LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Polur
(lurasidone hydrochloride)

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Summary Public Assessment Report

Polur
lurasidone hydrochloride

Film-coated tablet, 18,5 mg, 37 mg, 74 mg

This is a summary of the public assessment report (PAR) for Polur. 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 Polur 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 Latuda.

Polur contains the active substance lurasidone and belongs to a group of medicines called antipsychotics. It is used to treat symptoms of schizophrenia in adults (aged 18 years and over) and adolescents aged 13-17 years. Schizophrenia is a disorder with symptoms such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech and behaviour and emotional flatness. People with this disorder may also feel depressed, anxious, guilty, or tense. This medicine is used to improve your symptoms of schizophrenia.

How does Polur work?

Polur works by blocking receptors in the brain to which the substances dopamine and serotonin attach. Dopamine and serotonin are neurotransmitters (substances that allow nerve cells to communicate with each other) that are involved in the symptoms of schizophrenia. By blocking their receptors, lurasidone helps to normalise the activity of the brain, reducing the symptoms of schizophrenia.

How is Polur used?

The pharmaceutical form is film-coated tablet 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 Polur have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Latuda. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Polur?

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 Polur approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Latuda, 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 Polur?

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.

For more details, please see the full PAR for Polur on the following website: MRI - Home.

Other information about Polur

The full PAR for Polur can be found on the following website: MRI - Home. For more information about treatment with Polur, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-09.