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EPAR summary for the public

Nevanac

nepafenac

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

What is Nevanac?

Nevanac is an eye drop suspension that contains the active substance nepafenac (1 and 3 mg/ml).

What is Nevanac used for?

Nevanac is used in adults to prevent and treat the pain and inflammation that can occur after an operation to remove a cataract from the eye.

Nevanac is also used to reduce the risk of macular oedema (swelling in the macula, the central part of the retina at the back of the eye) that can occur after cataract surgery in adult diabetes patients.

The medicine can only be obtained with a prescription.

How is Nevanac used?

One drop of Nevanac is given into the affected eye(s), either three times a day with the 1 mg/ml strength, or once a day if using the 3 mg/ml strength. Treatment should begin one day before the cataract operation. Treatment is continued after the operation for 2 to 3 weeks when used to prevent pain and inflammation, or up to 60 days when used to reduce the risk of macular oedema. An extra drop should be given 30 to 120 minutes before the operation begins. If other eye medicines are also being used, there should be a gap of at least five minutes between using each medicine.

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How does Nevanac work?

The active substance in Nevanac, nepafenac, is a 'prodrug' of amfenac. This means that it is converted into amfenac in the eye. Amfenac is a non-steroidal anti-inflammatory drug (NSAID). It works by blocking an enzyme called cyclo-oxygenase, which produces prostaglandins, substances that are involved in the inflammation process. By reducing the production of prostaglandins in the eye, Nevanac can reduce complications caused by eye surgery, such as inflammation, pain and swelling.

How has Nevanac been studied?

For the prevention and treatment of pain and inflammation, Nevanac 1 mg/ml has been studied in four main studies involving a total of 1,201 patients undergoing cataract surgery. One study compared Nevanac 1 mg/ml used once, twice or three times a day with placebo (dummy eye drops) in 220 patients. Another three studies, in a total of 981 patients, compared Nevanac used three times a day, either with placebo, with ketorolac eye drops (another NSAID) or with both placebo and ketorolac. The main measure of effectiveness was either the proportion of patients in whom treatment had been successful (with no or few signs of inflammation in the eye), or the proportion of patients whose treatment had failed (with signs of moderate or severe inflammation in the eye). These were measured two weeks after surgery.

The company also carried out studies to show that Nevanac 3 mg/ml given once a day was more effective than placebo and had the same effect in preventing and treating pain and inflammation as Nevanac 1 mg/ml given three times a day.

For reducing the risk of macular oedema, Nevanac has been compared with placebo in three main studies involving 1483 diabetes patients with retinopathy (damage to the retina) undergoing cataract surgery. The first main study used Nevanac 1 mg/ml whereas the other 2 main studies used Nevanac 3 mg/ml. The main measure of effectiveness was the number of patients who developed macular oedema within 90 days of surgery.

What benefit has Nevanac shown during the studies?

Nevanac was more effective than placebo and as effective as ketorolac in reducing signs of inflammation. In the study comparing different numbers of drops daily, the patients using Nevanac 1 mg/ml three times a day had the lowest failure rate. When Nevanac was compared with placebo, around 70% of the patients using Nevanac had no signs of inflammation after two weeks, compared with 17% to 59% of those using placebo. In the study comparing Nevanac with ketorolac, around 65% of both groups of patients showed no or few signs of inflammation.

In diabetes patients, Nevanac was more effective than placebo in reducing the risk of macular oedema. In the first study, 3.2% of patients taking Nevanac 1 mg/ml developed macular oedema (4 out of 125), compared with 16.7% of patients taking placebo (21 out of 126). In the second and third study, 2.3% and 5.9% of patients taking Nevanac 3 mg/ml developed macular oedema, respectively, compared with between 17.3% and 14.3% of patients taking placebo.

What is the risk associated with Nevanac?

The most common side effects with Nevanac (seen in up to 1 in 100 patients) are inflammation of the surface of the eye, defects in the cornea, the sensation of a foreign body in the eye, and crust forming at edge on the eyelids. For the full list of all side effects reported with Nevanac, see the package leaflet.

Nevanac must not be used in people who are hypersensitive (allergic) to nepafenac, to any of the other ingredients or to other NSAIDs. Like other NSAIDs, Nevanac must not be used in patients who have previously had an attack of asthma, hives or inflammation of the nasal passages when they take aspirin or other NSAIDs. Nevanac contains benzalkonium chloride, which is known to discolour soft contact lenses. Additionally, contact lens wear is not recommended during the postoperative period following cataract surgery. Therefore, patients should be advised not to wear contact lenses during treatment with Nevanac.

Why has Nevanac been approved?

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

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

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

Other information about Nevanac

The European Commission granted a marketing authorisation valid throughout the European Union for Nevanac on 11 December 2007.

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

This summary was last updated in 07-2016.