EMA/497953/2020
EMEA/H/C/005205

Zynrelef (*bupivacaine / meloxicam*)

An overview of Zynrelef and why it is authorised in the EU

What is Zynrelef and what is it used for?

Zynrelef is a painkiller used in adults to reduce pain from small to medium-sized wounds after an operation. It contains the active substances bupivacaine and meloxicam.

How is Zynrelef used?

Zynrelef is a prolonged-release solution that is applied to the wound during surgery before the wound is closed. Prolonged-release means that the active substances are released slowly over several hours after application.

The medicine can only be obtained with a prescription and it should be used in a setting (such as a hospital) where trained staff and equipment are available to treat patients who get side effects involving the heart or central nervous system.

For more information about using Zynrelef, see the package leaflet or contact your doctor or pharmacist.

How does Zynrelef work?

Bupivacaine is a local anaesthetic which temporarily numbs the area to which it has been applied by blocking pain signals to the brain. Meloxicam, a non-steroidal anti-inflammatory drug (NSAID), reduces pain and inflammation and strengthens the effect of bupivacaine.

What benefits of Zynrelef have been shown in studies?

Two main studies in 830 patients have shown that Zynrelef is effective at reducing pain from small to medium-sized wounds following surgery. The main measure of effectiveness was a total pain score for a 72-hour period, with lower scores indicating better pain control.

In the first study involving patients who had surgery to remove a bunion, the pain score in patients treated with Zynrelef was 323 compared with 445 for patients receiving placebo (a dummy treatment) and 393 for patients receiving bupivacaine (standard treatment). In the second study involving patients who had surgery to repair a hernia, the pain score was 269 with Zynrelef compared with 351

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for patients receiving placebo and 342 for patients receiving bupivacaine. In both these studies Zynrelef had some effect in reducing the use of opioid pain medication after surgery.

What are the risks associated with Zynrelef?

The most common side effect with Zynrelef (which may affect more than 1 in 10 people) is dizziness.

Zynrelef should not be used in patients with hypersensitivity (allergy) to the active substances or to any amide-type local anaesthetic or an NSAID including acetylsalicylic acid (also known as aspirin). The medicine should also not be used in women during the last 3 months of pregnancy, in patients who have undergone certain heart surgeries or who have severe heart failure (when the heart does not pump as well as it should), poor liver function or severe kidney failure (inability of the kidneys to work properly) that is not being treated with dialysis (to remove unwanted fluids and substances from the blood).

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

Why is Zynrelef authorised in the EU?

Zynrelef has been shown to provide effective pain relief from small to medium-sized wounds after surgery. Its effect on reducing the need for opioid pain relief was considered modest but clinically significant. The medicine's side effects are similar to those of bupivacaine alone and are considered manageable. The European Medicines Agency therefore decided that Zynrelef's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Zynrelef have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Zynrelef are continuously monitored. Side effects reported with the medicine are carefully evaluated and any necessary action taken to protect patients.

Other information about Zynrelef

Zynrelef received a marketing authorisation valid throughout the EU on 24 September 2020.

Further information on Zynrelef can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zynrelef.

This overview was last updated in 09-2020.