

MEDICATION GUIDE
VALCHLOR® (val-klor)
(mechlorethamine) gel

Important information: VALCHLOR is for use on skin only. Do not get VALCHLOR near or in your eyes, mouth, or nose.

What is the most important information I should know about VALCHLOR?

Keep VALCHLOR away from your eyes, mouth, and nose.

- If VALCHLOR gets in your eyes it can cause eye pain, burning, swelling, redness, sensitivity to light, and blurred vision. It may also cause blindness and permanent injury to your eyes. If VALCHLOR gets in your eyes, rinse your eyes right away for at least 15 minutes with a large amount of water, normal saline, or an eye wash solution.
- If VALCHLOR gets in your mouth or nose it can cause pain, redness, and ulcers. Rinse the affected area right away for at least 15 minutes with a large amount of water.

Get medical help right away if VALCHLOR gets in your eyes, mouth, or nose. Talk with your healthcare provider before using VALCHLOR about how to get medical help.

What is VALCHLOR?

VALCHLOR is a prescription medicine used on the skin (topical) to treat people with Stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma who have received previous skin treatment. It is not known if VALCHLOR is safe and effective in children.

Do not use VALCHLOR if you are severely allergic to mechlorethamine. Tell your healthcare provider if you have had an allergic reaction to mechlorethamine.

Before using VALCHLOR, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. VALCHLOR may harm your unborn baby. Avoid becoming pregnant during treatment with VALCHLOR. Tell your healthcare provider right away if you think you are or may become pregnant during treatment with VALCHLOR.
 - **Females** who are able to become pregnant should use a barrier method of birth control, such as a male condom or spermicide, during treatment with VALCHLOR.
 - **Males** with female partners who are able to become pregnant should use a barrier method of birth control, such as a male condom or spermicide, during treatment with VALCHLOR.
- are breastfeeding or plan to breastfeed. It is not known if VALCHLOR passes into your breast milk. Do not breastfeed during treatment with VALCHLOR.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use VALCHLOR?

- Use VALCHLOR exactly as your healthcare provider tells you.
- Caregivers must wear disposable nitrile gloves when applying VALCHLOR.
- Wash your hands thoroughly with soap and water after touching or applying VALCHLOR.
- Safely throw away used disposable nitrile gloves in household trash.
- Apply VALCHLOR right away or within 30 minutes after you take it out of the refrigerator.
- Return VALCHLOR to the refrigerator right after each use.
- Apply a thin layer of VALCHLOR 1 time each day (or as instructed by your healthcare providers) to completely dry affected areas of the skin at least 4 hours before or 30 minutes after showering or washing.
- Let the treated areas dry for 5 to 10 minutes after applying VALCHLOR before covering with clothing.
- Moisturizers may be applied to the treated areas 2 hours before or 2 hours after applying VALCHLOR.
- You should not use air or water-tight bandages on areas of the skin treated with VALCHLOR.

What should I avoid while using VALCHLOR?

VALCHLOR is flammable. Avoid fire, flame, and smoking until VALCHLOR has dried.

What are the possible side effects of VALCHLOR?

See “What is the most important information I should know about VALCHLOR?”

VALCHLOR can cause serious side effects, including:

- **Risk of secondary exposure to VALCHLOR.** You may have a risk of inflammation of your skin (dermatitis), injury to your eyes, mouth, or nose, and certain types of cancers. Caregivers who accidentally come into contact with VALCHLOR must wash the affected area thoroughly with soap and water right away for at least 15 minutes and remove any contaminated clothing.
Get medical help right away if VALCHLOR gets in your eyes, mouth, or nose.
- **Inflammation of your skin (dermatitis)** is common with VALCHLOR and may sometimes be severe. Your risk for dermatitis is increased if VALCHLOR is applied to your face, genital area, anus, or skin folds. Tell your healthcare provider if you develop skin reactions such as redness, swelling, itching, blisters, ulcers, and skin infections.
- **Increased risk of certain types of skin cancers.** Certain types of skin cancer can develop on areas of your skin that are treated with VALCHLOR and areas of your skin that are not treated with VALCHLOR. Your healthcare provider will check your skin for skin cancers during and after your treatment with VALCHLOR. Tell your healthcare provider if you get any new skin lesions.

The most common side effects of VALCHLOR include: redness, swelling, itching, skin ulcers or blisters, skin infection, and darkening of areas of your skin.

VALCHLOR may cause fertility problems in females and males. This could affect the ability to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of VALCHLOR.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VALCHLOR?

- Store VALCHLOR in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep VALCHLOR away from food in the refrigerator.
- With clean hands, place VALCHLOR back in the box it came in and return it to the refrigerator right after each use.
- Talk with your pharmacist before you use VALCHLOR that has been out of the refrigerator for more than 1 hour a day.
- Safely throw away VALCHLOR that is not used after 90 days. Unused VALCHLOR, empty tubes, and used disposable nitrile gloves should be safely thrown away in household trash.
- **Keep VALCHLOR and all medicines out of the reach of children.**

General information about the safe and effective use of VALCHLOR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VALCHLOR for a condition for which it was not prescribed. Do not give VALCHLOR to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about VALCHLOR that is written for health professionals.

What are the ingredients in VALCHLOR?

Active ingredient: mechlorethamine

Inactive ingredients: diethylene glycol monoethyl ether, propylene glycol, isopropyl alcohol, glycerin, lactic acid, hydroxypropylcellulose, sodium chloride, menthol, edetate disodium, butylated hydroxytoluene.

Manufactured for: Helsinn Therapeutics (U.S.), Inc., Iselin, NJ 08830

For more information, go to www.VALCHLOR.com or call 1-855-482-5245

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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