LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ibuprofen Zentiva
(ibuprofen)

SE/H/2058/01-02/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

Ibuprofen Zentiva
ibuprofen

Film-coated tablet, 400 mg, 600 mg, 800 mg

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

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

What is Ibuprofen Zentiva and what is it used for?

Ibuprofen Zentiva 400 mg and 600 mg are 'generic medicines'. This means that Ibuprofen Zentiva 400 mg and 600 mg are similar to a 'reference medicine' already authorised in the European Union (EU) called Brufen.

Ibuprofen Zentiva 800 mg is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is a different strength than the reference product Brufen.

The company has provided additional own data to demonstrate the safety and efficacy of Ibuprofen Zentiva regarding this difference from the reference medicine.

The reference medicine for Ibuprofen Zentiva is Brufen. Ibuprofen Zentiva is used for the treatment of rheumatic conditions such as arthritic diseases (e.g. rheumatoid arthritis), non-articular rheumatic conditions (e.g. osteoarthritis) or other muscular and joint disorders, and soft tissue injuries.

In addition, Ibuprofen Zentiva 400 mg can be used for short-term symptomatic treatment of mild to moderate pain, such as headaches (including migraine headache), backaches and pains of muscles and joints, toothache, period pain and acute pain and fever associated with the common cold.

Ibuprofen Zentiva 400 mg and 600 mg is recommended for adults and adolescents from 40 kg bodyweight (over 12 years) while 800 mg is recommended for adults only.

How does Ibuprofen Zentiva work?

Ibuprofen Zentiva 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 Ibuprofen Zentiva used?
Ibuprofen Zentiva 400 mg and 600 mg is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Brufen. For Ibuprofen Zentiva 800 mg, because Ibuprofen Zentiva is a hybrid application of Brufen,

clinical studies have been provided for Ibuprofen Zentiva to show efficacy for the difference of Ibuprofen Zentiva from the reference product 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 Ibuprofen Zentiva?

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

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

Why is Ibuprofen Zentiva approved?

For Ibuprofen Zentiva 200 mg ang 400 mg it was concluded that, in accordance with EU requirements, Ibuprofen Zentiva 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.

Ibuprofen Zentiva 800 mg is also similar to a reference medicine containing the same active substance, but is a different strength than the reference medicine Brufen. The company has provided additional own data to demonstrate the safety and efficacy of Ibuprofen Zentiva regarding this difference from the reference medicine.
No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Ibuprofen Zentiva'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 Zentiva?

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

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

This summary was last updated in 2021-03.