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EPAR summary for the public

Potactasol

topotecan

This is a summary of the European public assessment report (EPAR) for Potactasol. 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 Potactasol.

What is Potactasol?

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

Potactasol is a 'generic medicine'. This means that Potactasol 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 Potactasol used for?

Potactasol is a cancer 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 cancer 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 (the cancer has spread beyond the cervix).

The medicine can only be obtained with a prescription.

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

How is Potactasol used?

Treatment with Potactasol 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 dose of Potactasol to be used depends on the type of cancer that it is being used to treat and the patient's weight and height. When Potactasol is used on its own for ovarian cancer, it is given by infusion over 30 minutes. For both ovarian and lung cancer, Potactasol 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, Potactasol 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.

Doses of Potactasol may need to be adjusted or treatment delayed, depending on side effects. For full details, see the summary of product characteristics, also part of the EPAR.

How does Potactasol work?

The active substance in Potactasol, topotecan, is a cancer 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. Potactasol also affects non-cancer cells, which causes side effects.

How has Potactasol been studied?

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

What are the benefits and risks of Potactasol?

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

Why has Potactasol been approved?

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

Other information about Potactasol

The European Commission granted a marketing authorisation valid throughout the European Union for Potactasol to on 06 January 2011.

The full EPAR for Potactasol 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 Potactasol, 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 10-2015.