LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pamol Novum (paracetamol)

SE/H/2567/01/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

Pamol Novum
paracetamol

Film-coated tablet, 500 mg

This is a summary of the public assessment report (PAR) for Pamol Novum. 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 Pamol Novum 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 Panodil Novum.

Product on prescription
Pamol Novum is used to relieve fever and pain conditions, e.g. fever during cold, headache, toothache, period pain, muscle and joint pain, rheumatic pain and high fever (hyperpyrexia).

Product without prescription
Adults and adolescents over 40 kg (over 12 years): Pamol Novum is used to relieve temporary fever and pain conditions, e.g. fever during cold, headache, toothache, period pain, muscle and joint pain.

Pamol Novum is suitable for people with sensitive stomach or ulcers and people at high risk of developing bleeds.

How does Pamol Novum work?
Pamol Novum contains paracetamol which relieves pain and reduces fever.

How is Pamol Novum used?
The pharmaceutical form 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 Pamol Novum have been shown in studies?
Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Panodil Novum. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Pamol Novum?
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 Pamol Novum 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 Panodil Novum, 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 Pamol Novum?
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.

Other information about Pamol Novum
The full PAR for Pamol Novum can be found on the following website: MRI - Home. For more information about treatment with Pamol Novum, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-10.