

PACKAGE LEAFLET

Agenzia Italiana del Farmaco

Package leaflet: Information for the Patient

nickel sulfate hexahydrate allergEAZE 5%, ointment nickel sulfate hexahydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What nickel sulfate hexahydrate allergEAZE 5% is and what it is used for
2. What you need to know before you use nickel sulfate hexahydrate allergEAZE 5%
3. How to use nickel sulfate hexahydrate allergEAZE 5%
4. Possible side effects
5. How to store nickel sulfate hexahydrate allergEAZE 5%
6. Contents of the pack and other information

1. What nickel sulfate hexahydrate allergEAZE 5% is and what it is used for

Nickel sulfate hexahydrate allergEAZE 5% is a medicinal product only for diagnostic use. Nickel sulfate hexahydrate allergEAZE 5% patch test is used in patients with suspected allergic contact dermatitis to nickel. It contains nickel that can trigger contact allergies on the skin.

Allergic contact dermatitis is an inflammatory response of the skin caused by repeated exposure to foreign substances to which you are allergic.

The test is performed at the doctor's office.

2. What you need to know before you use nickel sulfate hexahydrate allergEAZE 5%

Do not use nickel sulfate hexahydrate allergEAZE 5%

- If your general well-being is significantly impaired (e.g. you have an infection).
- If you are allergic to any of the ingredients of this medicine (listed in Section 6).
- If you, at the time of testing, have severe or generalised dermatitis. The patch testing should be done after resolution of the acute phase.
- Existing dermatological pathology at the application site of the patch test.
- If your skin has been exposed to UV (sun) light intensively in the test area in the past 4 weeks.

Warnings and precautions

- Before applying the patch test, your doctor will make sure the patch test application area is free of any ongoing skin conditions that may interfere with the test results.
- During the application period, you should avoid wetting the patch test application area (e.g. excessive exercise and sweating, bathing or showering).
- Your doctor should suspend, if possible, your medicines such as corticosteroids that suppress the immune system as these may cause false-negative test results.
- Anaphylactic reactions have been reported very rarely with some substances; however, no anaphylactic reactions with nickel sulfate hexahydrate are known in the literature.
- If you have earlier had anaphylactoid reactions the use of nickel sulfate hexahydrate allergEAZE 5% should be considered carefully.

Active sensitisation is in general rare for patch tests but possible, and it is probable if a positive reaction occurs approximately 10-21 days after the application of the patch test. A subsequent patch test with a positive reaction within 72-96 hours can be considered a case of active sensitization of the previous patch test.

Children and adolescents

Nickel sulfate hexahydrate allergEAZE 5% has been used in children in case of suspicion of allergic contact dermatitis to nickel and/or in case of diffuse dermatitis non responding to conventional treatments. Your doctor will decide if your child should be tested. Interpretation of patch test results requires experience in the pediatric population, 96-hour readings and subsequent readings if necessary are also recommended in young children.

Other medicines and nickel sulfate hexahydrate allergEAZE 5%

Tell your doctor or healthcare professional if you are taking, have recently taken, or might plan to take any other medicines, including medicines obtained without prescription, before nickel sulfate hexahydrate allergEAZE 5% is applied. Remember that your doctor may not be aware of what you are taking.

- Corticosteroids and medicines that weaken immune system (immunosuppressive medicines) can cause false negative test results. Your doctor will decide if you must stop corticosteroid treatment prior to testing. If you are not sure if any of your medicines contain corticosteroids, talk to your doctor.
- If you are undergoing treatment with medicines against cancer (cytostatic medicines) or immunosuppressive therapy, patch testing should be postponed.

Pregnancy, breastfeeding and fertility

No experimental data are available on the use of the Nickel sulfate hexahydrate allergEAZE 5% patch test in pregnant women.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or healthcare professional for advice before using this medicine.

Patch testing for allergy should not be carried out during pregnancy or while breastfeeding, unless it is considered absolutely necessary. Your doctor will decide if you should use a patch test or not.

Driving and using machines

Nickel sulfate hexahydrate allergEAZE 5% is unlikely to affect your ability to drive or use machines. Talk to your doctor about this if you have any concerns.

3. How to use nickel sulfate hexahydrate allergEAZE 5%

Method of administration

The following steps are performed by a qualified healthcare personnel:

- 5 mm of ointment (20-25 mg) is applied into the application chamber of the test device (patch test) using the syringe containing the medicinal product.
- The patch test is then applied to healthy, dry skin (usually on the patient's upper back or, if not possible, on the skin of the surface of the upper arm).

Duration of treatment

The patch test must be removed by qualified healthcare personnel, 48 hours after application.

- Your doctor will read the test result at least 30 minutes after removal and again 1 day (72 hour reading) or 2 days (96 hour reading) afterwards, when any allergic reactions are fully developed, and possible mild irritating reactions have subsided.

Assessment of skin reactions is performed by the doctor according to an established protocol.

Instructions for this assessment can be found in the information for healthcare professionals (see section “**Interpretation**” at the end of this document).

If you use more nickel sulfate hexahydrate allergEAZE 5% than you should

When used properly, overdosing is not possible.

If you have any further questions about the use of this product, ask your doctor.

4. Possible side effects

Like all medicines, nickel sulfate hexahydrate allergEAZE 5% may cause side effects, although not everybody gets them.

The following adverse reactions have been reported from published scientific literature for patch testing (frequency cannot be estimated from the available data):

- Sensitisation to the substance, you are being tested with,
- Skin reactions at the patch test application site. The reactions include itching, reddening of the skin and possibly blistering. These reactions are expected and may indicate a contact allergy,
- Scar,
- Localised transient pale (hypopigmentation) or darker area (hyperpigmentation) of the skin,
- Irritant reactions,
- Flare-up of a pre-existing reddening of the skin,
- Infection of the skin at the application site, Mild to moderate allergic reactions such as skin redness or itching.
- Anaphylactic reaction (systemic reaction, possibly with a life-threatening drop of blood pressure), no anaphylactic reactions with nickel sulfate hexahydrate are known in the literature

If you experience severe discomfort at the patch test application site, it is necessary to contact a doctor. Your doctor may decide to remove the patch test.

In rare cases, patch testing can lead to serious allergic reactions, including systemic reactions (allergic shock). Warning signs of an allergic shock reaction may include itching of the palms and soles of the feet, feel generally uncomfortable, feeling of warmth, difficult breathing, rapid heartbeat, change in tone of voice, feeling lightheaded, tightness in the throat, and agitation/anxiety. No anaphylactic reactions with nickel sulfate hexahydrate are known in the literature.

Inform your doctor or healthcare professional immediately if you experience any of these reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

[https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.](https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse)

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store nickel sulfate hexahydrate allergEAZE 5%

Do not store above 25 °C.

After opening the product is stable for 3 months.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the labels after EXP (or Scad.). The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your doctor or healthcare professional how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What nickel sulfate hexahydrate allergEAZE 5% contains

- The active substance is nickel sulfate hexahydrate.
- The excipient is paraffin, white soft (petrolatum).

What nickel sulfate hexahydrate allergEAZE 5% looks like and contents of the pack

Blue to green ointment in a syringe.

Pack size: Polyethylene pouch with 1 pre-filled syringe (barrel: polypropylene; plunger: polyethylene) closed by a cap (polyethylene) containing 5 mL (4.7 g) of ointment.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

Interpretation

Interpretation of the patch test reaction should be done in accordance with the interpretation method recommended by the International Contact Dermatitis Research Group (ICDRG).

Symbol	Morphology	Assessment
-	No reaction	Negative reaction
?+	Faint erythema only	Doubtful reaction
+	Erythema, infiltration, possibly papules	Weak positive reaction
++	Erythema, infiltration, papules, vesicles	Strong positive reaction
+++	Intense erythema, infiltrate, coalescing vesicles	Extreme positive reaction
IR	Various morphologies (e.g., soap effect, bulla, necrosis)	Irritant reaction