

Prescription Label

Patient Name:

Species:

Drug Name & Strength:

Directions (amount to give how often & for how long):

Prescribing Veterinarian's Name & Contact Information:

Refills:

[Content to be provided by prescribing veterinarian]

Neomycin, Isoflupredone, and Tetracaine Combinations (Topical)

(nee-oh-mye-sin, eye-soe-flue-pre-done, teh-trah-kane)

Description:

Topical skin and/or ear treatment

Other Names for this Medication:

Neo-Predef® with Tetracaine, Tritop®

Common Dosage Forms:

Veterinary: Topical powder containing neomycin 3.5 mg with isoflupredone acetate 1 mg and tetracaine hydrochloride 5mg per gram of powder in 15 g bottles; ointment containing neomycin 3.5 mg with isoflupredone acetate 1 mg and tetracaine hydrochloride 5mg per gram of ointment in 10 g tubes. **Human:** None.

This information sheet does not contain all available information for this medication and has not been reviewed by FDA Center for Veterinary Medicine. This sheet can help answer commonly asked questions but is not a substitute for medical advice. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- Combination of ingredients allows for efficient delivery of multiple medications with each application.
- Prevent your animal from licking or chewing at affected areas for 20-30 minutes after application.
- Do not allow medication to get in your animal's eyes.
- Always wash hands after applying medication or consider wearing gloves while applying.
- Store powder in a dry place; avoid touching the tip of the bottle to wet surfaces.

How is this medication useful?

This topical combination contains multiple active ingredients to treat skin and ear conditions. The FDA (U.S. Food & Drug Administration) has approved this topical combination for treatment or adjunctive therapy of certain ear and skin conditions in dogs, cats, and horses. This medicine may also be applied as a dressing for minor cuts, wounds, lacerations, abrasions, and at surgical sites following surgery. The FDA allows veterinarians to prescribe products containing this drug in different species or for other conditions in certain situations. You and your veterinarian can discuss why this drug is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given?

Many things might affect how well this drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- Other drugs can interact with this medication, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.
- Tell your veterinarian about any conditions or diseases your animal may have now or has had in the past.
- If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how
 well it did or didn't work.
- If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this drug.
- Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

This medication should help your animal feel better within 1 to 2 hours. Your animal's clinical signs should improve after that time. The effects of this medication are moderate in duration, meaning they may last for a few days, although the benefits may be prolonged if your animal has decreased kidney and/or liver function.

When should this medication not be used or be used very carefully?

No drug is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this drug in your animal.

This drug **SHOULD NOT** be used in:

- Animals that are allergic to any of the ingredients found in this combination product.
- Animals that have tuberculosis infections of the skin.
- Animals with ruptured ear drums (if medicine being used in the ears).

This drug should be used WITH CAUTION in patients:

- With small body size (eg, toy breeds).
- That require treatment of large areas.
- Dogs in any stage of pregnancy and cats or horses in the last stage of pregnancy.

If your animal has any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication?

In dogs and cats, topical skin treatments are typically well tolerated.

Side effects that usually are not serious include:

• Redness or discomfort at the site of application.

You don't have to be overly concerned if you see any of these signs unless they are severe, worsen, or continue to be a problem. Contact your veterinarian if this happens.

Side effects that may be serious or indicate a serious problem:

- Infections that do not respond to treatment, do not appear to be healing, or are getting worse.
- Loss of appetite, vomiting, or diarrhea.
- Development of sores around the mouth.
- Increased thirst (eg, frequent drinking of large quantities of water) and frequent urination.
- Thinning of the skin, progressive hair loss and skin redness, increased skin tears, or infections at the application site.

If you see any of these signs, contact your veterinarian immediately.

If my animal gets too much of this medication (an overdose), what should I do?

An overdose could occur if your animal eats the topical medication, if the treatment area covers a large part of your animal's body, or if too much medicine is applied. If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center** (888-426-4435); a consultation fee is charged for these services.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has prescribed. It's a good idea to always check the prescription label to be sure you are giving the drug correctly.

- Clean the application site before application. Trim hair only as necessary.
- If using the powder, apply with short, sharp squeezes to the sides of the bottle. Do not touch the tip of the bottle to moist, wet, or weeping surfaces.
- When using the ointment, apply in small amounts and spread or rubbed gently at the affected area.
- Avoid contact with eyes, mouth, and nose.
- Do not allow animal to lick or chew at affected sites as this will delay healing and possibly introduce more infection to the area. If necessary, your veterinarian may place a collar on your animal to prevent licking and chewing of the area.
- These combination products can be given for various lengths of time. Be sure you understand how long your veterinarian wants you to continue giving this medication. Prescription refills may be necessary before the therapy will be complete. Before stopping this medication, talk to your veterinarian, as there may be important reasons to continue its use.

What should I do if I miss giving a dose of this medication?

If you miss a dose, give it when you remember, but if it is close to the time for the next dose, either 1) skip the dose you missed, give it at the next scheduled time, and then return to the regular dosing schedule, or 2) give it when you remember and then wait the amount of time between doses recommended by your veterinarian before giving another dose. Do not double-up or give extra doses.

How should I store this medication?

- Store this medication in the original container at room temperature and protected from light. The bottle of powder should be stored in a dry place with the cap securely in place.
- If your veterinarian or pharmacist has made (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- Keep away from children and other animals.

Can handling this medication be hazardous to me, my family, or other animals?

It is recommended to wear gloves while applying these medicated products. Always wash your hands after applying the medication.

How should I dispose of this medication if I don't use it all?

- Do not flush the contents of these products down the toilet or wash it down the sink. If a community drug "take-back" program is available, use this option. If there is no take-back program, mix the contents with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash.
- Do not save leftover product for future use or give it to others to use.

What other information is important for this medication?

- Certain skin infections may resolve completely with use of topical treatments, but others may also require oral medications.
- Medications may be absorbed across the skin and have effects throughout the body when applied to large areas or areas with open sores; small animals and patients receiving prolonged treatment may also be affected. Effects on the rest of the body can happen with any topically applied medication; however, the risk is greater with steroids, especially with use of potent steroids such as isoflupredone.
- Residual activity from steroid-containing products may affect allergy testing. Unless your veterinarian tells you otherwise, stop using steroid-containing products 2 weeks before allergy testing.
- Use of this drug may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

If you have any other questions about this medication, contact your veterinarian or pharmacist.