

Temat [EXT] AskEMA - Response to ASK-276640 - Letter received on 03-04-2025



Od AskEMA No-Reply <AskEMA.noreply@ema.europa.eu>

Do <wajss@agh.edu.pl>

Data 2025-04-23 08:42

Dear Dr Wajss,

Thank you for your letter informing us about the campaign on muscarinic receptor antagonists, in particular atropine, tropicamide and cyclopentolate. Most muscarinic receptor antagonists have not been evaluated by EMA but have been evaluated at national level in the EU, in accordance with national authorisation procedures. EMA therefore does not hold detailed information on these medicines. This is held by the national medicines' regulatory authorities in these respective EEA countries.

However, EMA has recently recommended a marketing authorisation for the medicine Ryjunea (atropine eye drops) as a 0.1 mg/ml eye drop solution to slow the progression of myopia in patients aged 3 years and older, with a progression rate of 0.5 D or more per year and a severity of -0.50 diopters (D) to -6.0D. The medicine is currently awaiting the legal decision on the marketing authorisation by the European Commission. Once this is issued in the coming weeks, EMA will publish the full product information, risk management plan and assessment report with the details of the assessment, in the following link: [Ryjunea | European Medicines Agency (EMA)]<https://www.ema.europa.eu/en/medicines/human/EPAR/ryjunea>. The product information of the medicine contains several warnings and precautions, such as increased sensitivity to bright light and undesirable effects you refer to, such as vision blurred, photophobia in the SmPC (summary of product characteristics) and according text in the Package Leaflet including the advice to wear a sunglasses:

"Photophobia

Atropine sulfate causes photophobia by dilating the pupil and paralyzing the ciliary muscle, allowing excessive light to enter the eye and impairing its ability to adjust to bright light. Photophobia was the most commonly reported adverse reaction in clinical trials, typically presenting as mild to moderate in severity.

Vision blurred

Mild or moderate blurred vision is associated with atropine sulfate. In approximately 85% of patients, it resolves by itself during treatment.

Warnings and precautions

You or your child may experience photophobia (increased sensitivity of the eyes to bright light) and accommodative dysfunction (blurred vision due to difficulty focusing the eyes) when using Ryjunea. If your eyes are more sensitive to light, you are advised to wear sunglasses to reduce discomfort."

A risk of irreversible retinal damage has not been identified during the assessment of Ryjunea. For the Ryjunea there is an obligation to conduct and submit results from a post-authorisation efficacy and safety study, which includes additional long-term safety data. These will be assessed next year and if needed any additional measures set. For all medicines you mention, EMA together with the EU regulatory network continuously monitor safety and efficacy data including from clinical trials and post-marketing surveillance in the context of its regular benefit risk evaluations (periodic safety update report, PSUR, evaluations). To date no safety signal has been raised for solar retinal toxicity.

Your article will be considered into EU regulatory monitoring activities. Should a safety issue be confirmed EMA will take regulatory measures as necessary, including an update to the product information.

Kind Regards,

We would be grateful if you could take part in a short survey on our service. Please access the survey through the following link: <https://ec.europa.eu/eusurvey/runner/AskEMASurvey5137ad0a-8a76-4425-26ed-93ab3c955448>

European Medicines Agency

Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
Send us a question.

Go to www.ema.europa.eu/contact Telephone: +31 (0)88 781 6000

We received your question(s) on: 04/04/2025

Subject of your enquiry: Letter received on 03-04-2025

Your question(s): To: European Medicines Agency Dr. Eng. Pawet Wajss Faculty of Energy and Fuels, AGH University of Krakow Al. A. Mickiewicza 30, 30-059 Krakow, Poland Email: [wajss@agh.edu.pl,mailto:wajss@agh.edu.pl] Tel. +48 600 388 727 Domenico Scarlatti laan 6, 1083 HS Amsterdam, Nederland Dear Sir/Madam, I am writing to formally request action regarding the public health risk associated with the use of muscarinic receptor antagonists (parasympatholytics) and the insufficient communication from manufacturers, distributors, doctors, and medical staff concerning the potential risks of their use. These drugs, by blocking muscarinic (M3) receptors, prevent the contraction of the sphincter muscle of the pupil, responsible for pupil constriction. This group includes atropine, tropicamide, and cyclopentolate. Research findings published in the peer-reviewed scientific journal *OphthaTherapy. Therapies in Ophthalmology* (vol. 11, no. 1/2024, pp. 60-67) indicate that the use of these preparations may lead to a significant risk of retinal damage due to exposure to solar radiation in cases of pupil dilation (mydriasis). Analyses indicate that after the use of drugs inducing mydriasis, the risk of retinal damage exceeds the safety thresholds defined in international standards IEC 60825 and IEC 62471. Solar radiation has been classified as a high-risk hazard (Risk Group 3), meaning that even short-term exposure may lead to irreversible retinal damage, particularly in the macula, which is responsible for the sharpest vision. I am concerned that information about this risk is not widely disseminated among medical personnel or patients. The summaries of product characteristics and package leaflets contain only general warnings about "bright light" or "illumination" without specifically addressing the risks associated with solar radiation. I consider it essential to take action to introduce detailed and explicit warnings in product documentation and to provide patients with appropriate protective measures. To raise public awareness about this issue, the international social campaign *Cover Eyes* has been launched and is available at covereyes.com. This campaign, available in 24 languages, aims to inform both specialists and patients about the danger and to suggest preventive measures. Therefore, I respectfully request: # Analyzing the attached scientific publication and taking actions to verify the safety of muscarinic receptor antagonist drugs. # Sponsoring the *Cover Eyes* campaign, which would significantly increase its reach and # Informing me of the actions taken and any potential opportunities for cooperation to protect public I have attached the aforementioned scientific publication. Sincerely, Dr. Eng. Pawet Wajss