

PATIENT GUIDE

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

A medicine for Stage
IA/IB MF-CTCL that is

CLEAR*

Artistic rendition of Stage IA/IB MF-CTCL.
Not an actual patient.

*In a clinical study, 119 VALCHLOR patients were evaluated over a 12-month period. 45.4% (54 out of 119 patients) experienced a partial response to the medication and 14.3% (17 out of 119 patients) achieved a complete response or clear skin in up to 5 index lesions. A complete response was achieved when the Composite Assessment of Index Lesion (CAILS) score was 0, combining skin lesion ratings for redness, scaling, plaque elevation, and surface area.



VALCHLOR gel is a clear option to help patients with Stage IA/IB MF-CTCL

IMPORTANT SAFETY INFORMATION

VALCHLOR® (mechlorethamine) gel is for use on skin only. Do not get VALCHLOR near or in your eyes, mouth, or nose as it can cause pain, redness, swelling, burning, and ulcers.

Please see additional Important Safety Information on page 2, as well as the full [Prescribing Information and Medication Guide](#).

IMPORTANT SAFETY INFORMATION

VALCHLOR® (mechlorethamine) gel is for use on skin only. Do not get VALCHLOR near or in your eyes, mouth, or nose as it can cause pain, redness, swelling, burning, and ulcers. It can also cause sensitivity to light, blurred vision, and may also cause blindness or permanent eye injury. 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 eyewash solution. If it gets in your nose or mouth, rinse the affected area right away for at least 15 minutes with a large amount of water. Get medical help right away.

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 your medical conditions including if you are pregnant, planning a pregnancy, or breastfeeding:

- Avoid becoming pregnant during treatment with VALCHLOR. VALCHLOR may harm your unborn baby.
- Females who are able to become pregnant, and 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.
- It is not known if VALCHLOR passes into breast milk. Do not breastfeed during treatment with VALCHLOR.

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

SERIOUS SIDE EFFECTS INCLUDE:

Risk of secondary exposure to VALCHLOR for caregivers who accidentally come into contact with VALCHLOR may include risk of skin inflammation (dermatitis); injury to eyes, mouth, or nose; and certain types of cancer. If accidental contact occurs, thoroughly wash the affected area 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.**

Skin inflammation (dermatitis) is common with VALCHLOR and may sometimes be severe. 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 treated and non-treated areas with VALCHLOR. Your healthcare provider will check your skin for skin cancers during and after treatment. Tell your healthcare provider if you get any new skin lesions.

Most common side effects 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 are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Keep VALCHLOR and all medicines out of the reach of children.

APPLYING VALCHLOR

When applying VALCHLOR, caregivers must wear disposable nitrile gloves, which should be safely thrown away in the household trash. Wash hands with soap and water after touching or applying VALCHLOR. Apply right away or within 30 minutes once taken out of the refrigerator. Refrigerate VALCHLOR right after each use. Apply a thin layer to completely dry skin at least 4 hours before or 30 minutes after showering or washing. Let treated area 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. Do not use airtight or watertight bandages on areas treated with VALCHLOR.

Please see the full [Prescribing Information and Medication Guide](#) for VALCHLOR.

 **VALCHLOR®**
(mechlorethamine)gel
0.016%

Living with Stage IA/IB MF-CTCL is a journey

Not an actual patient.



What Stage IA/IB MF-CTCL may look like

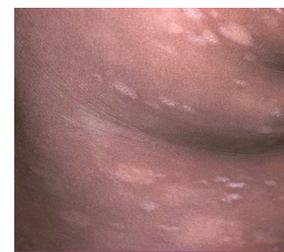
Your stage of MF-CTCL is based on how much of your body has red patches of skin and/or scaly raised scabs called plaques.



Patches



Plaques



Hypopigmentation

Actual patient examples.

Stage IA: patches and/or plaques cover **up to 10%** of the skin

Stage IB: patches and/or plaques cover **10% or more** of the skin

- Most patients have Stage IA/IB MF-CTCL for several years
- In some cases, it can progress to later-stage disease

Living with Stage IA/IB MF-CTCL

You were likely dealing with symptoms (eg, redness, itching, scaling) for a long time before tests showed that you have early MF-CTCL. The good news is now you know what kind of disease you have and that your doctor can select the right medicine that may help give you some relief.

- MF-CTCL is a serious chronic disease, but it doesn't have to change everything about your life
- You will need to use medication on an ongoing basis to help manage the disease, so it's important to consider a treatment that fits into your daily routine

Please see additional Important Safety Information on page 2, as well as the full [Prescribing Information and Medication Guide](#).

What is MF-CTCL?

MF-CTCL is the most common cutaneous T-cell lymphoma. The disease is typically slow growing and may be mistaken for other inflammatory skin conditions, such as eczema or psoriasis. MF-CTCL may be present for years or even decades before it's diagnosed.

Getting a CLEAR picture of Stage IA/IB MF-CTCL

You are not alone. Stage IA/IB MF-CTCL is thought to affect 16,000 to 20,000 patients in the United States. MF-CTCL is a progressive disease with distinct stages, each of which has a different treatment approach.

Although MF-CTCL can occur anywhere on your body, it often appears on skin that is covered by clothing and unexposed to sunlight.

WHAT IS VALCHLOR?

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IMPORTANT SAFETY INFORMATION (CONTINUED)

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

VALCHLOR gel is a CLEAR medicine for Stage IA/IB MF-CTCL

Not an actual patient.



VALCHLOR® (mechlorethamine) gel is made specifically to help fight the skin symptoms of Stage IA/IB MF-CTCL, and the gel formulation can be applied at home.

VALCHLOR is the first and only FDA-approved gel form of a medicine for patients with Stage IA/IB MF-CTCL who have already been on skin treatment. It received FDA approval after validated testing to prove that it was an effective treatment for up to 12 months.

VALCHLOR is a clinically proven medicine that:

- Provides mechlorethamine in a topical clear gel form
- Helps clear the signs of the disease from skin
- Is applied topically and is not absorbed into the bloodstream
- Can be used at home or wherever you need it (Refrigeration required. Please see pages 6-7 for handling and storage information.)

It may take several months to see results with VALCHLOR

Stage IA/IB MF-CTCL can be unpredictable. Seeing and feeling the impact of VALCHLOR may take time, but it's important to stick with the treatment for as long as your doctor recommends.

**Patients who experienced results in the clinical trial
saw a 50% reduction in their skin lesions**

IMPORTANT SAFETY INFORMATION (CONTINUED)

Before using VALCHLOR, tell your healthcare provider about all your medical conditions including if you are pregnant, planning a pregnancy, or breastfeeding.

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Clearing skin is a journey

Artistic rendition of Stage IA/IB MF-CTCL. Not an actual patient.

Inflammation of your skin (dermatitis) is a common side effect with VALCHLOR® (mechlorethamine) gel

Dermatitis is the most common side effect while using VALCHLOR and may be severe. **Immediately tell your doctor if you develop skin reactions such as redness, swelling, itching, blisters, ulcers, and skin infections.** Your doctor can help you manage side effects, including dermatitis (inflammation of the skin), which may help you to continue with your treatment.

- Do not apply VALCHLOR to your face, genital area, anus, or in skin folds, as there is a high risk for skin irritation in these areas
- Speak to your doctor or nurse about any concerns with your treatment
- Immediately tell your doctor or nurse if you see any signs of dermatitis

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(mechlorethamine)gel
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Once a day, on your schedule

Use VALCHLOR® (mechlorethamine) gel exactly as your doctor tells you. Tell your doctor right away if you are pregnant, plan to become pregnant, are breastfeeding, or plan to breastfeed. Men and women who are able to have children should use a barrier method of birth control (condom or spermicide) during treatment with VALCHLOR. Tell your doctor if you get any new lesions.



VALCHLOR can be used at home

1X Once-daily application

 **Quick drying within 10 minutes**
(you can put it on and go about your day)

 **Moisturizers may be applied**
(use on affected areas of your skin 2 hours before or 2 hours after using VALCHLOR)

 **Non-greasy gel**
(once dry, unlikely to stain clothing or bedsheets)

Important things to remember when using VALCHLOR

- Keep VALCHLOR away from eyes, mouth, and nose. If contact occurs, rinse thoroughly for at least 15 minutes with a large amount of water or eye wash solution
- VALCHLOR is flammable; avoid fire, flame, and smoking until VALCHLOR has dried

How to use VALCHLOR

VALCHLOR is for topical use only. Please follow the important instructions for application and handling procedures.



1. Open tube. Apply VALCHLOR right away or within 30 minutes of taking it out of the refrigerator.



2. Squeeze a small amount on your fingertip. Caregivers must wear disposable nitrile gloves when applying VALCHLOR.



3. Gently spread a thin layer of VALCHLOR on dry skin. Apply a thin layer of VALCHLOR to completely dry skin at least 4 hours before or 30 minutes after showering or washing.



4. Allow the gel to dry before getting dressed. Let the treated areas dry for 5 to 10 minutes after applying VALCHLOR before covering with clothing. **Do not** use air or water-tight bandages on areas treated with VALCHLOR.



5. Wash your hands thoroughly with soap and water after touching or applying VALCHLOR. If there is accidental skin exposure to VALCHLOR, caregivers must immediately wash exposed areas thoroughly with soap and water for at least 15 minutes and remove contaminated clothing.



6. Place VALCHLOR back in the box it came in and return it to the refrigerator right after each use.

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How to store VALCHLOR



Store VALCHLOR® (mechlorethamine) gel in the refrigerator between **36°F and 46°F** (2°C and 8°C)



Keep VALCHLOR **from touching food when stored in the refrigerator**



With clean hands, **place VALCHLOR 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 outside of the refrigerator for more than 1 hour in a day



Safely throw away any VALCHLOR that is not used within 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 and pets



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You have a partner on your treatment journey



The VALCHLOR Support™ team is here to help you with your treatment

- When your doctor prescribes VALCHLOR® (mechlorethamine) gel, the two of you will fill out and sign a form that authorizes a specialty pharmacy to ship VALCHLOR directly to you
- A nurse from the specialty pharmacy will call you to arrange delivery and answer any questions you may have about your prescription
- Please note that VALCHLOR is not available at your local pharmacy



VALCHLOR is delivered directly to your doorstep safely and securely for at-home application

Please read the VALCHLOR **Medication Guide** that comes with your VALCHLOR prescription.

It is important to remember that you should talk to your doctor if you have any questions about your medical condition or treatment.

You can depend on VALCHLOR Support™

VALCHLOR is a special medicine and it comes with a lot of support. Contacting **VALCHLOR Support™ at 1-855-4-VALCHLOR (1-855-482-5245)** can help you with the following:

- Help answer questions about your prescription, VALCHLOR, and what to expect during treatment
- Outreach via phone call and text message provided by specially trained pharmacists and nurses to help with your treatment
- Reimbursement specialists can assist you with:
 - Initial prescription enrollment and insurance verification for VALCHLOR
 - Scheduling of VALCHLOR shipments directly to you
 - VALCHLOR refill reminders
 - Financial assistance if you are eligible (see below)
 - Assistance with claims support

Eligible patients* are provided with financial assistance

- If you are privately insured, VALCHLOR is covered by most health plans
- If you don't have a prescription plan, you may be eligible for a patient assistance program
- If you have limited coverage, alternative funding resources may be available

Eligible patients pay no more than \$10 per prescription fill*

*The VALCHLOR copay program is only available for US and Puerto Rico residents who are 18 or older and have commercial health insurance with copay/coinsurance exceeding \$10 per prescription fill. Patients ineligible for the VALCHLOR copay program include those enrolled in Medicare, Medicaid, VA/DoD (Tricare), the Indian Health Service, or any other federal- or state-funded healthcare program, or where prohibited by law. The VALCHLOR copay program is not prescription drug coverage or insurance. Helsinn Therapeutics, Inc. reserves the right to terminate or modify this program at any time without notice. Other terms and conditions apply.

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Not actual patients.

VALCHLOR Support™ is here for you if you have questions along your treatment journey



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Call **1-855-4-VALCHLOR (1-855-482-5245)** for more information.

Visit www.valchlor.com today to learn more.

The Cutaneous Lymphoma Foundation offers information, support, and other resources at www.cfoundation.org and **1-248-644-9014**.

 **HEL SINN**

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