European Medicines Agency

Doc. Ref.: EMEA/356093/2009
EMEA/H/C/1031

Topotecan Actavis
topotecan

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Topotecan Actavis?
Topotecan Actavis is a powder to be made up into a solution for infusion (drip into a vein). It contains the active substance topotecan.
Topotecan Actavis is a 'generic medicine'. This means that Topotecan Actavis is similar to a 'reference medicine' already authorised in the European Union (EU) called Hycamtin. For more information on generic medicines, see the question-and-answer document here.

What is Topotecan Actavis used for?
Topotecan Actavis is an anticancer medicine.
It is used on its own to treat patients with small cell lung cancer, when the cancer has relapsed (come back). It is used when giving the original treatment again is not recommended.
It is also used together with cisplatin (another anticancer medicine) to treat women with cancer of the cervix, when the cancer has come back after radiotherapy, or when the disease is at an advanced stage (stage IVB: the cancer has spread beyond the cervix).
The medicine can only be obtained with a prescription.

How is Topotecan Actavis used?
Treatment with Topotecan Actavis should only be given under the supervision of a doctor experienced in the use of chemotherapy. Infusions should be carried out in a specialised cancer ward. The patient's blood levels of white blood cells, platelets and haemoglobin should be checked before treatment, to ensure that they are above set minimum levels. The doses may need to be adjusted or other medicines given to the patients, when the level of white blood cells remains particularly low.
The dose of Topotecan Actavis to be used depends on the type of cancer that it is being used to treat and the patient's weight and height. For lung cancer, Topotecan Actavis is given every day for five days with a three-week interval between the start of each course. Treatment may continue until the disease gets worse.
When used with cisplatin in cervical cancer, Topotecan Actavis is given as an infusion on days 1, 2 and 3 (with cisplatin given on day 1). This is repeated every 21 days for six courses or until the disease gets worse.
For full details, see the Summary of Product Characteristics (also part of the EPAR).

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How does Topotecan Actavis work?
The active substance in Topotecan Actavis, topotecan, is an anticancer medicine that belongs to the group 'topoisomerase inhibitors'. It blocks an enzyme called topoisomerase I, which is involved in the division of DNA. When the enzyme is blocked, the DNA strands break. This prevents the cancer cells from dividing and they eventually die. Topotecan Actavis also affects non-cancer cells, which causes side effects.

How has Topotecan Actavis been studied?
Because Topotecan Actavis is a generic medicine, the company has provided data from the published literature on topotecan. No additional studies were needed as Topotecan Actavis is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Hycamtin.

What are the benefit and risk of Topotecan Actavis?
Because Topotecan Actavis is a generic medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Topotecan Actavis been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Topotecan Actavis has been shown to be comparable to Hycamtin. Therefore, the CHMP's view was that, as for Hycamtin, the benefit outweighs the identified risk. The Committee recommended that Topotecan Actavis be given marketing authorisation.

Other information about Topotecan Actavis:
The European Commission granted a marketing authorisation valid throughout the EU for Topotecan Actavis to Actavis Group PTC ehf. on 24 July 2009.

The full EPAR for Topotecan Actavis can be found here.

This summary was last updated in 06-2009.