European Medicines Agency

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Topotecan Teva
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 Teva?
Topotecan Teva is a concentrate that is made up into a solution for infusion (drip into a vein). It contains the active substance topotecan.
Topotecan Teva is a 'generic medicine'. This means that Topotecan Teva 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 Teva used for?
Topotecan Teva is an anticancer medicine. It is used on its own to treat patients with:
- metastatic cancer of the ovary (when the cancer has spread to other parts of the body). It is used after at least one other treatment has failed;
- 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 cervical cancer (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 Teva used?
Treatment with Topotecan Teva 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 Teva to be used depends on the type of cancer that it is being used to treat and the patient's weight and height. Topotecan Teva is given as an infusion lasting 30 minutes 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 Teva is given 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).

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

How does Topotecan Teva work?
The active substance in Topotecan Teva, 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 Teva also affects non-cancer cells, which causes side effects.

How has Topotecan Teva been studied?
Because Topotecan Teva is a generic medicine, the company has provided data from the published literature on topotecan. No additional studies were needed as Topotecan Teva 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 Teva?
Because Topotecan Teva is a generic medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Topotecan Teva been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Topotecan Teva 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 Teva be given marketing authorisation.

Other information about Topotecan Teva:
The European Commission granted a marketing authorisation valid throughout the EU for Topotecan Teva to Teva Pharma B.V. on 21 September 2009.

The full EPAR for Topotecan Teva can be found here.
The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 09-2009.