LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Comboval
(paracetamol, ibuprofen)

SE/H/2093/001/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Comboval
(paracetamol and ibuprofen)

Solution for infusion, 10 mg/ml +3 mg/ml

This is a summary of the public assessment report (PAR) for Comboval. It explains how Comboval were assessed, and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Comboval.

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

What is Comboval and what is it used for?

Comboval is used in 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.

How does Comboval work?

Comboval contains the active substances paracetamol and ibuprofen. Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). Paracetamol works in a different way to ibuprofen, but both substances work together to reduce pain.

How is Comboval used?

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

The company provided its own data on efficacy and safety studies. These studies have shown that Comboval is effective in 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 from Comboval?

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Comboval approved?

The Swedish Medical Products Agency decided that Comboval's benefits are greater than its risks and recommended that it can be approved for use.

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

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

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

This summary was last updated in 2022-03.