LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ibuprofen Mylan
(ibuprofen)

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ibuprofen

Oral suspension in sachet, 400 mg/10 ml

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

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

What is Ibuprofen Mylan and what is it used for?

Ibuprofen Mylan is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Ibuprofen Mylan is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Ibuprofen Mylan 400 mg is used for short term treatment of mild to moderate pain and/or fever in adults and adolescents over 12 years (above 40 kg).

How does Ibuprofen Mylan work?

The active ingredient (which makes the medicine work) is ibuprofen. It belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Ibuprofen Mylan reduces fever and relieves pain.

How is Ibuprofen Mylan used?

The pharmaceutical form of Ibuprofen Mylan is oral suspension in sachet for oral use.

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

A prescription might be needed for this medicine in Sweden.

What benefits of Ibuprofen Mylan have been shown in studies?

As ibuprofen is a well-known substance, and its use in short term treatment of mild to moderate pain and/or fever in adults and adolescents over 12 years (above 40 kg). is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of ibuprofen in short term treatment of mild to moderate pain and/or fever in adults and adolescents over 12 years (above 40 kg).

What are the possible side effects of Ibuprofen Mylan?

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

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

Why is Ibuprofen Mylan approved?

The use of Ibuprofen Mylan in short term treatment of mild to moderate pain and/or fever in adults and adolescents over 12 years (above 40 kg) is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Ibuprofen Mylan'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 Ibuprofen Mylan?

A risk management plan has been developed to ensure that Ibuprofen Mylan 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 Ibuprofen Mylan, 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 Ibuprofen Mylan

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

This summary was last updated in 2020-03.