

Summary Public Assessment Report

Alimemazin Evolan (alimemazine tartrate)

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(alimemazine tartrate)

Capsules, hard; 20 mg

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

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

What is Alimemazin Evolan and what is it used for?

Alimemazin Evolan is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as hard capsules instead of film-coated tablets and also in a higher strength than the reference product. The company has provided additional own data to demonstrate the safety and efficacy of Alimemazin Evolan regarding these differences from the reference medicine.

The reference medicine for Alimemazin Evolan is Theralen 5 mg film-coated tablets.

Alimemazin Evolan is used:

- in short-term treatment of sleep disorders in adults.
- as a tranquilizer before anesthesia in adults and children over 12 years.

How does Alimemazin Evolan work?

Alimemazin Evolan has calming properties and makes you sleep better.

How is Alimemazin Evolan used?

The pharmaceutical form of Alimemazin Evolan is hard 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 only be obtained with a prescription.

What benefits of Alimemazin Evolan have been shown in studies?

Because Alimemazin Evolan is a hybrid application of Theralen, clinical studies have been provided for Alimemazin Evolan to show efficacy for the difference of Alimemazin Evolan from the reference product Theralen.

What are the possible side effects of Alimemazin Evolan?

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

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

Why is Alimemazin Evolan approved?

This medicine is similar to a reference medicine containing the same active substance, but is available as hard capsules instead of film-coated tablets and also in a higher strength than the reference product. The company has provided additional own data to demonstrate the safety and efficacy of Alimemazin Evolan regarding this difference from the reference medicine. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Alimemazin Evolan'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 Alimemazin Evolan?

A risk management plan has been developed to ensure that Alimemazin Evolan 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 Alimemazin Evolan, 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 Alimemazin Evolan

The marketing authorisation for Alimemazin Evolan was granted on 2018-01-12 in Sweden.

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

This summary was last updated in 2023.03.10.