IMPORTANT: PLEASE READ INSTRUCTIONS FOR USE

Topical Hapten - Gel/Liquid

Indications:
Patch testing with Haptens 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.

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 paediatrician 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;
- Minimisation of exposure and adjustment for the limited surface area available for patch placement are required.

Mode of action :
Topical haptens are topical tests performed by specially trained physicians. An inflammatory skin reaction to any particular hapten confirms the presence of contact allergy to this specific substance.

Medicinal ingredients: Please refer to the label of each particular topical Hapten.

Non-medicinal ingredients: Hapten may contain: Acetone, Ethanol, Petrolatum, Softisan, Sorbitan sesquioleate and/or Water. Please refer to the label of each particular topical Hapten.

Dosage forms:
Topical haptens are supplied in topical gel (semi-solid) or topical liquid.

Do not use Haptens if the patient:
- Is 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.

Note: Pregnancy and lactation may be a conditional contraindication as there are no data on the safety of the test for the mother and child.

Warnings
- 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.
- Use only on intact skin.
- Although very rare, acute allergic reactions, including anaphylaxis may occur. Appropriate medical treatment must be available in case of an acute allergic reaction.
- 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.
- 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.

Interactions:
To date, no relevant interactions with topical haptens are known.

Method of use:
- Patch testing should be undertaken only by a specially trained physician who fully understands the hazards of the applied substances/products. A patient should not attempt to self-apply the product.
- Dispense a string of 5-6 mm (gel) or 1 drop (about 25 µl, liquid) of hapten preparation into a patch test chamber.
- The upper back is the preferred site for patch testing. The outer surface of the upper arms or thighs can be used if the back is not suitable for patch testing, or is fully used already*.
- Apply patch test unit on patient's back and leave on for 48 hours. Subsequent reading of results is also performed at 3 or 4 days, and can extend up to 7 days 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.

Symbol	Morphology	Assessment
-	Negative reaction	No 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

Considerations*:
The physician 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.

If allergic contact dermatitis is suspected in patients under immunosuppression, it is recommended to proceed with patch testing, but to keep in mind that false-negative reactions may occur, and, if possible, to repeat patch testing at a later stage.
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.

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.

Usual dose:
A string of 5-6 mm (gel) or about 25 µl (1 drop, liquid) of hapten preparation into a chamber of an IQ Ultra™ or IQ Ultimate™ patch test unit. The optimal doses of topical hapten-gel (semi-solid) or topical hapten-liquid may differ if using patch test units from other manufacturers.

Possible side effects:
- Pigmentation changes
- Persisting reaction
- Ulceration
- Flare up of clinical dermatitis
- Subjective discomfort.
- Unexpected irritant reactions
- Scarring and necrosis
- Patch test 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 hapten is or has been, respectively, the cause of the dermatitis.

Sensitization by patch testing is a rare but potential complication of 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.

Instruct patients to report any side effects.

Storage conditions:
Haptens must be stored at 5-8°C, protected from direct light.
Keep out of reach and sight of children.

For more information about Haptens,
visit: www.dormer.com or call 416 242-6167.

This leaflet was prepared by Dormer Laboratories Inc.
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Last Revised 11 August, 2017

*Extracted from: Johansen, J. Det al., (2015), European Society of Contact Dermatitis guideline for diagnostic patch testing – recommendations on best practice. Contact Dermatitis, 73: 195–221. doi:10.1111/cod.12432