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Questions and answers on Etopophos and associated names (etoposide, 100 and 1000 mg powder for solution for infusion)

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

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

What is Etopophos?

Etopophos is a cancer medicine used to treat: testicular cancer, lung cancer, ovarian cancer, gestational trophoblastic neoplasia (a rare tumour of the womb that occurs during pregnancy) and cancers of the blood (Hodgkin's and non-Hodgkin's lymphoma and acute myeloid leukaemia).

Etopophos contains the active substance etoposide (as etoposide phosphate) and is available as a powder to be made into a solution for infusion into a vein.

Etopophos is marketed in the following EU member States: France, Germany, Sweden and the United Kingdom. It is also available in the EU under the trade name Etopofos.

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

Why was Etopophos reviewed?

Etopophos 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.

Etopophos 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 Etopophos 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 Etopophos should be used in combination with other cancer treatments to treat the following cancers:

- testicular cancer, including cancer that is resistant to treatment or has come back;
- small-cell lung cancer;
- Hodgkin's and non-Hodgkin's lymphoma;
- acute myeloid leukaemia;
- high-risk gestational trophoblastic neoplasia as first- and second-line treatments;
- non-epithelial ovarian cancer.

In addition, the CHMP recommended Etopophos 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.

For blood cancers (Hodgkin's and non-Hodgkin's lymphoma and acute myeloid leukaemia), Etopophos is recommended for both adults and children, while its other uses are for adults only.

4.2 Posology and method of administration

Etopophos is given as a slow intravenous infusion. The recommended dose for adults is 50 to 100 mg per m^2 of body surface area for 5 days in a row or 100 to 120 mg/m^2 on days 1, 3 and 5. The course of treatment may be repeated but not sooner than 21 days after the start of the first course.

4.3 Contra-indications

Etopophos should not be administered during vaccination with yellow fever or other live vaccines in patients with weakened immune systems and should not be given to 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.