EMA/813620/2015
EMEA/H/C/001089

EPAR summary for the public

Zutectra

human hepatitis-B immunoglobulin

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

What is Zutectra?

Zutectra is a solution for injection. It is available as a prefilled syringe containing 500 international units (IU) of the active substance, human hepatitis B immunoglobulin.

What is Zutectra used for?

Zutectra is used in adults who have had a liver transplant because of liver failure that was caused by hepatitis B infection. Zutectra is used to prevent re-infection with the hepatitis B virus in patients without active infection (i.e. those who test negative for the presence of the hepatitis B protein (HBsAg) and for hepatitis B DNA (HBV-DNA)). The use of standard antiviral medicines to prevent hepatitis B re-infection should be considered together with Zutectra.

The medicine can only be obtained with a prescription.

How is Zutectra used?

Zutectra is given as an injection under the skin once a week or every 2 weeks. The recommended dose normally ranges from 500 IU to 1,000 IU, and exceptionally up to 1,500 IU. The dose is established based on the patient's blood levels of antibodies against the hepatitis B virus.

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

Zutectra treatment starts at least one week after the liver transplant. Before starting Zutectra, the patient will need to receive medicines that contain the same active substance as in Zutectra, but given into a vein.

Zutectra injections can be given by the patients themselves or their caregiver once they have been trained appropriately. The patient or caregiver will also be trained on how to keep a treatment diary and what to do if severe side effects occur. For full details, see the summary of product characteristics (also part of the EPAR).

How does Zutectra work?

The active substance in Zutectra, human hepatitis B immunoglobulin, is a purified antibody extracted from human blood. Antibodies are proteins naturally found in the blood that help the body to fight infections and other diseases. Zutectra prevents the patient from being re-infected with hepatitis B by keeping the blood levels of human hepatitis B immunoglobulins high enough, so that they can attach to the virus and stimulate the immune system to destroy it.

How has Zutectra been studied?

Zutectra has been studied in one main study involving 30 adults who had undergone liver transplants. Zutectra treatment was started at least three months after the liver transplant. The main measure of effectiveness was the number of patients who had a blood level of hepatitis B immunoglobulin above 100 IU per litre after 18 to 24 weeks. This level is considered adequate to protect against re-infection with the hepatitis B virus.

In another study in 49 patients, Zutectra was given at least one week (approximately 8-11 days) after the liver transplant. The main measure of effectiveness was the number of patients in whom treatment failed, defined as blood levels of hepatitis B immunoglobulins falling below 100 IU per litre or re-infection by hepatitis B virus during the 24 weeks of treatment.

What benefit has Zutectra shown during the studies?

Zutectra has been shown to be effective at maintaining antibody levels required to protect against hepatitis B re-infection.

In the first study, all 23 of the patients who completed treatment had antibody levels above 100 IU per litre. In the second study, all of the 49 patients had antibody levels above 100 IU per litre and none of them was re-infected during the 24 weeks of treatment.

What is the risk associated with Zutectra?

The most common side effects with Zutectra (seen in between 1 and 10 patients in 100) are reactions at the injection site, such as pain, urticaria (itchy rash), haematoma (blood under the skin) and erythema (reddening of the skin). For the full list of all side effects reported with Zutectra, see the package leaflet.

Zutectra must not be used in people who are hypersensitive (allergic) to the active substance, to any of the other ingredients or to human immunoglobulins. Zutectra must not be given into a blood vessel.

Why has Zutectra been approved?

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

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

A risk management plan has been developed to ensure that Zutectra 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 Zutectra, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Zutectra

The European Commission granted a marketing authorisation valid throughout the EU for Zutectra on 30 November 2009.

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

This summary was last updated in 12-2015.