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Update as of 2 June 2025:

The company for Atropine sulfate FGK has requested a re-examination of EMA's May 2025 opinion. Upon receipt of the grounds of this request, the Agency will re-examine its opinion and issue a final recommendation.

Refusal of the marketing authorisation for Atropine sulfate FGK (atropine sulfate)

The European Medicines Agency has recommended the refusal of a paediatric use marketing authorisation (PUMA) for Atropine sulfate FGK, a medicine intended for the treatment of myopia (short-sightedness) in children aged 6 to 10 years.

The Agency issued its opinion on 22 May 2025. The company that applied for authorisation, FGK Representative Service GmbH, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Atropine sulfate FGK and what was it intended to be used for?

Atropine sulfate FGK was developed as a medicine to slow the progression (worsening) of myopia in children aged 6 to 10 years with myopia between -0.50 and -6.00 dioptres (D). A dioptre is a measure of a person's ability to see; a negative dioptre indicates difficulty seeing in the distance.

Atropine sulfate FGK contains the active substance atropine sulfate and was to be available as eye drops. One drop was to be put in each eye at bedtime. Atropine sulfate is authorised in several countries of the European Union for the treatment of other eye conditions or to dilate the pupil before an eye examination.

How does Atropine sulfate FGK work?

Myopia is usually caused by the eyeball becoming longer. The active substance in Atropine sulfate FGK, atropine sulfate, binds to receptors (targets) in the eye called muscarinic receptors, blocking their activity. The exact way in which Atropine sulfate FGK works is not fully understood, but by blocking

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these receptors, it is thought to stimulate changes to the shape of the eye, which in turn prevent further elongation of the eyeball and therefore slow the progression of the myopia.

What did the company present to support its application?

The company presented data from three main studies. The first study involved 576 children aged 3 to 17 years who had myopia of -0.50 to -6.00 D. For the first 3 years of the study, children were given either Atropine sulfate at a concentration of 0.01% or 0.02%, or placebo eye drops (a dummy treatment). The main measure of effectiveness was the proportion of patients' eyes whose myopia had worsened by less than 0.5 D after 3 years of treatment with either Atropine sulfate 0.02% or placebo.

The second main study involved 250 children aged 6 to 16 years who had myopia of at least -1.00 D. Children were treated with Atropine sulfate 0.01% or placebo for 2 years. The third main study involved 187 children aged 5 to 12 years who had myopia ranging from -1.00 to -6.00 D. Children were either treated with Atropine sulfate 0.01% or with placebo for 2 years. In both studies, the main measure of effectiveness was the change in myopia after 2 years of treatment.

What were the main reasons for refusing the marketing authorisation?

The three main studies submitted by the company failed to show effectiveness of Atropine sulfate FGK. In the first main study, there was no statistically significant difference between Atropine sulfate 0.02% and placebo in terms of the proportion of children whose myopia progressed by less than 0.50 D after 3 years of treatment. This means that the small difference observed may be due to chance. Results from the first main study suggested that Atropine Sulfate FGK 0.01% may be more effective than placebo. However, the European Medicines Agency considered that, since the study failed to show effectiveness of the 0.02% concentration, it was unclear why the lower 0.01% concentration would be shown effective. Additionally, the second and third main studies failed to show effectiveness of the 0.01% concentration.

The Agency concluded that the effectiveness of Atropine sulfate FGK had not been sufficiently demonstrated, and therefore recommended refusing marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that a clinical trial with Atropine sulfate FGK is ongoing in China, and that there are no consequences for patients in this clinical trial.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.