EMA/99258/2015
EMEA/H/C/000778

EPAR summary for the public

Abraxane

paclitaxel

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

What is Abraxane?

Abraxane is a powder that is made up into a suspension for infusion (drip) into a vein. It contains the active substance paclitaxel attached to a human protein called albumin.

What is Abraxane used for?

Abraxane is used to treat the following cancers in adults:

- metastatic breast cancer, when the first treatment has stopped working and standard treatment including an 'anthracycline' (another type of cancer medicine) is not suitable. 'Metastatic' means that the cancer has spread to other parts of the body.
- metastatic adenocarcinoma of the pancreas, as a first treatment in combination with another cancer medicine, gemcitabine.
- non-small cell lung cancer, as a first treatment in combination with the cancer medicine carboplatin when the patient cannot have surgery or radiotherapy.

The medicine can only be obtained with a prescription.

How is Abraxane used?

Abraxane should only be given under the supervision of a specialist cancer doctor in units that are specialised in giving 'cytotoxic' (cell-killing) medicines. It should not be interchanged with other medicines containing paclitaxel.

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Abraxane is given into a vein over a period of 30 minutes.

In metastatic breast cancer Abraxane is given on its own every three weeks. The recommended dose is 260 mg per square metre of body surface area (calculated using the patient's height and weight).

In metastatic adenocarcinoma of the pancreas Abraxane is given in 4-week treatment cycles. The recommended dose is 125 mg per square metre of body surface area once a day on days 1, 8 and 15 of each cycle. Immediately after giving Abraxane gemcitabine should be given at a dose of 1000 mg per square metre of body surface area.

In non-small cell lung cancer, treatment is carried out in 3-week cycles with Abraxane given on days 1, 8 and 15 of each cycle and carboplatin given on day 1 immediately after Abraxane. The recommended dose of Abraxane is 100 mg per square metre of body surface area.

For additional information, see the summary of product characteristics (also part of the EPAR).

How does Abraxane work?

The active substance in Abraxane, paclitaxel, belongs to the group of cancer medicines known as the 'taxanes'. Paclitaxel blocks a stage of cell division in which the cell's internal 'skeleton' is dismantled to allow the cell to divide. By keeping this structure intact the cells cannot divide and they eventually die. Abraxane also affects non-cancer cells such as blood and nerve cells, which can cause side effects.

Paclitaxel has been available as a cancer medicine since 1993. In Abraxane, unlike conventional paclitaxel-containing medicines, the paclitaxel is attached to a human protein called albumin in tiny particles known as 'nanoparticles'. This makes it easy to prepare a suspension of paclitaxel, which can be infused into a vein.

How has Abraxane been studied?

For metastatic breast cancer, Abraxane has been studied in one main study involving 460 women, around three-quarters of whom had received an anthracycline in the past. Around half of the patients in the study had already received treatments for their cancer after it had become metastatic. Abraxane given on its own was compared with a conventional paclitaxel-containing medicine given together with other medicines to reduce side effects. The main measure of effectiveness was the number of patients who 'responded' after at least five weeks of treatment. A response was defined as the patient's main tumours disappearing or shrinking in size by at least 30%.

For metastatic adenocarcinoma of the pancreas, Abraxane was studied in one main study involving 861 patients who received either Abraxane in combination with gemcitabine or gemcitabine alone. The main measure of effectiveness was how long patients lived.

For non-small cell lung cancer, the Abraxane-carboplatin combination was compared with a combination of a conventional paclitaxel-containing medicine and carboplatin in 1,052 patients. The main measure of effectiveness was the percentage of patients who responded to treatment.

What benefit has Abraxane shown during the studies?

In metastatic breast cancer, Abraxane was more effective than conventional paclitaxel-containing medicines. Overall, in the main study, 31% of the women receiving Abraxane responded to treatment (72 out of 229), compared with 16% of the women receiving conventional paclitaxel-containing medicines (37 out of 225).

When looking only at the patients who were receiving their first treatment for metastatic breast cancer, there was no difference between the medicines in terms of measures of effectiveness such as the time until the disease got worse and survival. In contrast, Abraxane was more effective than conventional paclitaxel-containing medicines in patients who had taken other treatments for metastatic breast cancer before. Therefore, the company withdrew its application for the use of Abraxane as first-line treatment during the assessment of the medicine.

In metastatic adenocarcinoma of the pancreas, Abraxane was shown to improve overall survival. Patients survived for around 8.5 months on treatment with the combination of Abraxane and gemcitabine, compared with 6.7 months on gemcitabine alone.

In non-small cell lung cancer, 33% of patients receiving Abraxane and carboplatin responded to treatment compared with 25% of those receiving conventional paclitaxel and carboplatin.

What is the risk associated with Abraxane?

The most common important side effects with Abraxane (seen in more than 1 patient in 10) are neutropenia (low levels of neutrophils, a type of white blood cells), gastrointestinal disorders (disorders of the digestive system), peripheral neuropathy (nerve damage including damage to the nerves in the hand and feet), arthralgia (joint pain) and myalgia (muscle pain). For the full list of all side effects reported with Abraxane, see the package leaflet.

Abraxane must not be used in patients who are breast-feeding or who have low levels of neutrophils in the blood before starting treatment. For the full list of restrictions with Abraxane, see the package leaflet.

Why has Abraxane been approved?

The CHMP noted that Abraxane was more effective than conventional paclitaxel-containing medicines in patients with metastatic breast cancer whose first treatment had stopped working, and that, unlike other paclitaxel-containing medicines, patients to be treated with Abraxane do not need pre-treatment with other medicines to prevent hypersensitivity reactions. In addition, Abraxane given in combination with gemcitabine was shown to improve survival in patients with metastatic adenocarcinoma of the pancreas compared with treatment with gemcitabine alone and was effective in combination with carboplatin in the treatment non-small cell lung cancer. The Committee decided that Abraxane'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 Abraxane?

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

Other information about Abraxane

The European Commission granted a marketing authorisation valid throughout the European Union for Abraxane on 11 January 2008.

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

This summary was last updated in 02-2015.