

Temat [EXT] Response to inquiry to the Danish Medicines Agency**Od** SIGDK (Fællespostkasse) <SIGDK@dkma.dk>**Do** wajss@agh.edu.pl <wajss@agh.edu.pl>**Data** 2025-04-30 10:45

Dear Dr. Wajss,

Thank you for your letter and inquiry to the Danish Medicines Agency (DKMA).

As you mention in your letter, several types of eyedrops can cause mydriasis. Of the mentioned three active substances atropine, cyclopentolate and tropicamide, the following medicines are approved for use in Denmark:

- “Mydriaserit”, “Mydrane” and “Mydriacyl” (tropicamide)
- “Cyclogyl” (cyclopentolate)

Section 4.4 in the product information of “Mydriaserit” (*Théa*), “Mydriacyl” (*Alcon*) and “Cyclogyl” (*Paranova*, *Orifarm* and *Alcon*) all include a section describing that the eyes should be protected from sharp light. The product information of Mydrane (*Théa*) does not include such warning. There are currently no approved eyedrops containing atropine marketed in Denmark.

We perform ongoing monitoring of our national database containing Danish adverse events reports. By April 22nd 2025, we have no reported suspected adverse events regarding damages to the retina when using eyedrops containing the three active substances of interest in the Danish database. The DKMA registers and analyzes potential adverse reactions to medications that citizens or healthcare providers submit to us. The information that we receive allows us to continually assess the safety of medicines on the market in Denmark. Any unknown adverse reactions to eyedrops causing mydriasis should be detected by this pharmacovigilance system, if this has been reported to us.

Furthermore, the DKMA sends Danish adverse events reports to the European database and works closely with EMA in regards to ensuring the safety profiles of all medicines. Moving forward, your article will be considered into EU regulatory monitoring activities. If a safety issue is identified and confirmed, EMA will take regulatory measures and this could include an update to the product information if deemed necessary.

Best regards,

Emma

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