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EPAR summary for the public

Topotecan Hospira

topotecan

This document is a summary of the European Public Assessment Report (EPAR) for Topotecan Hospira. 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 Hospira.

What is Topotecan Hospira?

Topotecan Hospira is a concentrate that is made up into a solution for infusion (drip into a vein). It contains the active substance topotecan.

Topotecan Hospira is a 'hybrid medicine'. This means that Topotecan Hospira is similar to a 'reference medicine' already authorised in the European Union (EU). The reference medicine Hycamtin is available as a powder to be made up into a solution for infusion and not as a concentrate.

What is Topotecan Hospira used for?

Topotecan Hospira is used on its own to treat 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 Hospira used?

Treatment with Topotecan Hospira 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

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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 Hospira 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 Hospira 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 Hospira 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).

How does Topotecan Hospira work?

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

How has Topotecan Hospira been studied?

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

What are the benefit and risk of Topotecan Hospira?

Because Topotecan Hospira produces the same levels of the active substance in the body as the reference medicine, its benefit and risk are taken as being the same as the reference medicine's.

Why has Topotecan Hospira been approved?

The CHMP concluded that, in accordance with EU requirements, Topotecan Hospira 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 Hospira be given marketing authorisation.

Other information about Topotecan Hospira:

The European Commission granted a marketing authorisation valid throughout the EU for Topotecan Hospira on 10 June 2010.

The full EPAR for Topotecan Hospira 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 Hospira, 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 02-2015.