LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Mopetia
(paliperidone palmitate, paliperidone)

SE/H/2337/01-05/DC

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Mopetia, Poltraxin
paliperidone palmitate, paliperidone

Prol.-release susp. for inj. in pre-filled syringe, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg

This is a summary of the public assessment report (PAR) for Mopetia. 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 Mopetia 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 Xeplion.

Schizophrenia is a disease with "positive" and "negative" symptoms. Positive means an excess of symptoms that are not normally present. For example, a person with schizophrenia may hear voices or see things that are not there (called hallucinations), believe things that are not true (called delusions), or feel unusually suspicious of others. Negative means a lack of behaviours or feelings that are normally present. For example, a person with schizophrenia may appear withdrawn and may not respond at all emotionally or may have trouble speaking in a clear and logical way. People with this disease may also feel depressed, anxious, guilty, or tense.

Mopetia can help alleviate the symptoms of your disease and stop your symptoms from coming back.

How does Mopetia work?

Mopetia contains the active substance paliperidone which belongs to the class of antipsychotic medicines and is used as a maintenance treatment for the symptoms of schizophrenia in adult patients stabilised on paliperidone or risperidone.

If you have shown responsiveness to paliperidone or risperidone in the past and have mild to moderate symptoms your doctor may start treatment with Mopetia without prior stabilisation with paliperidone or risperidone.

How is Mopetia used?
The pharmaceutical form is prolonged-release suspension for injection.

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 Mopetia 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, Xeplion. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Mopetia?

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 Mopetia 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 Xeplion, 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 Mopetia?
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 Mopetia on the following website: MRI - Home.>

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

This summary was last updated in 2025-09.