European Medicines Agency

Doc. Ref.: EMEA/320256/2009
EMEA/H/C/216

Paxene
paclitaxel

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 of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

Medicinal product no longer authorised

What is Paxene?
Paxene is a concentrate that is made up into a solution for infusion (drip into a vein). It contains the active substance paclitaxel.

What is Paxene used for?
Paxene is an anticancer medicine. It is used for the treatment of the following types of cancer:
- advanced AIDS-related Kaposi's sarcoma (a skin cancer often found in AIDS patients), when treatment with anthracyclines (another type of anticancer medicine) has failed;
- metastatic breast cancer, when other treatments have failed or cannot be used. 'Metastatic' means that the cancer has spread to other parts of the body;
- advanced cancer of the ovary (when the cancer has started to spread out of the ovary), in combination with cisplatin (another anticancer medicine);
- metastatic cancer of the ovary, when other treatments such as platinum-containing combination therapy have failed;
- non-small cell lung cancer, in combination with cisplatin, when patients cannot have surgery or radiation therapy.

The medicine can only be obtained with a prescription.

How is Paxene used?
Treatment with Paxene should be given by an oncologist (cancer specialist) in a specialised cancer ward. To prevent severe allergic reactions, all patients must first be treated with corticosteroids to reduce inflammation, antihistamines to reduce swelling and itchiness, and H_2 antagonists to reduce stomach acid. Paxene is given as an infusion lasting three hours, or occasionally 24 hours. It is given using an infusion pump every two to three weeks. The dose of Paxene, how often it is given and how long treatment continues depend on the type of cancer being treated and which other anticancer medicines are being given together with Paxene. For more information, see the Package Leaflet.

How does Paxene work?
The active substance in Paxene, paclitaxel, belongs to the group of anticancer medicines known as the taxanes. Paclitaxel blocks the cell's ability to break down the 'skeleton' that allows cells to divide and multiply. With the skeleton still in place the cell cannot divide, and eventually die. Paxene also affects non-cancer cells such as blood cells, which causes side effects.

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

© European Medicines Agency, 2009. Reproduction is authorised provided the source is acknowledged.

How has Paxene been studied?
As Paxene is very similar to another authorised medicine containing paclitaxel called Taxol, the studies supporting the use of Taxol were used to support the use of Paxene. The company also used data published in scientific journals.
Paxene has been studied in 107 patients with Kaposi's sarcoma, 312 patients with metastatic breast cancer, 120 patients with metastatic ovarian cancer, over 900 patients with advanced ovarian cancer and over 1,000 patients with lung cancer. In the studies, Paxene was used with other anticancer medicines and compared with other treatments. The main measures of effectiveness were the number of patients whose cancer responded to treatment, how long the patients lived without their disease getting worse and how long they survived.

What benefit has Paxene shown during the studies?
Treatment with Paxene improved the response rates for various types of cancer. In some cases, these were significantly better than with standard anticancer therapy. Paxene also increased how long patients survived for some types of cancer. The results of these studies were used to draw up the recommendations on how the medicine should be used.

What is the risk associated with Paxene?
The most common side effects with Paxene (seen in more than 1 patient in 10) are infection, severe neutropenia (very low levels of neutrophils, a type of white blood cell), severe leucopenia (very low white blood cell counts), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts), myelosuppression (a condition when the bone marrow cannot make enough blood cells), minor hypersensitivity reactions (allergic reactions), loss of appetite, neuropathy (nerve damage), paraesthesia (unusual sensations like pins and needles), somnolence (sleepiness), hypotension (low blood pressure), nausea (feeling sick), vomiting, diarrhoea, mucosal inflammation (inflammation of the moist body surfaces), constipation, stomatitis (inflammation of the lining of the mouth), abdominal (tummy) pain, alopecia (hair loss), arthralgia (joint pain), myalgia (muscle pain), asthenia (weakness), pain and oedema (swelling). For the full list of all side effects reported with Paxene, see the Package Leaflet.
Paxene should not be used in people who may be hypersensitive (allergic) to paclitaxel or any of the other ingredients. Paxene must not be used in patients with severe liver disease, severe uncontrolled infections or low levels of neutrophils. It must not be used in women who are pregnant or breast-feeding.

Medicinal product no longer authorised

Why has Paxene been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Paxene's benefits are greater than its risks for treatment of advanced AIDS-related Kaposi's sarcoma, metastatic breast cancer, advanced cancer of the ovary in combination with cisplatin, metastatic cancer of the ovary where platinum-containing combination therapy has failed, and non-small cell lung cancer. The Committee recommended that Paxene be given marketing authorisation.

Other information about Paxene:
The European Commission granted a marketing authorisation valid throughout the European Union for Paxene to Norton Healthcare Limited on 19 July 1999. The marketing authorisation was renewed on 19 July 2004 and on 19 July 2009.

The full EPAR for Paxene is available here.

This summary was last updated in 07-2009.