LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Aregzilap
(aripiprazole monohydrate)

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Summary Public Assessment Report

Aregzilap
aripiprazole monohydrate

Powder and solvent for prolonged-release suspension for injection, 300 mg, 400 mg

This is a summary of the public assessment report (PAR) for Aregzilap. 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 Aregzilap 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 Abilify Maintena.

Aregzilap contains the active substance aripiprazole in a vial. Aripiprazole belongs to a group of medicines called antipsychotics. Aregzilap is used to treat schizophrenia - a disease with symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious, or tense.

Aregzilap is intended for adult patients with schizophrenia who are sufficiently stabilized during treatment with aripiprazole taken by mouth.

How does Aregzilap work?
Aripiprazole is understood to work by balancing the activity of two key chemical messengers in the brain: dopamine and serotonin. Ariprazole partially stimulates certain dopamine and serotonin receiving sites while blocking others. This dual action allows aripiprazole to adjust brain chemical activity, increasing the effect when it is too low and decreasing it when it is too high.

How is Aregzilap used?
The pharmaceutical form is powder and solvent for prolonged-release suspension for injection for intramuscular 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 Aregzilap have been shown in studies?
Because the product is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Abilify Maintena. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Aregzilap?
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 Aregzilap approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Abilify Maintena, 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 Aregzilap?
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 Aregzilap
The full PAR for Aregzilap can be found on the following website: MRI - Home. For more information about treatment with Aregzilap, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-09.