

Osurnia®: how a dog's ear infection treatment can injure the owner's eye

Osurnia® is an ear gel "indicated in dogs for the treatment of otitis externa and acute manifestations of recurrent otitis externa associated with strains of bacteria *Staphylococcus pseudintermedius* and fungi *Malassezia pachydermatis*", from the pharmaceutical company Elanco Europe. It has had a European marketing authorisation since July 2014 and is subject to veterinary prescription.

This veterinary medicine is a combination of three active substances: terbinafine (antifungal), florfenicol (antibiotic) and betamethasone acetate (corticoid). One tube of gel per infected ear is applied in a single dose and repeated after seven days.

The European Medicines Agency's Committee for Veterinary Medicinal Products (CVMP) and ANSES (ANMV) alerted veterinarians to cases of eye injury in pets and humans after exposure to Osurnia® and reminded them of the precautions to be taken when using this veterinary medicine.

Since it was first placed on the market, 16 cases of adverse effects in humans have been reported, mostly in the United States. In 14 cases, the victim was the person administering the product, but in two cases it was another person nearby.

Fourteen cases involved accidental eye exposure due to splashing of the product. One case involved dermal exposure (around the lips). Lastly, in one case, nausea was reported following Osurnia® administration. The accidents generally occurred when the treated dog shook its head during or immediately after application. Four of the people involved were the animals' owners, but accidents were also observed when the medicinal product was administered by veterinary assistants (4 cases) or the veterinarians themselves (2 cases).

The first eye symptoms appeared immediately after contact. These were mainly eye irritation, conjunctivitis, redness, burning and itching. Despite prompt rinsing of the affected eye with clean water, these signs sometimes persisted or even worsened. For example, two cases of corneal ulcers were reported.

In France, no cases of human exposure following the use of this veterinary medicinal product on an animal have been notified to ANSES to date.

Eye injuries have also been reported in dogs when using this ear product, although contact with the eye was not always confirmed. Symptoms observed in the dogs included corneal ulcers, blinking, decreased visual acuity, conjunctivitis, redness and swelling around the eyes.

Every precaution (such as restraining the dog or wearing safety glasses) should be taken to avoid contact of Osurnia® with the eyes of dogs and people around them. In the event of accidental contact, the affected eyes should be rinsed immediately with plenty of clean water and medical advice should be sought.

The European Medicines Agency, in conjunction with national authorities, is continuing to monitor the adverse effects of this veterinary medicine and will take any regulatory action deemed necessary.

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TO FIND OUT MORE, VISIT:

The SPC and package leaflet for Osurnia can be found on the EMA website:
https://www.ema.europa.eu/en/documents/product-information/osurnia-epar-product-information_fr.pdf