INDICATIONS AND USAGE

ZYCLARA Cream, 3.75% is a white to faintly yellow cream available in single-use packets and pump bottles. Each packet contains 20 mg (approximately 2.5 g) of imiquimod 3.75% cream. Each pump bottle, when actuated after opening, contains 25 mg (approximately 2.5 g) of imiquimod 3.75% cream. Partially-used packets should be discarded and not reused.

ZYCLARA Cream, 2.5% is a white to faintly yellow cream available in pump bottles. Each pump bottle, when actuated after opening (2 full actuations of the pump) of ZYCLARA Cream may be applied to the treatment area at each application. ZYCLARA Cream should be applied once daily before bedtime to the skin of the affected area (either entire face or balding scalp). ZYCLARA Cream is not intended for children under the age of 12 years. A 16-week, open-label, Phase 3 clinical trial of ZYCLARA Cream resulted in an overall incidence of local skin reactions in the treatment area of 72% in adult patients with actinic keratosis. Partially-used packets should be discarded and not reused.

Patients should wash their hands before and after applying ZYCLARA Cream.

Local skin reactions in the treatment area are common and generally resolve with continued therapy. Patients should be instructed to avoid applying ZYCLARA Cream to the eyes or mouth and to wash their hands after use. The application site should be gentle to minimize skin irritation. Patients should be instructed to avoid applying ZYCLARA Cream to the eyes or mouth and to wash their hands after use. The application site should be gentle to minimize skin irritation. The use of ZYCLARA Cream should be limited to the treatment area and to patients with xeroderma pigmentosum.

Clinical trials showed that ZYCLARA Cream is safe and effective in the treatment of actinic keratosis.

Patients should be advised to avoid exposure to UV light (sunlight or tanning beds) after application of ZYCLARA Cream. ZYCLARA Cream should not be applied to treated skin in the presence of infections, skin conditions, or inflammation.

Local skin reactions in the treatment area were reported in 1.5% of patients treated with placebo. The most common local skin reactions were erythema and edema in 32% and 24% of patients, respectively. In the clinical trials, 1.1% of patients treated with ZYCLARA Cream had a local skin reaction that was severe or serious. The most common local skin reactions reported in clinical trials were erythema, edema, and pruritus.

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zyclara (imiquimod) cream

For patients being treated for actinic keratosis in children less than 18 years of age.

What is ZYCLARA Cream?

ZYCLARA Cream is a prescription medicine for the treatment of actinic keratosis (AK) in adults and children 2 years of age and older.

It is not known if ZYCLARA Cream is safe and effective in children less than 12 years of age.

It is not known if ZYCLARA Cream is safe and effective for the treatment of actinic keratosis in children less than 18 years of age.

How should I use ZYCLARA Cream?

Before you use ZYCLARA Cream, talk to your healthcare provider about the best way to treat your AK.

To use ZYCLARA Cream:

1. After you apply ZYCLARA Cream, wash your hands well.
2. Rub the cream into all the way to the affected area or areas.
3. Allow the area to dry.

How do I apply ZYCLARA Cream?

Firmly press the top of the pump all the way down to dispense the cream onto your hand or finger.

When using ZYCLARA Cream:

• Do not leave ZYCLARA Cream on your skin longer than prescribed.
• Do not use more ZYCLARA Cream than you need to cover the affected area.

What are the ingredients in ZYCLARA Cream? How do I store ZYCLARA Cream?

Inactive ingredients: isostearic acid, cetyl alcohol, stearyl alcohol, white petrolatum, propylparaben, sorbic acid, methylparaben, white mineral oil, xanthan gum, purified water, benzyl alcohol, methylparaben, and propylparaben.

These ingredients have been approved by the U.S. Food and Drug Administration for use in this product.

What is ZYCLARA Cream used for?

ZYCLARA Cream is available for the treatment of actinic keratosis (AK). It is not known if ZYCLARA Cream is safe and effective for the treatment of AK in children less than 12 years of age.

How do I use ZYCLARA Cream?

Open a packet of ZYCLARA Cream just before use.

Place the amount of cream to be used in your palm.

Pull their foreskin back and clean before treatment and clean daily after treatment.

After you apply ZYCLARA Cream, wash your hands well.

How long should I use ZYCLARA Cream?

ZYCLARA Cream should be used for a maximum of 27 days (2 cycles) for AK on any one site.

How do I store ZYCLARA Cream pump:

• Do not expose ZYCLARA Cream pump to freezing or temperatures less than 5°C (41°F) or greater than 30°C (86°F).
• Do not freeze.
• Do not use the pump if it is broken, cracked, or deformed.

How do I use ZYCLARA Cream pump:

When dispensing the cream, slightly tilt the pump as shown in Figure 1.

How do I use ZYCLARA Cream pump:

Before using the first actuation of the pump, prime the pump by pressing the top of the pump all the way down repeatedly until the cream appears.

For the treatment of AK, ZYCLARA Cream should be applied once daily to the skin of the affected area (either entire face or balding scalp) for two weeks, then stop using for two weeks, then applied once daily again for two weeks.

For the treatment of external genital warts, ZYCLARA Cream should be applied once daily for external genital warts for 16 weeks.

Important: ZYCLARA Cream is being prescribed for AK or genital warts.

What are the possible side effects of ZYCLARA Cream? How do I store ZYCLARA Cream?

• Do not use ZYCLARA Cream on or near eyes or vagina.
• Do not use ZYCLARA Cream on scrotal skin.

These are not all the possible side effects of ZYCLARA Cream. For more information, ask your healthcare provider or pharmacist.

What is the recommended dose of ZYCLARA Cream for AK?

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