



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/119451/2025
EMA/H/C/006324

Ryjunea (*atropine sulfate*)

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

What is Ryjunea and what is it used for?

Ryjunea is a medicine used in children aged 3 years and older to slow progression (worsening) of myopia (short sightedness). It is used for myopia of -0.5 to -6.0 dioptres that is progressing at a rate of 0.5 dioptres or more each year. A dioptre is a measure of a person's ability to see; a negative dioptre indicates difficulty seeing in the distance.

Ryjunea contains the active substance atropine sulfate and is a 'hybrid' medicine. This means that it is similar to a reference medicine containing the same active substance, but there are certain differences between the two. Ryjunea is available at a different dose to the reference medicine and has a different authorised use. The reference medicine for Ryjunea is Atropin-POS.

How is Ryjunea used?

Ryjunea can only be obtained with a prescription and is available as eye drops to be given once a day in each eye before bedtime.

Treatment can be started in children from 3 to 14 years old and should be assessed regularly. The doctor may reduce the dose or stop Ryjunea treatment once the myopia has stabilised during adolescence. If the myopia starts getting worse again, treatment may be restarted.

Treatment should only be started by an ophthalmologist (a doctor specialised in ophthalmology, the diagnosis and treatment of eye conditions) or another healthcare professional qualified in ophthalmology.

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

How does Ryjunea work?

Myopia is usually caused by the eyeball becoming longer. The active substance in Ryjunea, atropine sulfate binds to receptors (targets) in the eye called muscarinic receptors, blocking their activity. The exact way in which Ryjunea works is not fully understood, but by blocking these receptors, it is thought to stimulate changes to the shape of the eye, which in turn prevent further elongation of the eyeball.



What benefits of Ryjunea have been shown in studies?

A main study involving 852 children aged 3 to 14 years with myopia of -0.5 dioptres to -6.0 dioptres found that Ryjunea slowed the progression of myopia over 24 months. In children whose myopia was worsening at a rate of at least 0.5 dioptres per year, myopia worsened by 0.34 dioptres in those given the authorised dose of Ryjunea compared with 0.54 dioptres in those given a placebo eye drop (eye drop without any active substance).

What are the risks associated with Ryjunea?

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

The most common side effect with Ryjunea (which may affect more than 1 in 10 people) is photophobia (abnormal sensitivity of the eyes to light). Other common side effects (which may affect up to 1 in 10 people) include eye irritation and blurred vision.

Ryjunea must not be given to people known to be hypersensitive (allergic) to any ingredients in Ryjunea or to other anticholinergic medicines. It must also not be given to patients with primary glaucoma or angle-closure glaucoma (damage to the eye nerve caused by high pressure in the eye because fluid cannot drain out of the eye; this is due to problems with either the drainage system (primary) or the shape of the eye (angle-closure)).

Why is Ryjunea authorised in the EU?

Ryjunea has been found to offer some benefit to children with myopia that is progressing at a rate of at least 0.5 dioptres per year, although there are some uncertainties about the long-term benefits. The safety of Ryjunea is acceptable. The European Medicines Agency therefore decided that Ryjunea's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Ryjunea will provide further information on the effectiveness and safety of Ryjunea by providing further results from the main study collected up to 48 months. The study will also look at the effect of stopping treatment on myopia and its progression, including potential rebound effects (worsening of myopia after stopping treatment).

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

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

Other information about Ryjunea

Ryjunea received a marketing authorisation valid throughout the EU on 2 June 2025.

Further information on Ryjunea can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/ryjunea

More information about Atropin-POS can be found in the national registers of relevant Member States.

This overview was last updated in 06-2025.