LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Paracetamol Accord (paracetamol)

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Summary Public Assessment Report

Paracetamol Accord
(paracetamol)

500 mg effervescent tablets

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

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

What is Paracetamol Accord and what is it used for?

Paracetamol Accord is a 'generic medicine'. This means that Paracetamol Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Panodil Brus, 500 mg, effervescent tablet.

Paracetamol Accord contains paracetamol which belongs to the group of medicines called analgesics and antipyretics.

How does Paracetamol Accord work?

Paracetamol Accord is used to relieve mild to moderate pain and/or fever.

How is Paracetamol Accord used?

The pharmaceutical form of Paracetamol Accord is effervescent tablets 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.

The medicine can only be obtained with a prescription.

What benefits of Paracetamol Accord have been shown in studies?

No additional studies were needed as Paracetamol Accord is a generic medicine considered to be bioequivalent to the reference medicine, Panodil Brus.

What are the possible side effects of Paracetamol Accord?

Because Paracetamol Accord 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 Paracetamol Accord approved?

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

A risk management plan has been developed to ensure that Paracetamol Accord 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 Paracetamol Accord, 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 Paracetamol Accord

The marketing authorisation for Paracetamol Accord was granted on <date of issue of the Marketing Authorisation> in Sweden.

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

This summary was last updated in 2019-08.