LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Zenaxel
(quetiapine fumarate)

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Summary Public Assessment Report

Zenaxel
quetiapine fumarate

Oral suspension, 25 mg/ml

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

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available in a different strength.

The reference medicine for the product is Seroquel.

The company has provided additional own data to demonstrate the safety and efficacy of the product regarding this difference from the reference medicine.

Zenaxel can be used to treat several illnesses, such as:

- Bipolar depression: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.

How does Zenaxel work?

Zenaxel contains a substance called quetiapine. This belongs to a group of medicines called anti-psychotics.

How is Zenaxel used?

The pharmaceutical form is suspension 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 Zenaxel have been shown in studies?

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

What are the possible side effects from Zenaxel?

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 Zenaxel 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 Seroquel, 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 Zenaxel?

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 Zenaxel

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

This summary was last updated in 2025-09.