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EPAR summary for the public

Savene

dexrazoxane

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

What is Savene?

Savene is a powder and diluent that are made up into a solution for infusion (drip into a vein). It contains the active substance dexrazoxane.

What is Savene used for?

Savene is used to treat extravasation of anthracyclines (a group of anticancer medicines). Extravasation happens when an anticancer medicine that is normally injected into a vein leaks or is accidentally injected in the tissue surrounding the vein, where it can cause serious damage.

Because the number of patients who have extravasation of anthracyclines is low, the condition is considered 'rare', and Savene was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 September 2001.

The medicine can only be obtained with a prescription.

How is Savene used?

Savene must be used under the supervision of a doctor who has experience in the use of anticancer medicines.

The first infusion of Savene is given as soon as possible after the accident, and no later than six hours after it happened. Two further infusions are then given, one on day 2 and another on day 3, at the

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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same time as the first infusion. The infusion should last between one and two hours, and be given at a site other than where the extravasation happened.

How does Savene work?

The active substance in Savene, dexrazoxane, is an antidote to anthracyclines. The way it works is not entirely clear, but may be linked to the way the medicine attaches to iron in the body to form a 'chelate' and to its effect on some enzymes, such as topoisomerase II. Together, these effects can reduce the amount of tissue damage caused by anthracycline extravasation.

Dexrazoxane has been in use since the 1990s as a medicine to help prevent the cardiomyopathy (harm to the heart muscle) associated with the use of anthracyclines.

How has Savene been studied?

Savene has been tested in two main studies involving a total of 80 patients who had extravasation of anthracyclines such as epirubicin or doxorubicin. Savene was not compared with any other medicines in these studies. The studies looked at how many patients needed surgery to correct the damage due to the extravasation.

What benefit has Savene shown during the studies?

Only one patient among the 54 in whom the effectiveness of Savene could be measured had tissue damage requiring surgery.

What is the risk associated with Savene?

The most common side effects with Savene (seen in more than 1 patient in 10) are nausea (feeling sick), and pain and infection at the site of the injection. Patients can also develop low blood levels of white blood cells and platelets. Although this may be caused by their anti-cancer treatment, it can also be caused by Savene, because it is a cytotoxic (a medicine that destroys cells that are multiplying) that can affect the bone marrow. Patients will be monitored for these side effects before, during and after treatment. For the full list of all side effects reported with Savene, see the package leaflet.

Savene should not be used in people who may be hypersensitive (allergic) to dexrazoxane or any of the other ingredients. It must not be used in women who could become pregnant or who are breastfeeding, or in patients receiving vaccination against yellow fever.

Why has Savene been approved?

Anthracycline extravasation is a condition that can currently be managed using various methods, but for which there is no standard authorised treatment. The CHMP concluded that Savene had shown its ability to treat anthracycline extravasation, allowing patients to continue their anticancer treatment. The Committee decided that Savene's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Savene:

The European Commission granted a marketing authorisation valid throughout the European Union for Savene on 28 July 2006.

The full EPAR for Savene can be found here. For more information about treatment with Savene, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Savene is available here.

This summary was last updated in 08-2011.