

**The only  
FDA-approved  
scabies treatment  
that can deliver a  
“complete cure”.<sup>1,2</sup>**

For more information, please visit  
[www.spinosadrx.com/scabies](http://www.spinosadrx.com/scabies).

## **Important Safety Information<sup>2</sup>**

### **Indication**

Spinosad Topical Suspension 0.9% is a scabicide indicated for the topical treatment of scabies infestations in adult and pediatric patients four (4) years of age and older.

### **Adjunctive Measures**

- Wash in hot water or dry-clean any bedding, clothing and towels used by anyone having scabies.
- If any member of a household presents with scabies, all household members should be treated with Spinosad Topical Suspension 0.9%.

### **Important Safety Information**

Spinosad Topical Suspension 0.9% contains benzyl alcohol and is not recommended for use in pediatric patients below the age of 4 years. The safety and effectiveness of Spinosad Topical Suspension 0.9% have not been established in pediatric patients less than 4 years of age with scabies infestation. Most common adverse events were: application site irritation (3%)\* and dry skin (2%).

\*Application site irritation also includes application site pain and burning sensation.

**Consult the Full Prescribing and Patient Information in pocket and your doctor for more complete information on Spinosad Topical Suspension 0.9%.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**



**The only  
FDA-approved  
scabies treatment  
that can deliver a  
“complete cure”.<sup>1,2</sup>**

**Spinosad**  
Topical Suspension 0.9%



## Before using Spinosad Topical Suspension 0.9%, tell your healthcare provider about all of your medical conditions, including if you or your child:<sup>2</sup>

- Have any skin conditions or sensitivities
- Are pregnant or plan to become pregnant. It is not known if Spinosad Topical Suspension 0.9% can harm your unborn baby.
- Are breastfeeding or plan to breastfeed
  - Wash the breast area with soap and water to remove Spinosad Topical Suspension 0.9% before breastfeeding to avoid exposure to your baby.
  - Talk to your healthcare provider about the best way to feed your baby during treatment with Spinosad Topical Suspension 0.9%.

## Why rely on Spinosad Topical Suspension 0.9%?

Spinosad Topical Suspension 0.9% is the only topical prescription therapy that meets the FDA's new criteria for delivering a "complete cure" of scabies infestations. That means all signs and symptoms of scabies can be resolved with a single, full-body application.<sup>1,2</sup>

## What is Spinosad Topical Suspension 0.9%?

Spinosad Topical Suspension 0.9% is a prescription medicine used to treat scabies in adults and children 4 years of age and older. It is not known if Spinosad Topical Suspension 0.9% is safe and effective in children under 4 years of age.<sup>2</sup>

## How does Spinosad Topical Suspension 0.9% work?

Spinosad Topical Suspension 0.9% kills scabies mites where they live, eat, and breed on the outer layer of the skin. What's more, the active compound in Spinosad Topical Suspension 0.9%.<sup>2-3</sup>

- Only penetrates the first layer of the skin
- Is not associated with toxic conditions
- Is not absorbed into the bloodstream or vital organs

## How should I store Spinosad Topical Suspension 0.9%?

Store Spinosad Topical Suspension 0.9% at room temperature between 68°F to 77°F (20°C to 25°C). Keep Spinosad Topical Suspension 0.9% and all medicines out of the reach of children.<sup>2</sup>

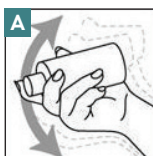
## Safety & Spinosad Topical Suspension 0.9%<sup>2</sup>

In Spinosad Topical Suspension 0.9% clinical trials, some patients experienced negative symptoms, including painful skin, skin burning sensation, and dry skin. However, other symptoms are also possible. Call your doctor for medical advice about any negative symptoms you may experience.

## Proper application is key to success.<sup>2</sup>

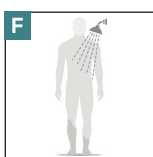
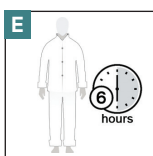
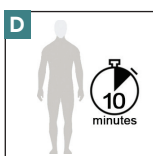
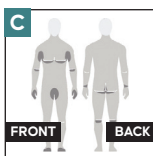
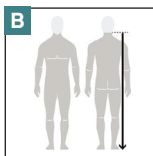
Spinosad Topical Suspension 0.9% is a safe, effective way to treat scabies infestations when you carefully follow the application instructions.

*If you do not completely cover your body with Spinosad Topical Suspension 0.9%, some mites may escape treatment.*



## Application Instructions<sup>2</sup>

**Important:** Read the entire brochure before use. For complete instructions in English and Spanish, refer to our website at [www.spinosadrx.com/scabies/administration](http://www.spinosadrx.com/scabies/administration).



- Shake the Spinosad Topical Suspension 0.9% bottle well right before use. (See Figure A.)
- Apply Spinosad Topical Suspension 0.9% to the skin.
- Apply enough Spinosad Topical Suspension 0.9% to completely cover your body from your neck to the soles of your feet, including the folds of your skin, between your fingers and toes, and underneath your fingernails and toenails. (See Figures B-C.)
- If you're balding, apply Spinosad Topical Suspension 0.9% to your scalp, hairline, temples, and forehead.
- Allow Spinosad Topical Suspension 0.9% to soak into your skin and dry for 10 minutes. Use a clock or timer after your body is completely covered with Spinosad Topical Suspension 0.9%. After 10 minutes, you can get dressed. (See Figure D.)
- Leave Spinosad Topical Suspension 0.9% on your skin for at least 6 hours before showering or bathing. (See Figures E-F.)

**NOTE:** Children will need an adult to apply Spinosad Topical Suspension 0.9% for them. Remember to wash your hands after applying Spinosad Topical Suspension 0.9% to someone else.

**Important:** For use on skin only. Do not get Spinosad Topical Suspension 0.9% in your eyes, mouth, or vagina.

## What is scabies?<sup>4</sup>

Scabies is a parasitic infestation on your skin caused by microscopic, human itch mites called *Sarcoptes scabiei*. They live just beneath the skin's surface, laying eggs that cause an itchy skin rash. The itching is often severe and is usually worse at night.

## What are the signs and symptoms of a scabies infestation?<sup>5</sup>

If you have scabies, you might see tracks of tiny blisters or bumps that typically appear in the folds of the skin, though almost any part of the body may be involved.

## How did I get scabies?<sup>4</sup>

Scabies is contagious and can spread quickly through close physical contact in the household, child care groups, and school settings. It is also spread easily to sexual partners.

## How long can scabies mites live?<sup>4</sup>

On a person, scabies mites can live for up to 1-2 months. Off a person, they usually do not survive more than 48-72 hours.

## How is scabies treated?<sup>4</sup>

Products used to treat scabies are called scabicides because they can kill scabies mites, eggs, or both. FDA-approved scabicides are available only with a doctor's prescription; no over-the-counter products have been tested and FDA-approved for humans.

## How can the spread of scabies be prevented?<sup>2,4</sup>

- Avoid skin-to-skin contact with anyone who has scabies, including sexual partners.
- Avoid touching and sharing items such as bedding, clothing, towels and linens of any person who has scabies.
- Get all household members treated if any member of the household has scabies.
- Machine-wash any used bedding, clothing, towels and linens in hot water and dry in a hot dryer, or disinfect the items by sealing them in a closed plastic bag for at least 72 hours.

**References:** 1. ParaPRO, LLC & Concentrics Research (2018). A Phase 3, Randomized, Double Blind, Placebo-Controlled Study to Assess the Safety, Efficacy and Pharmacokinetics of Spinosad Topical Suspension 0.9% for the Treatment of Scabies (Clinical Study Protocol, Amd. 6.0, pp. 1-66). 2. Spinosad Topical Suspension Prescribing Information. 3. Data on File, ParaPRO LLC. 4. Parasites - Scabies, CDC; <https://www.cdc.gov/parasites/scabies/>. Accessed July 6, 2021. 5. Scabies Symptoms; WebMD; <https://www.webmd.com/skin-problems-and-treatments/ss/slideshow-scabies-overview>. Accessed July 6, 2021.

**Please see Important Safety Information on back and Full Prescribing and Patient Information in pocket for Spinosad Topical Suspension 0.9%.**