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EPAR summary for the public

Hycamtin

topotecan

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

What is Hycamtin?

Hycamtin is a cancer 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 and as capsules (0.25 and 1 mg).

What is Hycamtin used for?

Hycamtin 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 (has spread beyond the cervix).

The medicine can only be obtained with a prescription.

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How is Hycamtin used?

Treatment with Hycamtin 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 Hycamtin to be used depends on the type of cancer that it is being used to treat and the patient's weight and height. When Hycamtin is used on its own for ovarian cancer, it is given by intravenous infusion over 30 minutes. For lung cancer, Hycamtin can be given as an infusion or, for adults, as capsules. For both ovarian and lung cancer, Hycamtin 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, Hycamtin 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 Hycamtin 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 Hycamtin work?

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

How has Hycamtin been studied?

Hycamtin as an infusion has been studied in more than 480 women with ovarian cancer who had failed one treatment with platinum-containing cancer medicines. Three studies were 'open', meaning that the medicine was not compared to any other treatment and the patients knew that they were receiving Hycamtin. The fourth study involved 226 women, and compared Hycamtin with paclitaxel (another cancer medicine). The main measure of effectiveness was the number of patients whose tumours responded to treatment.

Hycamtin has also been studied in three main studies in 656 patients with relapsed small cell lung cancer. One study compared Hycamtin capsules with symptom control alone and another compared Hycamtin as an infusion with cyclophosphamide, doxorubicin and vincristine (a standard combination of chemotherapy). The third study compared Hycamtin given as an infusion and as capsules. The effectiveness was measured by looking at survival or response rates.

Hycamtin as an infusion has been studied in 293 women with advanced cervical cancer, where the effectiveness of a combination of Hycamtin and cisplatin was compared with that of cisplatin alone. The effectiveness was measured by looking at overall survival.

What benefit has Hycamtin shown during the studies?

In ovarian cancer, the studies showed the effectiveness of Hycamtin, with an overall response rate of about 16%. In the main study, 21% of the patients who received Hycamtin (23 out of 112) responded to treatment, compared with 14% of the paclitaxel patients (16 out of 114).

In lung cancer, looking at the results obtained in all three studies, the response rate was 20% (480 patients received Hycamtin). Compared with symptom control alone, Hycamtin prolonged survival by

12 weeks. It was as effective as the standard combination chemotherapy. Hycamtin given as capsules was as effective as Hycamtin given as an infusion.

In cervical cancer, patients receiving the combination of Hycamtin and cisplatin survived an average of 9.4 months, compared with 6.5 months for the patients who received cisplatin only.

What is the risk associated with Hycamtin?

The most common side effects with Hycamtin (seen in more than 1 patient in 10) are neutropenia (low white blood cell counts), febrile neutropenia (neutropenia with fever), thrombocytopenia (low platelet counts), anaemia (low red blood cell counts), leucopenia (low white blood cell counts), nausea (feeling sick), vomiting and diarrhoea (all of which may be severe), constipation, abdominal (tummy) pain, mucositis (mouth sores), alopecia (hair loss), loss of appetite (which may be severe), infections, pyrexia (fever), asthenia (weakness) and fatigue (tiredness).

Hycamtin must not be used in patients who are breast-feeding, or in patients who have severe bone marrow depression (low white blood cell and platelet counts) before treatment. For the full list of all side effects and restrictions with Hycamtin, see the package leaflet.

Why has Hycamtin been approved?

The CHMP decided that Hycamtin's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Hycamtin?

A risk management plan has been developed to ensure that Hycamtin is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Hycamtin, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Hycamtin

The European Commission granted a marketing authorisation valid throughout the European Union for Hycamtin on 12 November 1996.

The full EPAR for Hycamtin 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 Hycamtin read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2015.