

Summary Public Assessment Report

Paracetamol Medical Valley (paracetamol)

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paracetamol

Film-coated tablet, 500 mg, 1 g

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

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

What is Paracetamol Medical Valley and what is it used for?

Paracetamol Medical Valley is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Paracetamol Medical Valley is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Paracetamol Medical Valley is used to relieve headache, toothache, menstrual pain, muscle and joint pain, rheumatic pain, fever during cold and hyperpyrexia.

How does Paracetamol Medical Valley work?

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

How is Paracetamol Medical Valley used?

The pharmaceutical form of Paracetamol Medical Valley is film-coated 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 in Sweden.

What benefits of Paracetamol Medical Valley have been shown in studies?

As paracetamol is a well-known substance, and its use to relieve headache, toothache, menstrual pain, muscle and joint pain, rheumatic pain, fever during cold and hyperpyrexia is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of paracetamol in its use to relieve headache, toothache, menstrual pain, muscle and joint pain, rheumatic pain, fever during cold and hyperpyrexia.

What are the possible side effects of Paracetamol Medical Valley?

For the full list of all side effects reported with Paracetamol Medical Valley, see section 4 of the package leaflet.

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

Why is Paracetamol Medical Valley approved?

The use of Paracetamol Medical Valley to relieve headache, toothache, menstrual pain, muscle and joint pain, rheumatic pain, fever during cold and hyperpyrexia is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Paracetamol Medical Valley'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 Paracetamol Medical Valley?

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

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

This summary was last updated in 2021-02.