



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Eye injuries in people and dogs when using Osrurnia ear gel for dogs

Caution is advised when applying the medicine

EMA's Committee for Medicinal Products for Veterinary Use is warning of cases of eye injuries to pets or their owners from accidental eye exposure to the medicine Osrurnia.

Osrurnia is an ear gel for the treatment of ear infections in dogs. Eye exposure in people mostly happened when the dog shook its head during or just after applying the medicine. It is not clear if cases in dogs were also due to accidental contact, although this was confirmed in a few reports.

The injuries in people include 2 cases of corneal ulcer (damage to the clear layer at the front of the eye), as well as reports of eye irritation, conjunctivitis, redness, burning, stinging and itchiness. The eye injuries in dogs included corneal ulcers, squinting, impaired vision, conjunctivitis, redness and swelling around the eye.

Care should be taken to prevent Osrurnia ear gel from contacting the eyes of people or dogs. If accidental exposure occurs, the eyes should be thoroughly rinsed with water and medical care sought.

Veterinary healthcare professionals will be informed in writing of this issue and are encouraged to report any suspected side effect to the relevant national authority or the company for Osrurnia.

EMA will continue to monitor the safety of the medicine and will take any regulatory action as appropriate.

Information for animal owners

- Osrurnia is an ear gel used to treat ear infections in dogs. If it contacts the eyes of people or dogs it can cause damage to them.
- Care should therefore be taken to prevent Osrurnia ear gel from contacting the eyes of people applying the medicine, or of other people nearby. This includes restraining the dog's head when applying the medicine, to prevent the animal shaking its head and splashing the medicine around.
- Care should also be taken to prevent Osrurnia ear gel from contacting the eyes of the dog being treated.
- If accidental exposure occurs to the eyes of people or dogs, rinse the eyes thoroughly with water for 10-15 minutes and seek medical care.



Information for veterinary healthcare professionals

- Before Osurnia is applied to dogs, veterinary healthcare professionals should examine the external ear canal to ensure that the eardrum is not perforated.
- Veterinarians should advise pet owners to take care when applying the medicine. The dog should be properly restrained during administration of Osurnia and appropriate measures should be taken to avoid accidental eye contact with the product.
- If accidental ocular exposure occurs the eyes should be flushed thoroughly with water for 10 to 15 minutes.
- Veterinarians should also advise pet owners to monitor dogs treated with Osurnia and to contact their veterinarian in case of any side effects in particular those affecting the eyes.
- Side effects relating to Osurnia should be reported to the appropriate local authorities ([national veterinary contacts](#)) or to the company that markets Osurnia, Elanco Europe Ltd.

More about the medicine

Osurnia is a veterinary medicine used in dogs to treat ear infections. It contains the active substances terbinafine, florfenicol and betamethasone acetate. Osurnia is available as a gel to be given into the ear. The contents of one tube of gel are given into each infected ear and treatment is repeated after one week.

Ear infections in dogs can be caused by bacteria or yeasts/fungi. They often lead to the ears being inflamed or painful.

More information on Osurnia can be found on the EMA website: ema.europa.eu/Find/medicine/Veterinary_medicines.