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Dynastat (*parecoxib*)

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

What is Dynastat and what is it used for?

Dynastat is a painkilling medicine for use in adults for the short-term relief of pain after an operation.

It contains the active substance parecoxib.

How is Dynastat used?

Dynastat is available as an injection and it can only be obtained with a prescription.

Dynastat can be given into a vein or a muscle. The first dose of 40 mg is followed by further doses of 20 or 40 mg every 6 to 12 hours, up to a maximum total dose of 80 mg a day.

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

How does Dynastat work?

The active substance in Dynastat, parecoxib, is converted to valdecoxib in the body. Valdecoxib is a non-steroidal anti-inflammatory drug (NSAID) that belongs to the group of medicines called cyclo-oxygenase-2 (COX-2) inhibitors. It blocks the COX-2 enzyme, resulting in reduced production of prostaglandins, substances that are involved in inflammation. By reducing prostaglandins, Dynastat helps to reduce the symptoms of inflammation, including pain.

What benefits of Dynastat have been shown in studies?

Dynastat was studied in over 2,500 adults who had surgical procedures including dental, orthopaedic (bone) and gynaecological surgery (surgery on the female reproductive system). Dynastat was compared with placebo (a dummy treatment) as well as with other painkillers such as ibuprofen, ketorolac, morphine, tramadol and valdecoxib. Dynastat was generally more effective than placebo and as effective as other painkillers. Dynastat also reduced the need for morphine.

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What are the risks associated with Dynastat?

The most common side effect with Dynastat (which may affect more than 1 in 10 people) is nausea (feeling sick). The most serious side effects (which may affect fewer than 1 in 100 people) include myocardial infarction (heart attack), severe reduction in blood pressure and allergic reactions.

Dynastat must not be used in patients who have had a serious allergic reaction to a medicine, have allergies to a class of medicines called sulfonamides or have certain illnesses including those affecting the gastrointestinal system, liver and heart. Women must not be given Dynastat during the last 3 months of pregnancy or if they are breast-feeding. It must not be used to relieve pain after certain types of heart surgery.

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

Why is Dynastat authorised in the EU?

Dynastat was found effective for relieving pain after surgery and its side effects are manageable.

The European Medicines Agency therefore decided that Dynastat'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 Dynastat?

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

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

Other information about Dynastat

Dynastat received a marketing authorisation valid throughout the EU on 22 March 2002.

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

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