

Summary Public Assessment Report

Paracetamol AGmed (paracetamol)

SE/H/2360/01/DC

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paracetamol

Solution for infusion, 10 mg/ml

This is a summary of the public assessment report (PAR) for Paracetamol AGmed. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Paracetamol AGmed and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Perfalgan.

The product is used in short-term treatment of moderate pain, especially following surgery, and for the short-term treatment of fever.

How does Paracetamol AGmed work?

This medicine contains the active substance paracetamol, and it is an analgesic (it relieves pain) and an antipyretic (it lowers fever).

How is Paracetamol AGmed used?

The pharmaceutical form is solution for infusion.

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 in Sweden.

What benefits of Paracetamol AGmed have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Perfalgan.

What are the possible side effects from Paracetamol AGmed?

Because the product 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 side effects, see section 4 of the package leaflet.

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

Why is Paracetamol AGmed approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be similar to the reference medicine. Therefore, the Swedish

Medical Products Agency decided that, as for Perfalgan, the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Paracetamol AGmed?”

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

A risk management plan has been developed to ensure that the product 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, 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.

- **Additional risk minimisation measures (including educational material)**

The educational material should contain the following key elements:

Additional Risk minimization measure: Dosing guide strip

Objective: To minimize the risk of overdose due to confusion between ml and mg in neonates and infants, and overdose in underweight adult patients by providing a sheet which summarizes key dosing instructions and a slider to aid healthcare professionals in determining appropriate weight-based dosing of paracetamol.

Additional Risk minimization measure: Poster

Objective: To minimize the risk of overdose due to confusion between ml and mg in neonates and infants by providing a poster which summarizes the weight-based administration protocol in that population of patients.

The key elements are in line with other iv paracetamol products and is endorsed.

Other information about Paracetamol AGmed

The full PAR for Paracetamol AGmed can be found on the following website: [MRI - Home](#). For more information about treatment with Paracetamol AGmed, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-04.