LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Paraibucomb

(paracetamol/ibuprofen)

SE/H/1947/01/DC

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Summary Public Assessment Report

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ibuprofen sodium dihydrate, paracetamol

This is a summary of the public assessment report (PAR) for Paraibucomb. It explains how Paraibucomb 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 Paraibucomb.

For practical information about using Paraibucomb, patients should read the package leaflet or contact their doctor or pharmacist.

What is Paraibucomb and what is it used for?

Paraibucomb is used in the short-term treatment of acute moderate pain in adults, where an intravenous route of administration is necessary.

How does Paraibucomb 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 Paraibucomb used?

The pharmaceutical form of Paraibucomb 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 Paraibucomb have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Paraibucomb 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 Paraibucomb?

For the full list of all side effects reported with Paraibucomb, see section 4 of the package leaflet.

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

Why is Paraibucomb approved?

It was noted that the effect of Paraibucomb 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 Paraibucomb'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 Paraibucomb?

A risk management plan has been developed to ensure that Paraibucomb 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 Paraibucomb, 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 Paraibucomb

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

This summary was last updated in 2020-09.