Spinosa® (Topical Suspension)

Spinosad 0.9%

Description: Spinosad is a scabicide preparation, which is highly effective against scabies infestations in adult and pediatric patients.

Composition: Each gm contains spinosad 9 mg.

Mode of action: Spinosad causes neuronal excitation in insects. After periods of hyperexcitation, lice and mites become paralyzed and die.

Pharmacokinetics: When applied topically, spinosad shows minimal absorption into the bloodstream. After topical application, detectable plasma levels of spinosad are either very low or absent. In clinical studies, plasma spinosad concentrations were below the level of quantification in most subjects following a single topical application to the scalp for lice treatment. The absorption in children follows a similar pattern, with minimal systemic exposure. Spinosad remains localized to the treated area, specifically targeting lice and scabies on the surface of the skin and scalp. Due to its minimal absorption, significant distribution into systemic circulation is not observed. Because spinosad is minimally absorbed, metabolism within the body is very limited. If any trace amounts are absorbed, spinosad is likely metabolized by the liver's CYP450 enzyme system. Spinosad is predominantly excreted as unchanged drug through the skin or external means (e.g., through washing off). Minimal amounts, if any, are excreted via urine or feces due to low systemic absorption. Due to its negligible systemic absorption, spinosad's systemic half-life is not well-defined in humans. It primarily remains active on the surface of the skin until washed off.

Indications:

♦Indicated for the topical treatment of scabies infestations in adult and pediatric patients 4 years of age and older

♦Indicated for the topical treatment of head lice infestations in adult and pediatric patients 6 months of age and older.

Dosage & administration:

Treatment of head lice infestations:

♦Shake bottle well

♦Apply a sufficient amount to cover dry scalp, then apply to dry hair

♦Rinse off with warm water after 10 minutes

♦Repeat treatment only if live lice are seen 7 days after first treatment

Treatment of scabies infestations:

♦Shake bottle well

♦Apply product to skin by rubbing it in to completely cover the body from the neck down to the soles of the feet

♦Patients with balding scalp should also apply product to the scalp, hairline, temples, and forehead

♦Allow to absorb in the skin and dry for 10 minutes before getting dressed

♦Leave on the skin for at least 6 hours before showering or bathing

Contraindications: None

Side effects: The most common side effects of Spinosad Topical Suspension include irritation (including pain and burning) at application sites and dry skin.

Use in pregnancy & lactation: Spinosad, the active ingredient in Spinosad Topical Suspension, is not absorbed systemically following topical application, and maternal use is not expected to result in fetal exposure to the drug. Spinosad Topical Suspension contains benzyl alcohol. Topical benzyl alcohol is unlikely to be absorbed through the skin in clinically relevant amounts; therefore, maternal use is not expected to result in fetal exposure to the drug. The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk for birth defect, loss, or other adverse outcomes.

Spinosad, the active ingredient in Spinosad Topical Suspension, is not systemically absorbed by the mother following topical application. Therefore, breastfeeding is not expected to result in the exposure of the child to spinosad. Advise breastfeeding women to remove Spinosad Topical Suspension from the breast with soap and water before breastfeeding to avoid direct infant exposure to Spinosad Topical Suspension. Spinosad Topical Suspension contains benzyl alcohol. Topical benzyl alcohol is unlikely to be absorbed through the skin of breastfeeding women in clinically relevant amounts; therefore, breastfeeding is not expected to result in exposure of the infant to Spinosad Topical Suspension [see Clinical Pharmacology. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Spinosad Topical Suspension and any potential adverse effects on the breastfed child from Spinosad Topical Suspension, or from the underlying maternal condition.

Precautions: Spinosad Topical Suspension contains benzyl alcohol and is not approved for use in neonates and infants below the age of 6 months. Systemic exposure to benzyl alcohol has been associated with serious adverse reactions and death in neonates and low birth-weight infants when administered intravenously.

Drug interactions: Generally has minimal drug interactions due to its low systemic absorption. while using spinosad with other topical medications, such as corticosteroids or retinoids, there could be an increased risk of local skin irritation or hypersensitivity, though this is more of a compounded side effect rather than a true drug interaction. Overall, spinosad 0.9% topical suspension is considered safe with minimal interaction concerns, especially when used as directed.

Overdosage: No specific antidotes for spinosad overdosage are known.

Storage: Keep out of the reach of children. Store in a dry place, below 25° C temperature and protected from light.

Packaging: Spinosad 0.9% Topical Suspension: Each bottle contains 60 ml of Spinosad 0.9% Topical Suspension.

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Opsonin Pharma
Ideas for healthcare

Manufactured by
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