LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Etoposide Accord (etoposide)

SE/H/1330/01/DC

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Summary Public Assessment Report

Etoposide Accord

(etoposide)

Concentrate for solution for infusion

This is a summary of the public assessment report (PAR) for Etoposide Accord. It explains how Etoposide Accord was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Etoposide Accord.

For practical information about using Etoposide Accord, patients should read the package leaflet or contact their doctor or pharmacist.

What is Etoposide Accord and what is it used for?

Etoposide Accord is a 'generic medicine'. This means that Etoposide Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Vepesid.

Etoposide Accord is used in combination with other anti-cancer medicines to treat:

- small-cell lung cancer
- acute monoblastic & acute myelomonoblastic leukaemia (cancer of the blood-forming tissues of bone marrow)
- testicular tumours (cancer of testis)

How does Etoposide Accord work?

This medicine contains the active substance etoposide. It works by interfering production cycle of DNA and slow or stop the growth of cancer cells.

How is Etoposide Accord used?

The pharmaceutical form of Etoposide Accord is concentrate for solution for infusion for intravenous use

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Etoposide Accord have been shown in studies?

No additional studies were needed as Etoposide Accord is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Vepesid.

What are the possible side effects of Etoposide Accord?

Because Etoposide Accord is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Etoposide Accord approved?

It was concluded that, in accordance with EU requirements, Etoposide Accord has been shown to have comparable quality and to be similar to the reference medicine Vepesid. Therefore, the Medical Products Agency in Sweden decided that, as for Vepesid, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Etoposide Accord?

A risk management plan has been developed to ensure that Etoposide Accord is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Etoposide Accord, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Etoposide Accord

The marketing authorisation for Etoposide Accord was granted on 2014-06-26 in Sweden.

The full PAR for Etoposide Accord can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Etoposide Accord, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2014-06