EMA/505468/2015
EMEA/H/C/002784

EPAR summary for the public

Zalviso

sufentanil

This is a summary of the European public assessment report (EPAR) for Zalviso. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Zalviso.

For practical information about using Zalviso, patients should read the package leaflet or contact their doctor or pharmacist.

What is Zalviso and what is it used for?

Zalviso is an opioid (a strong painkiller) that is used to treat pain occurring in adults after an operation. It contains the active substance sufentanil.

Zalviso is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, but Zalviso is available in a different form. The reference medicine for Zalviso is called Sufenta Forte, and is available as a solution for injection, whereas Zalviso is available as sublingual tablets (tablets to be dissolved under the tongue).

How is Zalviso used?

Zalviso is available as sublingual tablets containing 15 micrograms of sufentanil. The tablets are only for use in hospital and can only be obtained with a prescription from a doctor experienced in treating patients with opioids.

The patient places the Zalviso tablets under their tongue when needed using a special device. The device locks for 20 minutes after the patient has taken a tablet and does not allow the patient to take more than 3 doses in one hour. The device also uses an identifier so that only the patient who has been given a special thumb tag can release tablets. The tablets must be allowed to dissolve under the tongue and must not be chewed or swallowed. Treatment is continued over a period of up to 72 hours.

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For further information, see the package leaflet.

How does Zalviso work?

The active substance in Zalviso, sufentanil, is an opioid. It is a well-known substance, which has been used to control pain for many years. When the patient places a Zalviso tablet under the tongue, a dose of sufentanil is rapidly absorbed into the blood stream through the blood vessels in the lining of the mouth. This allows the medicine to be transported to receptors in the brain and spinal cord where sufentanil acts to relieve pain.

What benefits of Zalviso have been shown in studies?

Because Zalviso is a hybrid generic, the applicant presented data on the reference medicine in addition to results from its own studies.

One main study involved 178 patients who had abdominal surgery (surgery on the belly) and another involved 426 patients who had surgery on the knee or hip. In both cases Zalviso was compared with placebo (a dummy treatment). The main measure of effectiveness was based on a patient score that measured the decrease in intensity of pain over 48 hours of treatment. For abdominal surgery, the average decrease in pain intensity was 50 points greater with Zalviso than with placebo (106 versus 56). For knee and hip surgery the decrease in pain intensity was around 88 points greater with Zalviso (76 versus -11) than with placebo.

A third main study compared Zalviso with a patient-controlled pain relief system using morphine, another opioid, and involved 359 patients who had undergone major abdominal, knee or hip surgery. Of 177 patients using Zalviso, 139 rated their pain control as excellent or good (79%), compared with 118 of 180 (66%) using morphine.

What are the risks associated with Zalviso?

The most common side effects with Zalviso (which may affect more than 1 in 10 people) are nausea (feeling sick) and vomiting. The most serious side effect is respiratory depression (impaired breathing) which could potentially lead to the patient stopping breathing altogether. Zalviso must not be used in patients who already have significant impaired breathing.

For the full list of side effects and restrictions with Zalviso, see the package leaflet.

Why is Zalviso approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Zalviso's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee considered that an additional option for patient-controlled pain relief immediately after surgery, when the pain is worst, was beneficial, especially since it did not need to be given into a vein. Regarding safety, the side effects were those expected of opioids, and were considered manageable. However, considering the fact that post-operative pain improves by itself over time as well as the potential for addiction or the body becoming used to the opioid and requiring larger doses, the medicine and its administration device should only be used in a hospital setting, and restricted to use for a maximum duration of 72 hours.

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

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

Further information can be found in the summary of the risk management plan.

Other information about Zalviso

The European Commission granted a marketing authorisation valid throughout the European Union for Zalviso on 18 September 2015.

The full EPAR and risk management plan summary for Zalviso 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 Zalviso, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2015.