

ointments containing 400mg and over of camphor per package and risk of unintended oral ingestion

Final SPC and PL wording agreed by the PhVWP in July 2010

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SUMMARY OF PRODUCT CHARACTERISTICS

4.9. Overdose

Over dosage may result in skin irritation.

Misuse:

Swallowing of the ointment might cause gastrointestinal symptoms like vomiting and diarrhoea. Treatment is symptomatic.

Acute poisoning was observed after significant accidental consumption, with nausea, vomiting, abdominal pain, and headache, vertigo, feeling hot / flushing, convulsions, respiratory depression and coma.

Patients with severe gastrointestinal or neurological symptoms of poisoning should be observed and treated symptomatically. Do not induce vomiting.

PACKAGE LEAFLET

Section 3

In the case of accidental swallowing of <trade name> by a child, it is important to consult a physician without delay who can provide any necessary treatment. Do not try to induce vomiting.