

Summary Public Assessment Report

Paracetamol/Ibuprofen Vale Pharma (paracetamol/ibuprofen)

SE/H/1948/01/DC

Summary Public Assessment Report

Paracetamol/Ibuprofen Vale Pharma
ibuprofen sodium dihydrate, paracetamol

This is a summary of the public assessment report (PAR) for Paracetamol/Ibuprofen Vale Pharma. It explains how Paracetamol/Ibuprofen Vale Pharma was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Paracetamol/Ibuprofen Vale Pharma.

For practical information about using Paracetamol/Ibuprofen Vale Pharma, patients should read the package leaflet or contact their doctor or pharmacist.

What is Paracetamol/Ibuprofen Vale Pharma and what is it used for?

Paracetamol/Ibuprofen Vale Pharma is used in the short-term treatment of acute moderate pain in adults, where an intravenous route of administration is necessary.

How does Paracetamol/Ibuprofen Vale Pharma work?

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). Paracetamol works in a different way to ibuprofen, however both substances work together to reduce pain. The mechanism of analgesic action of paracetamol is not clearly defined, it appears that it induces analgesia by elevation of the pain threshold.

How is Paracetamol/Ibuprofen Vale Pharma used?

The pharmaceutical form of Paracetamol/Ibuprofen Vale Pharma is solution for infusion (for intravenous administration).

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Paracetamol/Ibuprofen Vale Pharma have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Paracetamol/Ibuprofen Vale Pharma is effective in treating “*adults for the short-term symptomatic treatment of acute moderate pain, where an intravenous route of administration is considered clinically necessary and/or when other routes of administration are not possible*”.

What are the possible side effects of Paracetamol/Ibuprofen Vale Pharma?

For the full list of all side effects reported with Paracetamol/Ibuprofen Vale Pharma, see section 4 of the package leaflet.

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

Why is Paracetamol/Ibuprofen Vale Pharma approved?

It was noted that the effect of Paracetamol/Ibuprofen Vale Pharma in the treatment of “*adults for the short-term symptomatic treatment of acute moderate pain, where an intravenous route of administration is considered clinically necessary and/or when other routes of administration are not possible*” was significantly better than treatment with placebo. This was shown in a pivotal phase III placebo-controlled, prospective, randomised, double-blind, parallel-design, multiple-dose study of Maxigesic® IV (AFT-MXIV-07) which was conducted to investigate the intravenous formulation in post bunionectomy surgery pain. The study investigated the effect and safety of Maxigesic® IV over comparable doses of iv paracetamol, iv ibuprofen and iv placebo. comparing the analgesic efficacy and safety of Maxigesic® IV with paracetamol alone, ibuprofen alone and placebo. Therefore, the Medical Products Agency in Sweden decided that Paracetamol/Ibuprofen Vale Pharma’s benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Paracetamol/Ibuprofen Vale Pharma?

A risk management plan has been developed to ensure that Paracetamol/Ibuprofen Vale Pharma 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 Paracetamol/Ibuprofen Vale Pharma, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Paracetamol/Ibuprofen Vale Pharma

The full PAR for Paracetamol/Ibuprofen Vale Pharma can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Paracetamol/Ibuprofen Vale Pharma, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2020-09.