

Summary Public Assessment Report

Entolex

Mentha × piperita L., aetheroleum
(peppermint oil)

SE/H/2369/01/DC

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peppermint oil

Gastro-resistant capsule, soft

This is a summary of the public assessment report (PAR) for Entolex. 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 Entolex and what is it used for?

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

Entolex is a herbal medicinal product which is used to relieve the symptoms of minor spasms (light cramps) of the gastrointestinal tract, flatulence and abdominal pain (stomach ache) especially in patients with IBS (irritable bowel syndrome).

How does Entolex work?

Entolex contains peppermint oil.

Several studies in healthy subjects or patients indicate that peppermint oil given orally relaxes the smooth muscles of the gastrointestinal tract, decreasing the abdominal distension, as the discomfort and abdominal pain.

How is Entolex used?

The pharmaceutical form is gastro resistant soft capsules 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 be obtained with or without a prescription in Sweden.

What benefits of Entolex have been shown in studies?

As peppermint oil is a well-known substance, and its use for *the symptomatic relief of minor spasms of the gastrointestinal tract, flatulence and abdominal pain, especially in patients with irritable bowel syndrome*. Entolex is indicated in adults, adolescents and children aged 8 years and above, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of peppermint oil in the treatment of the above-mentioned indication.

What are the possible side effects from Entolex?

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 Entolex approved?

The Swedish Medical Products Agency decided that 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 Entolex?

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 Entolex

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

This summary was last updated in 2024-03.