CHEMOTECHNIQUE DIAGNOSTICS

Topical Hapten

Package leaflet: Information for the User

IMPORTANT: PLEASE READ THIS INFORMATON BEFORE USING THE PRODUCT

Topical hapten – Gel/Liquid
Topical haptens are supplied in topical gel (semi-solid) or topical liquid. Please refer to the label of each particular Topical hapten for the medicinal ingredient.

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. WHAT TOPICAL HAPTEN – GEL/LIQUID IS AND WHAT IT IS USED FOR

Topical hapten – Gel/Liquid is test substances used for the aid of diagnosis of allergic contact dermatitis. Allergic contact dermatitis is a skin reaction caused by exposure to specific haptens after having developed contact allergy to one or more substance(s).
Topical hapten – Gel/Liquid are topical tests substances containing substance well-known to cause contact allergy in sensitized individuals. The test (i.e., Patch Testing) is performed by specially trained physicians.
An inflammatory skin reaction to any particular hapten confirms the presence of contact allergy to this specific substance. You may be allergic to more than one substance.

This medicine is for diagnostic use only.

Patch testing with topical hapten in gel or liquid should be considered in patients with:

- Suspected contact dermatitis, acute or chronic, including dermatitis related to occupational exposures;

- Other types of (chronic) dermatitis (eczema) not improving with treatment;

- Skin and mucous membrane eruptions (including delayed-type drug eruptions) in which delayed-type hypersensitivity is suspected

2. BEFORE YOU USE TOPICAL HAPTEN – GEL/LIQUID

Do not use Topical hapten – Gel/Liquid

- If on any cortisone or medications altering the immune system such as immunosuppressive treatment prior to and during the test period;
- Has a known history of severe allergic reaction (local or systemic) to the hapten in question or with severe or generalized active dermatitis;
- Has injured skin or the test area has recently been exposed to ultraviolet radiation (UV);
- Has dermatitis on the skin area aimed for the application of patch tests (typically the upper back) or on test sites recently treated with topical corticosteroids; wait at least 1 week after treatment;
- Considerably reduced general condition (e.g. infections);
- Hypersensitivity to any excipient listed in section 6.

Take special care Topical hapten – Gel/Liquid

- Before applying Topical hapten – Gel/Liquid, the test area should be carefully evaluated to ensure that the skin is free of conditions that could interfere with the test results. Use only on intact skin.
- Avoid intense exercise and perspiration while wearing the patch tests.
- Due to its anti-inflammatory properties, the use of corticosteroids may cause false negative test results.
- The use of Topical hapten – Gel/Liquid, in patients with a known history of anaphylactoid reactions to that topical hapten should be carefully evaluated before application.
- For external use only. Avoid contact with eyes.
- Avoid exposure of the patch test area to sunlight.
- Water submersion of the skin area where patch test units are applied should be avoided during the treatment period.
- If swallowed, contact a Poison Control Center right away.
- In case of symptom serious enough to interfere with daily activities, contact your doctor right away

The health care provider must always assess whether an established contact allergy is of present, past or unknown relevance, or is attributable to cross-reactivity. Both personal and occupational exposures need to be addressed. In the case of contact allergy to a chemically defined sensitizer, cross-reacting substances should also be looked for in the environment. In the case of unknown relevance of a positive patch test reaction, it is recommended to repeat the clinical examination, re-evaluate the history and exposure, and to perform use tests, spot tests, and chemical analysis, where indicated.
Patients with atopic dermatitis should be patch tested for the same reasons as other patients.
Although it has variable sensitivity, patch testing should be considered in patients with delayed cutaneous adverse drug reactions (CADRs).
A positive patch test result can help to confirm a possible culprit drug, therefore avoiding oral provocation. A negative patch test result, on the other hand, cannot exclude the contribution of a possible culprit drug, determined on clinical grounds.

Skin reactions that occur at the application site, e.g. itching or erythema with blisters, must be interpreted based on the contact allergy to be tested. See section 3 (Interpretation).

Patients with positive patch test reactions should be given written information, which should be specific for their situation, including the name(s) of substances. International Nomenclature of Cosmetic Ingredients (INCI) names may be provided; in other cases, International Non-proprietary Name (INN) are helpful. Chemical Abstract Service (CAS) numbers and common names are helpful in other fields. Information should be repeated during follow-up visits.

Using other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Use of systemic or local steroids in the test area or oral steroids should be discontinued for at least one week prior to the test. No interaction studies have been conducted.

Use of cytostatics or immunosuppressive agents (including steroids) may suppress a positive test reaction and cause a false negative test result. Ask your health care provider for advice before performing patch testing to determine if it is necessary to postpone patch testing.

Pregnancy and breast-feeding

Pregnancy and breast-feeding may be a conditional contraindication as there are no data on the safety of the test for the mother and child. Ask your health care provider for advice before patch testing.

Driving and using machines

Topical hapten – Gel/Liquid has no or negligible effect on the ability to drive and use machines. Ask your health care provider for advice if you feel unsure. You are responsible for evaluating if you are able to drive or use machines.

3. HOW TO USE TOPICAL HAPTEN – GEL/LIQUID

Patch testing should be undertaken only by a specially health care provider who fully understands the hazards of the applied substances/products. A patient should not attempt to self-apply the product.

The following steps are performed by specially trained health care providers:

For patch tests using IQ Ultra™, IQ Ultimate™ or BasIQ Ultra™:
If topical hapten in gel: Remove protective cap. Prime syringe before use. Priming is performed by discarding a single dose (a 5-6 mm string of gel / 25 µl). By priming, possible hapten degradation is avoided.
Apply a dose (5-6 mm string of gel / 25 µl) into the intended area of the patch test chamber.

Do not pull back plunger after hapten application. By pulling back the plunger, oxygen may enter the syringe barrel which may cause hapten degradation.

Put protective cap back after use.

If applications are done in a sequence, there is no need for priming before each new application.

If topical hapten in liquid: Remove screw cap. Apply one drop (25 µl) of the test preparation into the intended area of the patch test chamber. The optimal dose of topical hapten may differ if using patch test units of other brands.

Apply the patch test chamber filled with topical hapten to dry and intact skin that does not have scars, acne, dermatitis, or other conditions that may interfere with the test result. Place the patch test on the patient's upper back; possibly the outside of the upper arm can also be used if the back is not suitable for patch testing or is fully used already.

Remove the patch test chamber 48 hours after application. Reading of the test could be done 30 minutes after its removal and subsequent reading of results are performed at 3 or 4 days, when the allergic reactions have fully developed and mild irritation reactions have disappeared. In some cases, later readings may also be required and can extend up to day 7 upon physician recommendation.

Following physician observation, Allergic Contact Dermatitis (ACD) is confirmed if an inflammatory skin reaction occurs for a specific hapten.

The patch test is scored according to morphology. A positive patch test reaction is defined as a reaction that fulfills the criteria of at least a 1+ reaction.

Contact your health care provider if you experience a strong physical discomfort of the test area.

Interpretation

Evaluation of patch test reactions should only be performed by specially trained health care providers. The interpretation method should follow the recommendation issued by the International Contact Dermatitis Research Group (ICDRG) (see Table 1). A positive patch test reaction is defined as a reaction that fulfills the criteria of at least a 1+ reaction.

Table 1

+	**Weak positive reaction** • Erythema • Infiltration • Possible papules
++	**Strong positive reaction** • Erythema • Infiltration • Papules • Vesicles
+++	**Extremely positive reaction** • Intense erythema • Infiltrate • Coalescent vesicles
? +	**Doubtful reaction** • Faint erythema only
-	**Negative reaction** • No reaction
IR	**Irritant reaction** • Various morphologies, e.g. soap effect, bulla, necrosis

Use in children

Limited data in children are available from clinical trials. In general, epicutaneous patch test studies indicate that the same test concentrations can be used in the pediatric population as in adults.

For use in infants and children younger than 8 years old, patch test removal after 24 hours is recommended to avoid irritant skin reaction, and patch test reading is encouraged after at least 48 hours with additional delayed reading after 72 hours. Also, the following should be considered:

- Collaboration between pediatrician and dermatologist/allergist is strongly recommended and caution should be exercised in interpreting the responses;
- Special attention to properly securing the patch test units is necessary;
- Minimization of exposure and adjustment for the limited surface area available for patch placement are required.

If you use more Topical hapten – Gel/Liquid than you should

An overdose is not possible with proper administration. Improper use can lead to increased allergic reactions. In such cases, the health care provider must take preventive countermeasures.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Topical hapten – Gel/Liquid can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Possible side effects:
- Pigmentation changes
- Persisting reaction
- Ulceration
- Flare up of clinical dermatitis
- Subjective discomfort
- Unexpected irritant reactions
- Scarring and necrosis
- Active sensitization

A strong positive reaction may result in a flare-up of an existing, or sometimes a previous, dermatitis. Such flare-up reactions usually indicate that the responsible topical hapten is or has been, respectively, the cause of the dermatitis.

Sensitization by patch testing is a rare but potential complication of topical haptens. It is regarded as a positive patch test reaction generally 2 weeks after an initially negative response at the same patch test site. Rarely localized transient hyperpigmentation or hypopigmentation may occur.

A positive patch test reaction can rarely persist for up to several weeks.

Stop treatment and remove the patch test unit in case of a troublesome symptom or side effect that is not listed above or that becomes serious enough to interfere with the patient`s daily activities.

Extreme positive (+++) reactions with pronounced erythema, infiltration, and coalescing vesicles may present in extremely sensitive patients.
Excited Skin Syndrome (Angry Back) is a regional state of skin hyper-reactivity caused by the presence of a strong positive reaction which may result in other patch test sites to become reactive.
Reactions to the tape or adhesive may occur.

Side effects- acute measures

Although very rare, acute allergic reactions, including anaphylaxis may occur. Appropriate medical treatment must be available in case of an acute allergic reaction. If you experience sweating, dizziness, itching or other discomfort inform your health care provider immediately.
Reporting of suspected side effects

Instruct patients to report any side effects.

5. HOW TO STORE TOPICAL HAPTEN – GEL/LIQUID

Store dark at 2-8°C.
Keep out of reach and sight of children.

Do not use Topical hapten – Gel/Liquid after the expiry date which is stated on the label of the syringe/bottle. The expiry date refers to the last day of that month.

No special instructions for destruction. Unused medicines and waste must be disposed of according to current instructions. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Topical hapten – Gel/Liquid contains:

Topical hapten in gel or liquid. Please refer to the label of each particular topical hapten for medicinal ingredient.
1 g of gel contains 0.1-1000 mg of topical hapten.
1 g of liquid contains 0.1-1000 mg of topical hapten.

List of excipients

Petrolatum, Softisan 649, Sorbitan sesquioleate, Aqua purificata, Ethanol, Acetone.

What Topical hapten – Gel/Liquid looks like and contents of the pack:
If topical hapten in gel:

Multi-dose container: Non-sterile syringe.
Package size: 1 syringe with 5 ml of gel

If topical hapten in liquid:

Multi-dose container: Non-sterile plastic bottle.
Package size: 1 bottle of 8 ml liquid

7. MANUFACTURER

Chemotechnique MB Diagnostics AB
Modemgatan 9
23539 Vellinge
Sweden

8. DATE OF REVISION OF THE TEXT

2024-06-19

© Chemotechnique MB Diagnostics AB