EMA/781370/2022
EMEA/H/C/004586

Exparel liposomal (*bupivacaine*)

An overview of Exparel liposomal and why it is authorised in the EU

What is Exparel liposomal and what is it used for?

Exparel liposomal is a local anaesthetic that is used to treat pain after certain operations. It can be used in adults and children aged 6 years or older for local pain relief by injecting it around the edges of small to medium-sized surgical wounds. It is also used in adults for regional pain relief by injecting it around the nerves that supply the lower limbs or the shoulder. Exparel liposomal contains the active substance bupivacaine.

How is Exparel liposomal used?

Exparel liposomal is injected either around the edges of small to medium-sized surgical wounds or around the nerve supplying the operation site in the leg or shoulder area. The dose depends on the size of the operation site and the area that needs to be numbed, and the patient's physical condition.

Exparel liposomal should be given in a setting where trained personnel and appropriate resuscitation equipment are available to promptly treat patients in case they develop side effects of the heart and nervous system.

The medicine can only be obtained with a prescription. For more information about using Exparel liposomal, see the package leaflet or contact your doctor or pharmacist.

How does Exparel liposomal work?

The active substance in Exparel liposomal, bupivacaine, is an anaesthetic that temporarily numbs the area to which it has been applied by blocking pain signals to the brain.

Bupivacaine has been available since the 1960s. In Exparel liposomal, it is enclosed in 'liposomes' (tiny fat particles) which release bupivacaine slowly.

What benefits of Exparel liposomal have been shown in studies?

Four studies in 703 adults have shown that Exparel liposomal is effective at reducing pain scores when used for local pain relief around small to medium sized surgical wound sites and for regional pain relief in the surgery of the knee and around the shoulders.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

For local pain relief, patients given Exparel liposomal after an operation for haemorrhoids (piles) had a total pain score for a 3-day period of 142, compared with 203 for patients given placebo (a dummy treatment). In patients who had an operation to remove bunions, the total pain score for a 1-day period was 124 for Exparel liposomal compared with 146 for placebo.

For regional pain relief, patients given Exparel liposomal after knee replacement operation had a total pain score for a 3-day period of 419, compared with 516 for patients given placebo. In patients who had a shoulder joint replacement operation, the total pain score for a 2-day period was 136 for Exparel liposomal compared with 254 for placebo.

In one main study, 65 children from 6 to 16 years of age undergoing spine or cardiac surgery received Exparel liposomal. The study showed that the way Exparel liposomal is absorbed, modified and removed from the body is similar in children and adults. Based on these data, it can be concluded that at the dose tested, Exparel liposomal will have comparable effects across these age groups when used for local pain relief around small to medium-sized surgical wound sites.

What are the risks associated with Exparel liposomal?

The most common side effects with Exparel liposomal (which may affect more than 1 in 20 people) in adults are dysgeusia (taste disturbances) and oral hypoaesthesia (reduced sensation in the mouth). In children, anaemia (low levels of red blood cells), hypotension (low blood pressure), tachycardia (rapid heartbeat), vomiting, constipation, nausea, pruritus (itching) and muscle twitching may occur in more than 1 in 10 people.

The most important serious side effects are convulsions (fits), serious dysrhythmia (irregular heartbeat), serious hypotension (low blood pressure) and cardiac arrest.

Exparel liposomal must not be used in patients who are hypersensitive (allergic) to any of the ingredients of the medicine or to other local anaesthetics with a chemical structure related to the active ingredients (amide-type local anaesthetics). It must not be used as paracervical block anaesthesia (local anaesthetic injected at the top of the vagina) and must not be given by injection into a blood vessel or a joint.

For the full list of restrictions, see the package leaflet.

Why is Exparel liposomal authorised in the EU?

The European Medicines Agency decided that Exparel liposomal's benefits are greater than its risks and it can be authorised for use in the EU. Studies showed that Exparel liposomal was effective at managing pain after different surgical procedures. The safety profile was considered acceptable.

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

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

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

Other information about Exparel liposomal

Exparel liposomal received a marketing authorisation valid throughout the EU on 16 November 2020.

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

This overview was last updated in 10-2022.