EMEA/H/C/002261

EPAR summary for the public

Topotecan Eagle

topotecan

This is a summary of the European public assessment report (EPAR) for Topotecan Eagle. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Topotecan Eagle.

What is Topotecan Eagle?

Topotecan Eagle is a medicine that contains the active substance topotecan. It is available as a concentrate to be made up into a solution for infusion (drip into a vein).

Topotecan Eagle is a 'hybrid generic medicine'. This means that it is similar to a 'reference medicine' containing the same active substance. While the reference medicine, Hycamtin, is available as a powder to be made up into a concentrate, Topotecan Eagle is available as a ready-made concentrate. Topotecan Eagle also has a different (higher) strength from Hycamtin.

What is Topotecan Eagle used for?

Topotecan Eagle 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.

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How is Topotecan Eagle used?

Treatment with Topotecan Eagle 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 Eagle 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 Eagle 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 Eagle 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.

How does Topotecan Eagle work?

The active substance in Topotecan Eagle, 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 Eagle also affects non-cancer cells, which causes side effects.

How has Topotecan Eagle been studied?

The company provided data from the published literature on topotecan. No additional studies in patients were needed as Topotecan Eagle is given by infusion and contains the same active substance as the reference medicine, Hycamtin.

What are the benefits and risks of Topotecan Eagle?

Because Topotecan Eagle is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why has Topotecan Eagle been approved?

The CHMP concluded that, in accordance with EU requirements, Topotecan Eagle has been shown to have comparable quality and to be bioequivalent to Hycamtin. Therefore, the CHMP's view was that, as for Hycamtin, the benefit outweighs the identified risk. The Committee recommended that Topotecan Eagle be given marketing authorisation.

Other information about Topotecan Eagle

The European Commission granted a marketing authorisation valid throughout the European Union for Topotecan Eagle on 22 December 2011.

The full EPAR for Topotecan Eagle can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about

treatment with Topotecan Eagle, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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

This summary was last updated in 11-2011.