26/6/17
EMA/251790/2017 Rev. 1
EMEA/H/A-30/1425

Questions and answers on Vepesid and associated names (etoposide, 50 and 100 mg capsules)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 21 April 2017, the European Medicines Agency completed a review of Vepesid. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Vepesid in the European Union (EU).

What is Vepesid?

Vepesid is a cancer medicine used to treat: testicular cancer, lung cancer, ovarian cancer and cancers of the blood (Hodgkin's and non-Hodgkin's lymphoma and acute myeloid leukaemia).

Vepesid contains the active substance etoposide and is available as capsules to be taken by mouth.

Vepesid is marketed in 16 EU member States (Austria, Belgium, Croatia, Denmark, Estonia, Finland, Germany, Ireland, Italy, Luxembourg, the Netherlands, Romania, Slovenia, Spain, Sweden and the United Kingdom) as well as in Norway. It is also available in the EU under the trade name Vepesid K.

The company that markets these medicines is Bristol-Myers Squibb.

Why was Vepesid reviewed?

Vepesid is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Vepesid was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

On 14 October 2015, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Vepesid in the EU.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs and package leaflets should be harmonised across the EU.

The areas of the SmPC harmonised include:

4.1 Therapeutic indications

The CHMP recommended that Vepesid should be used in combination with other cancer treatments to treat the following cancers in adults:

- testicular cancer that is resistant to treatment or has come back;
- small-cell lung cancer;
- Hodgkin's lymphoma as second-line treatment;
- non-Hodgkin's lymphoma that is resistant to treatment or has come back;
- acute myeloid leukaemia that is resistant to treatment or has come back;
- non-epithelial ovarian cancer.

In addition, the CHMP recommended Vepesid for treating epithelial ovarian cancer that is resistant to treatments with platinum-containing medicines, with no specification that it should be used in combination with other medicines.

4.2 Posology and method of administration

The dose of Vepesid is based on the recommended dose for the intravenous etoposide medicines, with a 100 mg oral dose being comparable to a 75 mg intravenous one.

The usual dose of Vepesid is 100 to 200 mg per m^2 of body surface area for 5 days in a row or 200 mg/m^2/day on days 1, 3 and 5 every 3 to 4 weeks.

Vepesid capsules should be taken on an empty stomach.

4.3 Contra-indications

Vepesid should not be taken at the same time as vaccination with yellow fever or other live vaccines in patients with weakened immune systems and should not be taken by breast-feeding women.

Other changes

Other sections of the SmPC harmonised include section 4.4 (special warnings and precautions), section 4.6 (fertility, pregnancy and lactation) and section 4.8 (undesirable effects).

The amended information to doctors and patients is available here.

The European Commission issued a decision on this opinion on 26/6/17.