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EPAR summary for the public

Invega

paliperidone

This is a summary of the European public assessment report (EPAR) for Invega. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Invega.

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

What is Invega and what is it used for?

Invega is an antipsychotic medicine used in adults and adolescents from 15 years of age to treat schizophrenia, a mental illness with symptoms such as disorganised thinking and speech, hallucinations (hearing or seeing things that are not there), suspiciousness and delusions (false beliefs).

Invega is also used to treat adults with schizoaffective disorder. This is a condition in which the patient has episodes of elevated mood (mania) or low mood (depression) in addition to symptoms of schizophrenia.

Invega contains the active substance paliperidone.

How is Invega used?

Invega can only be obtained with a prescription. It is available as prolonged-release tablets (3, 6, 9 and 12 mg). 'Prolonged release' means that paliperidone is released slowly from the tablet over a few hours.

The recommended starting dose of Invega in adults is 6 mg once a day, taken in the morning; the starting dose in adolescents is 3 mg daily. Patients can take Invega either with food or between meals, but should not switch between taking it with food on one day and between meals on another. After assessing the symptoms, the doctor may adjust the dose to between 3 and 12 mg once a day in adults with schizophrenia and to between 6 and 12 mg once a day in patients with schizoaffective disorder. In

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adolescents with schizophrenia the maximum daily dose depends on the patient's body weight and should not be more than 6 mg in those who weigh less than 51 kg. For more information on the use of Invega, including the adjustment of doses in those with kidney disease and the elderly, see the summary of product characteristics (also part of the EPAR).

How does Invega work?

The active substance in Invega, paliperidone, is known as an 'atypical' antipsychotic because it is different from the older antipsychotic medicines that have been available since the 1950s. Paliperidone is an active breakdown product (metabolite) of risperidone, another atypical antipsychotic medicine that has been used in the treatment of schizophrenia since the 1990s. In the brain, paliperidone attaches to several different receptors (targets) on nerve cells. This disrupts signals sent between brain cells by 'neurotransmitters', substances that nerve cells use to communicate with neighbouring cells. Paliperidone acts mainly by blocking the receptors for the neurotransmitters dopamine and 5-hydroxytryptamine (also called serotonin), which are involved in schizophrenia. By blocking these receptors, paliperidone helps to normalise the activity of the brain and reduce symptoms.

What benefits of Invega have been shown in studies?

Schizophrenia

Three short-term studies innvolving 1,692 adults showed that Invega is more effective than placebo (a dummy treatment) and as effective as another antipsychotic medicine olanzapine at reducing symptoms of schizophrenia (as measured by a standard rating scale). In one of these studies, average symptom scores fell by between 17.9 and 23.3 points after 6 weeks in those taking Invega compared with a fall of 4.1 points with placebo. Symptom scores fell by 19.9 points in those taking olanzapine. Similar results were seen in the other two short-term studies, with higher doses of Invega being more effective than lower doses.

In an additional longer-term study involving 207 adults with schizophrenia who had initially been treated over 14 weeks, Invega was more effective than placebo in preventing new symptoms for up to 35 weeks.

Studies in adolescents have shown similar results with Invega to those seen in adults.

Schizoaffective disorder

Studies have shown that Invega can reduce symptoms scores and prevent symptoms in patients with schizoaffective disorder.

In one study, patients who were given Invega had a fall in their symptom score for mania of between 27.4 and 30.6 after 6 weeks compared with 21.7 in patients who were given placebo. In another study, the fall in symptom score for mania after 6 weeks was 20.0 in the Invega group and 10.8 in the placebo group. The two studies together involved a total of 614 patients.

In a third study of 334 previously treated patients, symptoms of depression came back in 15% (25 out of 164) of patients given paliperidone compared with 34% (57 out of 170) of patients given placebo.

What are the risks associated with Invega?

The most frequent side effects with Invega in adults are headache, insomnia (difficulty sleeping), sleepiness, parkinsonism (effects similar to Parkinson's disease such as shaking, muscle stiffness and

slow movement), dystonia (involuntary muscle contractions), tremor (shaking), dizziness, akathisia (restlessness), agitation, anxiety, depression, increased weight, nausea, vomiting, constipation, dyspepsia (heartburn), diarrhoea, dry mouth, tiredness, toothache, muscle and bone pain, back pain, asthenia (weakness), tachycardia (increased heart rate), high blood pressure, prolonged QT interval (an alteration of the electrical activity of the heart), upper respiratory tract infection (nose and throat infections) and cough. Side effects in adolescents are similar to those in adults, although some side effects may occur more frequently. For the full list of all side effects reported with Invega, see the package leaflet.

Invega must not be taken by people who are hypersensitive (allergic) to paliperidone or any of the other ingredients, or to risperidone.

Why is Invega approved?

The European Medicines Agency decided that Invega's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Invega?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Invega have been included in the summary of product characteristics and the package leaflet.

Other information about Invega

The European Commission granted a marketing authorisation valid throughout the European Union for Invega on 25 June 2007.

The full EPAR for Invega can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Invega, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2017.