LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Duofen
(paracetamol, ibuprofen)

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(paracetamol and ibuprofen)

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

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

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

What is Duofen and what is it used for?

Duofen is used in adults for the short-term symptomatic treatment of acute moderate pain, where an intravenous route of administration is necessary and/or when other routes of administration are not possible.

How does Duofen work?

Duofen 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 Duofen used?

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

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

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 Duofen approved?

The Swedish Medical Products Agency decided that Duofen'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 Duofen?

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

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

This summary was last updated in 2022-03.