) increase /hepatic flare)• Emergence of resistant HIV in HIV/HBV co-infected patients
Important potential risks	<ul style="list-style-type: none">• Mitochondrial toxicity (including lactic acidosis)
Missing information	<ul style="list-style-type: none">• Use in pregnancy• Use in patients with severe acute exacerbation of chronic hepatitis B

II.B Summary of important risks

The safety information in the Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Entecavir Medical Valley.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Entecavir Medical Valley.