LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ibetin
(ibuprofen)

SE/H/2057/01-02/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

Ibetin
ibuprofen

Film-coated tablet, 200 mg, 400 mg

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

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

What is Ibetin and what is it used for?

Ibetin is a 'generic medicine'. This means that Ibetin is similar to a 'reference medicine' already authorised in the European Union (EU) called Brufen.

Ibetin can be used for adults and adolescent patients (12-18 years old, 40 kg and above) for short-term symptomatic treatment of mild to moderate pain, such as:

- headache (including migraine headache),
- backaches and pains of muscles and joints,
- toothache,
- period pain.

Ibetin also relieves acute pain and fever associated with the common cold.

Children 6-12 years (20 – 40 kg) can be treated with Ibetin 200 mg tablets during acute pain and fever associated with common cold.

How does Ibetin work?

Ibetin contains ibuprofen, which belongs to a group of medicines called non-steroidal antiinflammatory drugs (NSAID). These medicines work by reducing pain, fever and inflammation.

How is Ibetin used?

The pharmaceutical form of Ibetin is film-coated tablet 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 Ibetin have been shown in studies?

Because Ibetin is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Brufen.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Ibetin?

Because Ibetin is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Ibetin approved?

It was concluded that, in accordance with EU requirements, Ibetin has been shown to have comparable quality and to be bioequivalent to the reference medicine Brufen. Therefore, the Medical Products Agency in Sweden decided that, as for Brufen, the 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 Ibetin?

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

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

This summary was last updated in 2021-03.