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Okedi (*risperidone*)

An overview of Okedi and why it is authorised in the EU

What is Okedi and what is it used for?

Okedi is a medicine used to treat schizophrenia in adults. It contains the active substance risperidone and is intended for use in patients in whom medicines containing risperidone have been effective and have not produced unacceptable side effects when given by mouth.

Okedi is a type of medicine called a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but it is presented in a different way. While the reference medicine for Okedi, Risperdal tablets, is taken daily by mouth, Okedi is provided as a monthly injection.

How is Okedi used?

Okedi is available as an injection to be given into the muscle of the upper arm or buttocks. It can only be obtained with a prescription and should be given by a healthcare professional. The starting dose is either 75 or 100 mg, depending on the patient's previous dose of risperidone by mouth, and injections are given every 28 days. Patients who are not currently treated with risperidone by mouth should be switched to such treatment for a period before starting Okedi.

For more information about using Okedi, see the package leaflet or contact your doctor or pharmacist.

How does Okedi work?

Risperidone is a so-called antipsychotic medicine that has been used in the treatment of schizophrenia for several decades. In the brain, risperidone attaches to receptors (targets) on nerve cells. This disrupts signals transmitted between brain cells by 'neurotransmitters', chemicals that allow nerve cells to communicate with each other. Risperidone acts mainly by blocking certain receptors for the neurotransmitters dopamine and 5-hydroxytryptamine (also called serotonin), which are involved in schizophrenia. By blocking these receptors, the medicine helps to normalise the activity of the brain and reduce symptoms of the disease.

The risperidone in Okedi is formulated as a suspension of tiny particles. After injection a small amount of the active substance is immediately available, with the remainder being slowly released over several weeks after injection, helping to prolong the action of the medicine.

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How has Okedi been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Risperdal, and therefore do not all need to be repeated for Okedi.

As for every medicine, the company provided studies on the quality of Okedi. The company also carried out studies that showed that levels of the active substance in the body after Okedi injection were comparable to those produced by the reference medicine taken by mouth, and that Okedi could therefore be expected to have the same effect.

In addition, the company provided results from a main study that looked at the effectiveness of Okedi in 390 patients who were having a flare-up of schizophrenia symptoms. Benefit was measured as the fall in a measurement of schizophrenia severity called the PANSS score. Average PANSS score fell by around 25 in patients given Okedi 75 or 100 mg, compared with a fall of 11 in those given placebo (a dummy treatment). About 30 to 40% in those given Okedi had a fall in PANSS score of at least 30%, compared with about 8% in those given placebo.

What are the benefits and risks of Okedi?

Because Okedi produces levels of active substance in the body comparable to those seen in the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Okedi authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Okedi has been shown to have comparable quality and to produce comparable levels of active substance to Risperdal.

Prolonged-release formulations offer advantages in patients with schizophrenia who have difficulty in sticking to regular dosing by mouth, but are problematic if severe side effects develop. The Agency's view was that the risk of these could be sufficiently identified by an initial period of giving risperidone by mouth and Okedi can therefore be authorised for use in the EU.

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

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

As for all medicines, data on the use of Okedi are continuously monitored. Suspected side effects reported with Okedi are carefully evaluated and any necessary action taken to protect patients.

Other information about Okedi

Okedi received a marketing authorisation valid throughout the EU on 14 February 2022.

Further information on Okedi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/okedi.

This overview was last updated in 02-2022.