

Patient Information

Natroba™ (Nah-TRO-buh) (spinosad) Topical Suspension, 0.9%

Important: For use on scalp hair and scalp only. Do not get NATROBA Topical Suspension in your eyes, mouth, or vagina.

Read the Patient Information that comes with NATROBA Topical Suspension before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is NATROBA Topical Suspension?

NATROBA Topical Suspension is a prescription medicine used to get rid of lice in scalp hair of children and adults.

It is not known if NATROBA Topical Suspension is safe for children under 4 years of age or in people over age 65.

Once NATROBA Topical Suspension is washed off, a fine-tooth comb may be used to remove treated lice and nits from the hair and scalp, but combing is not required. All personal items exposed to the hair or lice should be washed in hot water or dry-cleaned. See “How do I stop the spread of lice?” at the end of this leaflet.

What should I tell my healthcare provider before I use NATROBA Topical Suspension?

Tell your healthcare provider about all of your medical conditions, or the medical conditions of your child, including if you or your child:

- have any skin conditions or sensitivities
- are pregnant or planning to become pregnant. It is not known if NATROBA Topical Suspension can harm your unborn baby.
- are breastfeeding. Talk to your health care provider if you are breastfeeding.

How should I use NATROBA Topical Suspension?

- Use NATROBA Topical Suspension exactly as prescribed. Your healthcare provider will prescribe the treatment that is right for you. Do not change your treatment unless you talk to your healthcare provider.
- Use NATROBA Topical Suspension in one or two treatments that are one week apart. If live lice are seen one week (7 days) after you first used NATROBA Topical Suspension you will need to use NATROBA Topical Suspension again.
- Shake bottle well right before use.
- Use NATROBA Topical Suspension when your hair is dry. Do not wet your hair before applying NATROBA Topical Suspension.
- It is important to use enough NATROBA Topical Suspension to coat completely every single louse and to leave it on your scalp for the full 10 minutes. See the detailed Patient Instructions for Use at the end of this leaflet.
- Because you need to completely cover all of the lice with NATROBA Topical Suspension, you may need help in applying NATROBA Topical Suspension to your scalp and hair. Make sure that you and anyone who helps you apply NATROBA Topical Suspension reads and understands this leaflet and the Patient Instructions for Use.

- Children will need an adult to apply NATROBA Topical Suspension for them.
- Do not swallow NATROBA Topical Suspension. If swallowed, call your healthcare provider right away.
- Do not get into eyes. If NATROBA Topical Suspension gets in the eye, flush with water right away.
- Wash your hands after you apply NATROBA Topical Suspension.

What are the possible side effects of NATROBA Topical Suspension?

People using NATROBA Topical Suspension may have skin or eye:

- Redness
- Irritation

If skin or eye irritation happens, rinse with water right away, then call your healthcare provider or go to the emergency department

These are not all the side effects of NATROBA Topical Suspension. For more information, ask your healthcare provider.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NATROBA Topical Suspension?

- Store NATROBA in a dry place at room temperature, 20°C to 25°C (68° F to 77° F).

Keep NATROBA Topical Suspension and all medicines out of the reach of children.

What are the ingredients in NATROBA Topical Suspension?

Active ingredient: spinosad

Inactive ingredients: water, isopropyl alcohol, benzyl alcohol, hexylene glycol, propylene glycol, cetearyl alcohol, stearyl alcohol, cetareth-20, hydroxyethyl cellulose, butylated hydroxytoluene, FD&C yellow #6

General Information about NATROBA Topical Suspension

Medicines are sometimes prescribed for conditions other than those described in the patient information leaflets. Do not use NATROBA Topical Suspension for any condition for which it was not prescribed by your healthcare provider. Do not give NATROBA to other people, even if they have the same symptoms as you. It may harm them.

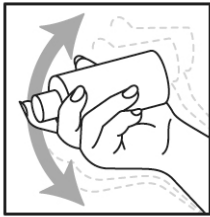
This leaflet summarizes the most important information about NATROBA Topical Suspension. If you would like more information, talk to your healthcare provider. You can also ask your healthcare provider for information about NATROBA Topical Suspension that is written for healthcare professionals.

Patient Instructions for Use

Completely cover the scalp with NATROBA Topical Suspension. Lice and nits live near the scalp. Use as much product as needed to completely cover the scalp first, and then apply outwards towards the ends of the hair.

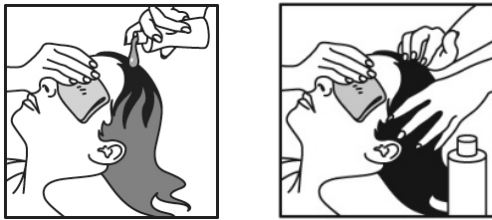
For very thick, medium length hair or long hair, an entire bottle (120mL) of NATROBA Topical Suspension may be needed to cover the scalp and hair. Less NATROBA Topical Suspension may be needed for shorter, thinner hair.

Step 1



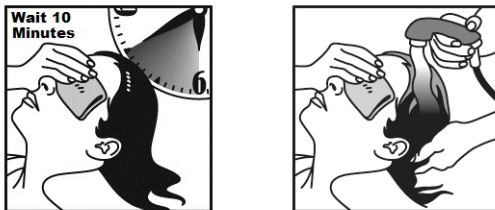
- Shake NATROBA Topical Suspension bottle well right before use.

Step 2



- Cover your face and eyes with a towel and keep your eyes closed tightly.
- Apply NATROBA Topical Suspension directly to **dry** hair.
- Completely cover the scalp first, and then apply outwards towards the ends of the hair.
- If not enough NATROBA Topical Suspension is used, some lice may escape treatment. It is important to use enough NATROBA Topical Suspension to cover your entire scalp and all scalp hair.

Step 3



- Allow NATROBA Topical Suspension to stay on your hair for 10 minutes. Use a timer or clock and start timing after you have completely covered your hair and scalp with NATROBA Topical Suspension.
- Continue to keep eyes covered to prevent dripping into your eyes.
- After 10 minutes, completely rinse NATROBA Topical Suspension from your hair and scalp with warm water.
- You or anyone who helps you apply NATROBA Topical Suspension should wash hands after application.
- It is okay to shampoo your hair any time after the treatment.

One week (7 days) after your first treatment, if live lice are seen, repeat the steps above.

How do I stop the spread of lice?

To help prevent the spread of lice from one person to another, here are some steps you can take:

- Avoid direct head-to-head contact with anyone known to have live, crawling lice.
- Do not share combs, brushes, hats, scarves, bandannas, ribbons, barrettes, hair bands, towels, helmets, or other hair-related personal items with anyone else, whether they have lice or not.
- Avoid sleepovers and slumber parties during lice outbreaks. Lice can live in bedding, pillows, and carpets that have recently been used by someone with lice.
- After finishing treatment with lice medicine, check everyone in your family for lice after one week. Be sure to talk to your healthcare provider about treatments for those who have lice.
- Machine-wash any bedding and clothing used by anyone having lice. Machine wash at high temperatures (150°F) and tumble in a hot dryer for 20 minutes.

This patient Leaflet has been approved by the U.S. Food and Drug Administration.

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