Exeltis
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Ivermectin 3 mg Tablets Prescribing Information: Scabies indication

Please consult the Summary of Product Characteristics (SmPC) before prescribing

Presentation: Each round white tablet contains 3 mg of ivermectin. **Indication:** Treatment of human sarcoptic scabies. Treatment is justified when the diagnosis of scabies has been established clinically and/or by parasitological examination. Without formal diagnosis treatment is not justified in case of pruritus. **Dosage and administration:** A single oral dose to provide ivermectin at 200 mcg/kg body weight. *Common scabies*: Recovery will be considered as definite only after 4 weeks of the treatment. Persistence of pruritus or scraping lesions does not justify a second treatment before 4 weeks. Administration of a second dose within 2 weeks after the initial dose should only be considered: a) when new specific lesions occur, b) when the parasitologic examination is positive at this date. *Profuse and crusting scabies*: In these heavily infected forms, a second dose within 8 to 15 days of ivermectin and/or concomitant topical therapy may be necessary to obtain recovery. *Paediatric population.* Safety in paediatric patients weighing less than 15 kg of body weight has not been established. *Elderly patients.* Treatment of an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. *Method of administration:* One single oral dose taken with water on an empty stomach. The dose may be taken at any time of the day, but no food should be taken within two hours before or after administration**.** In children less than 6 years of age and weighing at least 15kg, tablets should be crushed before swallowing. *Note for patients treated for scabies:* Contact persons should undergo a medical examination as soon as possible and if necessary should be given prompt antiscabies treatment. Hygienic measures to prevent reinfection should be taken into account and official recommendations regarding cleaning of clothing and bedding should be closely followed. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use**: For information on special warnings, precautions and interactions in indications other than scabies treatment please refer to SmPC. **Pregnancy and lactation:** Ivermectin should only be used in pregnancy when strictly indicated. Ivermectin may only be given to breastfeeding mothers if the expected benefit outweighs the potential risk to the infant. **Undesirable effects:** Transient hypereosinophilia, liver dysfunction including acute hepatitis, increased liver enzymes, hyperbilirubinemia and haematuria have been reported. Very rarely, toxic epidermal necrolysis and Stevens-Johnson syndrome have also been reported. In patients with scabies, transient exacerbation of pruritus may be observed at the start of treatment. **Please refer to SmPC for full details. Legal category:** POM. **Presentation and cost:** 4 x 3 mg tablets £49.20; **Marketing authorisation number:** PL 23218/0227. Further information is available from Exeltis UK Limited, Two Snowhill, 7th Floor, Birmingham, B4 6GA. **Date of last revision:** January 2024. **Job Number:** EXE-E/IPR-IVE-1232.

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Exeltis UK Limited on 01494 411775 or by email to uk.medinfo@exeltis.com