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Summary Public Assessment Report

Generics

IBUSTAD 200
IBUSTAD 400
ibuprofen

SK/H/0327/001-002/DC

Date: September 2025

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Generics

IBUSTAD 200, IBUSTAD 400 (hereinafter IBUSTAD)

Ibuprofen, film-coated tablets, 200 mg, 400 mg

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

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

What is IBUSTAD and what is it used for?

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

IBUSTAD 400 mg film-coated tablets are used in adults and adolescents older than 12 years and weighing more than 40 kg for the symptomatic treatment of pain and inflammation in arthritic diseases (e.g. rheumatoid arthritis), degenerative arthritic conditions (e.g. osteoarthritis), and in painful swelling and inflammation after soft tissue injuries.

Additionally, IBUSTAD 400 mg film-coated tablets are used for symptomatic treatment of:
- mild to moderate pain
- fever

IBUSTAD 200 mg film-coated tablets are used in adults and children weighing more than 20 kg (approximately 6 years and older) for the short-term treatment of fever and/or pain such as headaches, flu-like symptoms, dental pain, aches and pains and painful periods.

How does IBUSTAD work?

IBUSTAD contains ibuprofen as an active substance. It works by blocking cyclooxygenase (COX) enzymes, which are responsible for producing prostaglandins. Prostaglandins are hormone-like substances that cause pain, inflammation, and fever. By reducing prostaglandin production, ibuprofen effectively provides pain relief, reduces swelling, and lowers fever.

How is IBUSTAD used?

The pharmaceutical form of IBUSTAD is film-coated tablet and the route of administration is oral.

Tablets should be taken with a glass of water, swallowed whole, without chewing, crushing or breaking to prevent discomfort in the mouth or throat irritation.

Patients with a sensitive stomach are advised to take the tablets together with food. If taken shortly after eating, the onset of action of ibuprofen may be delayed.

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

IBUSTAD can be obtained with or without a prescription based on package size in Slovakia.
Packages with 20, 30, and 50 film-coated tablets are available without prescription.
Packages with 100 film-coated tablets are available with prescription.

What benefits of IBUSTAD have been shown in studies?

Because IBUSTAD 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 IBUSTAD?

Because IBUSTAD is a generic medicine and is bioequivalent to the reference 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 IBUSTAD approved?

It was concluded that, in accordance with EU requirements, IBUSTAD has been shown to have comparable quality and to be bioequivalent to Brufen. Therefore, the State Institute for Drug Control decided that, as for the reference medicine called Brufen, the benefits are greater than its risk and recommended that it can be approved for use.

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

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

The marketing authorisation for IBUSTAD was granted on 06 September 2025.

The full PAR for IBUSTAD can be found on the website. For more information about treatment with IBUSTAD, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in 10-2025.