

**PACKAGE LEAFLET**

Agenzia Italiana del Farmaco

## Package leaflet: Information for the Patient

### hydroabietyl alcohol allergEAZE 10%, ointment hydroabietyl alcohol

**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 hydroabietyl alcohol allergEAZE 10% is and what it is used for
2. What you need to know before you use hydroabietyl alcohol allergEAZE 10%
3. How to use hydroabietyl alcohol allergEAZE 10%
4. Possible side effects
5. How to store hydroabietyl alcohol allergEAZE 10%
6. Contents of the pack and other information

#### 1. What hydroabietyl alcohol allergEAZE 10% is and what it is used for

Hydroabietyl alcohol allergEAZE 10% is a medicinal product only for diagnostic use. Hydroabietyl alcohol allergEAZE 10% patch test is indicated in adult patients with suspected allergic contact dermatitis to hydroabietyl alcohol. It contains hydroabietyl alcohol 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 hydroabietyl alcohol allergEAZE 10%

##### Do not use hydroabietyl alcohol allergEAZE 10%

- 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 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 hydroabietyl alcohol are known in the literature.
- If you have earlier had anaphylactoid reactions the use of hydroabietyl alcohol allergEAZE 10% 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**

There are few clinical data available on the use of patch tests in children.

Children should only be tested with hydroabietyl alcohol allergEAZE 10% when there is a strong suspicion of allergic contact dermatitis to hydroabietyl alcohol. Your doctor will decide if your child should be tested.

### **Other medicines and hydroabietyl alcohol allergEAZE 10%**

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 hydroabietyl alcohol allergEAZE 10% 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 hydroabietyl alcohol allergEAZE 10% 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 take a patch test or not.

### **Driving and using machines**

Hydroabietyl alcohol allergEAZE 10% 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 hydroabietyl alcohol allergEAZE 10%**

### **Method of administration**

The following steps are performed by 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 panel 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 hydroabietyl alcohol allergEAZE 10% 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, hydroabietyl alcohol allergEAZE 10% 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,
- Localised transient pale (hypopigmentation) or darker area (hyperpigmentation) of the skin,
- Scar,
- Irritant reactions,
- Infection of the skin at the application site,
- Flare-up of a pre-existing reddening of the skin,
- 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 hydroabietyl alcohol 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 hydroabietyl alcohol 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 hydroabietyl alcohol allergEAZE 10%**

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 hydroabietyl alcohol allergEAZE 10% contains**

- The active substance is hydroabietyl alcohol.

- The excipient is paraffin, white soft (petrolatum).

### What hydroabietyl alcohol allergEAZE 10% looks like and contents of the pack

White to off-white ointment in a syringe.

Pack size: Polyethylene pouch with 1 prefilled syringe 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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### This leaflet was last revised in.

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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