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Tuzulby (*methylphenidate hydrochloride*)

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

What is Tuzulby and what is it used for?

Tuzulby is a medicine used to treat attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years.

It is used as part of a comprehensive treatment strategy that typically involves psychological, educational and other interventions and is used when these measures alone do not control their symptoms well enough.

Tuzulby contains the active substance methylphenidate hydrochloride and is a 'hybrid' medicine. This means that it is similar to a 'reference medicine' containing the same active substance, but there are differences between the two. Tuzulby tablets release the active substance over a longer period of time than the reference medicine does. The reference medicine is Ritalin.

How is Tuzulby used?

Tuzulby treatment must be started by a doctor specialised in childhood or adolescent behavioural problems. Before starting treatment, the doctor should check the patient's blood pressure and heart rate.

The recommended starting dose is 20 mg once a day taken in the morning. The dose may be increased weekly up to a maximum dose of 60 mg. Treatment should be stopped if symptoms do not improve, and doses may be reduced if the symptoms get worse or if the child has serious side effects.

The tablets are chewed and not swallowed whole or crushed. For more information about using Tuzulby, see the package leaflet or contact your doctor or pharmacist.

The medicine can only be obtained with a prescription.

How does Tuzulby work?

The active substance in Tuzulby, methylphenidate hydrochloride, is thought to work by increasing the levels of the neurotransmitters noradrenaline and dopamine in some areas of the brain. By doing this, it enhances activity in areas of the brain that control attention, the ability to focus, concentration and impulsive behaviours.

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After ingestion of the medicine, a small amount of the active substance is immediately available, with the remainder being slowly released over 8 hours, helping to prolong the action of the medicine.

What benefits of Tuzulby have been shown in studies?

Studies on the benefits and risks of the active substance have already been carried out with the reference medicine, Ritalin.

As for every medicine, the company provided studies on the quality of Tuzulby. The company also carried out a study that showed that giving Tuzulby produces similar levels of the active substance in the body as those seen with Ritalin. The company also presented results from a study which showed that children stabilised on Tuzulby for one week had better symptom scores for ADHD based on classroom observations than those taking placebo (a dummy treatment).

What are the risks associated with Tuzulby?

For the full list of side effects and restrictions with Tuzulby, see the package leaflet.

The most common side effects with methylphenidate treatment (which may affect more than 1 in 10 people) are decreased appetite, insomnia (difficulty sleeping), nervousness, headache, nausea and dry mouth.

Tuzulby must not be used in children who are allergic to the active substance or any of the other ingredients of the medicine. It must not be used in those with glaucoma (damage to the nerve in the eye, usually caused by high pressure in the eye), phaechromocytoma (a rare tumour in adrenal glands) or hyperthyroidism or thyrotoxicosis (conditions caused by excess thyroid hormones).

It must also not be used in children with a history of certain mental or psychiatric conditions, pre-existing heart disease and disorders affecting the circulation in the brain such as strokes. Finally, it should not be used in children taking antidepressants known as monoamine oxidase (MAO) inhibitors. For the full list of restrictions, see the package leaflet.

Why is Tuzulby authorised in the EU?

Studies show that Tuzulby produces similar levels of methylphenidate hydrochloride, the active substance, in the body Ritalin does. Methylphenidate hydrochloride is already widely used to treat ADHD and its safety is well known.

The European Medicines Agency therefore decided that Tuzulby's benefits are greater than its risks and that it can be authorised for use in the EU.

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

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

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

Other information about Tuzulby

Tuzulby received a marketing authorisation valid throughout the EU on 28 February 2025.

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

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