LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Altermol
(paracetamol and codeine)

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Summary Public Assessment Report

Altermol

(paracetamol and codeine)

Tablet; 500 mg/30 mg

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

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

What is Altermol and what is it used for?

Altermol is a ‘generic medicine’. This means that Altermol is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Citodon.

Altermol can be used in adults and adolescents over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

How does Altermol work?

Altermol contains two pain-relieving substances (paracetamol and codeine) that work in different ways. Paracetamol has both pain-relieving and fever-reducing effects. Codeine reinforces the pain-relieving effect.

This product contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. It can be used on its own or in combination with other pain killers such as paracetamol.

How is Altermol used?

The pharmaceutical form of Altermol is 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 Altermol have been shown in studies?

Because Altermol is a generic medicine and is considered to be therapeutically equivalent, to the reference product Citodon, their benefits and risks are taken as being the same as those of the reference product.

What are the possible side effects of Altermol?

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

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

Why is Altermol approved?

This medicine is similar to a reference medicine containing the same active substance. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that, as for Citodon, 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 Altermol?

A risk management plan has been developed to ensure that Altermol 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 Altermol, 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 Altermol

The marketing authorisation for Altermol was granted on 2015-11-12 in Sweden.

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

This summary was last updated in 2015-12.