



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 September Month 2023¹
EMA/PRAC/359903/2023
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 28-31 August 2023 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found [here](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Acetazolamide – Choroidal effusion and choroidal detachment (EPITT no 19924)

Summary of product characteristics

4.4 – Special warnings and precautions for use

Cases of choroidal effusion/detachment have been reported after the use of acetazolamide. Symptoms include acute onset of decreased visual acuity or ocular pain and can occur within hours after initiation of acetazolamide treatment. If choroidal effusion/detachment is suspected, acetazolamide should be discontinued as rapidly as possible.

4.8 – Undesirable effects

Eye disorders

Frequency 'not known': Choroidal effusion, choroidal detachment

¹ Expected publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



Package leaflet

2 - What you need to know before you take [product name]

Warnings and precautions

[This information should be added as separate paragraph, after issues that should be assessed before treatment.]

A decrease in vision or eye pain could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion or choroidal detachment). This can happen within hours of taking [product name]. Talk to your doctor promptly if you experience these symptoms.

4 - Possible side effects

Frequency 'not known': Decrease in vision or pain in your eyes due to accumulation of fluid in the vascular layer of the eye (choroidal effusion or choroidal detachment).