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EPAR summary for the public

Trevicta[1]

paliperidone

This is a summary of the European public assessment report (EPAR) for Trevicta. 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 Trevicta.

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

What is Trevicta and what is it used for?

Trevicta is an antipsychotic medicine used for the maintenance treatment of schizophrenia in adults whose disease has been stable on treatment with once-monthly injections of paliperidone. The symptoms of schizophrenia include disorganised thinking and speech, hallucinations (hearing or seeing things that are not there), suspiciousness and delusions (false beliefs).

Trevicta contains the active substance paliperidone.

How is Trevicta used?

Trevicta is available as a prolonged-release suspension for injection in pre-filled syringes (175 mg, 263 mg, 350 mg and 525 mg). Prolonged-release means that the active substance, paliperidone, is released slowly over a few months after being injected. The medicine can only be obtained with a prescription.

Trevicta is given by a healthcare professional. It is given every 3 months by slow injection into the upper part of the shoulder (deltoid muscle) or the buttocks. The dose of Trevicta is 3.5 times the dose of the monthly injections of paliperidone the patient was previously receiving.

For more information on the use of Trevicta, see the summary of product characteristics (also part of the EPAR).

[1] Previously known as Paliperidone Janssen.

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How does Trevicta work?

The active substance in this medicine, paliperidone, is an antipsychotic medicine. Paliperidone is an active breakdown product (metabolite) of risperidone, another antipsychotic medicine that has been used in the treatment of schizophrenia since the 1990s. In the brain, paliperidone attaches to several different receptors on the surface of nerve cells. This disrupts signals transmitted 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). By blocking these receptors, paliperidone helps to normalise the activity of the brain and reduce symptoms of the disease.

Paliperidone has been authorised in the European Union (EU) as Invega since 2007 for use by mouth to treat schizophrenia. It has also been authorised as Xeplion since 2011 for use by monthly injections for the maintenance treatment of schizophrenia. In Trevicta as in Xeplion, paliperidone has been attached to a fatty acid that allows it to be released slowly after being injected. This gives the medicine a long duration of action.

What benefits of Trevicta have been shown in studies?

Two studies have been conducted with Trevicta given every 3 months. In one of them (involving 1,016 patients) Trevicta was as effective as paliperidone monthly injections in preventing relapses of schizophrenia. In the second study (in 305 patients) Trevicta was more effective than placebo (a dummy treatment), with 9% of patients given the medicine suffering a relapse of their condition compared with 29% of those on placebo.

Because paliperidone for use by monthly injections has already been authorised in the EU as Xeplion, the company also used data from Xeplion to support the use of Trevicta.

What are the risks associated with Trevicta?

The most common side effects with Trevicta (seen in at least 5 in 100 patients) are insomnia (difficulty sleeping), headache, anxiety, upper respiratory tract infections (such as colds), reactions at the site of injection and increased weight.

For the full list of all side effects reported with Trevicta, see the package leaflet.

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

Why is Trevicta approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that paliperidone injections are effective in treating schizophrenia symptoms. Trevicta, which is given by injection every 3 months, is more effective than placebo and as effective as paliperidone monthly injection in preventing relapses of schizophrenia. The 3-monthly injection is expected to be more convenient to patients and improve their adherence to treatment, and no new safety concerns were raised with this formulation compared with the known safety profile of paliperidone. The Committee therefore decided that Trevicta'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 Trevicta?

A risk management plan has been developed to ensure that Trevicta 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 for Trevicta, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Trevicta

The European Commission granted a marketing authorisation valid throughout the European Union for Paliperidone Janssen on 5 December 2014. This authorisation was based on the authorisation granted to Xeplion in 2011 ('informed consent'). The name of the medicine was changed to Trevicta on 26 May 2016.

The full EPAR and risk management plan summary for Trevicta 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 Trevicta, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2016.