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## Aldara Cream

**Support for Patients with Actinic Keratosis** Your doctor and the makers of Aldara (imiquimod) Cream, 5% have provided this page to help you learn about and treat your actinic keratosis. It also contains a summary of information about Aldara Cream. Treating your skin with Aldara Cream stimulates your immune system to help your body get rid of the abnormal cells.

**Be Informed About Actinic Keratosis** People who have been treated for AK should have their skin screened yearly by a doctor or health care provider. Anyone who has previously had an AK is at higher risk for developing new AKs or skin cancer. Such individuals also should avoid excessive sun exposure by staying out of the sun during the hours of 10:00 am to 4:00 pm, when the sunlight is most direct. Also, a sunscreen with an SPF of 15 or higher should be used. Ideally, sunscreen should be applied 15 to 30 minutes prior to exposure and reapplied every 2 hours while outdoors, even on cloudy days. Covering areas of the skin exposed to the sun with clothing and wearing a hat is also recommended.

**Learning More About Aldara Cream** Read the patient information that comes with Aldara Cream before you start using it and each time you get a refill. There may be new information. This page does not take the place of talking with your doctor or health care provider about your medical condition or treatment. If you do not understand the information, or have any question about Aldara Cream, talk with your doctor or other health care provider.

**What is Aldara Cream?** Aldara Cream is a skin-use (topical) prescription medicine used to treat actinic keratosis on the face and scalp of adults with normal immune systems. Aldara Cream works from within by activating your body's own immune system to treat disease. Aldara Cream not only helps clear visible actinic keratosis, but also treat undeveloped actinic keratosis that are not yet visible. These previously unseen actinic keratosis may appear during treatment and may clear before they have a chance to develop further.

**What can I expect from Aldara Cream?** Results vary from person to person. Most people experience redness, swelling, itching, flaking, or scabbing at or around the affected area during the course of treatment. Patients may also experience application-site reaction such as itching and/or burning. Skin reactions may be of such an intensity that patients may require rest periods from treatment. Treatment with Aldara Cream can be resumed after the skin reaction has subsided, as determined by your doctor or health care provider. Skin reactions generally decrease in intensity or resolve after Aldara Cream treatment. Six percent of patients reported burning and less than 2 percent reported pain at the treatment area. Talk with your doctor or health care provider if you get any skin reactions that affect your daily activities or do not go away. Some actinic keratosis may not be visible before treatment with Aldara Cream begins. For some people, actinic keratosis that were not seen before may appear during treatment and may later go away. For best results with Aldara Cream, follow your doctor or health care provider's instructions closely.

**Who should not use Aldara Cream?** Aldara Cream has not been studied in children under 18 years of age for actinic keratosis. Children usually do not get actinic keratoses. Before using Aldara Cream, tell your health care provider about all your medical conditions, including if you: -are pregnant or planning to become pregnant. It is not know if Aldara Cream can harm your unborn baby -are breast-feeding. It is not known if Aldara Cream passes into your milk and if it can harm your baby. Talk about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Especially tell your doctor or health care provider if you have had other treatments for actinic keratosis. Aldara Cream administration is not recommended until the skin has completely healed from any previous drug or surgical treatment. Aldara Cream has potential to worsen inflammatory skin conditions, such as psoriasis, at the application site.

**How should I use Aldara Cream?** Use Aldara Cream exactly as prescribed by your health care provider. Aldara Cream is for skin use only. Do not take by mouth or use in or near your eyes, lips, or nostrils. Talk with your health care provider if you have any questions. Use Aldara Cream only on the area of your body to be treated, as instructed by your health care provider. The area should be no larger than approximately the size of your forehead or cheek (2 inches by 2 inches) Do not use Aldara Cream longer than prescribed. Using too much Aldara Cream, or using it too often, or for too long can increase your chances for having a severe skin reaction or other side effect. Talk with your doctor or health care provider if Aldara Cream does not work for you. Aldara Cream is usually used once a day for 2 days a week, 3 to 4 days apart, such as: Monday and Thursday or Tuesday and Friday. For this condition, Aldara Cream is usually left on the skin for about 8 hours. Treatment should continue for the full 16 weeks even if all actinic keratoses appear to be gone, unless you are told otherwise by your doctor or health care provider. The treatment period should not extend beyond 16 weeks due to missed doses or rest periods.

**How to apply Aldara Cream** Aldara Cream should be applied just before your bedtime: Wash the area to be treated with mild soap and water. Allow the area to dry. Open a new packet of Aldara Cream and apply a thin layer of Aldara Cream only to the affected area or areas to be treated. Do not use more Aldara Cream than is needed to cover the treatment area. Do not get Aldara Cream in your eyes Do not cover the treated area with an airtight bandage Safely throw away the open packet of Aldara Cream so that children and pets cannot get it. The open packet should be thrown away even if all the Aldara Cream was not completely used After applying Aldara Cream, wash your hands well Leave the cream on the affected area for about 8 hours, then wash off If you get Aldara Cream in your mouth or in your eyes, rinse well with water right away What if I forget a dose? Apply the missed dose of cream as soon as you remember and then continue on your regular schedule. What should I avoid while using Aldara Cream? Do not cover the treated site with bandages or other closed dressings. Cotton gauze dressings can be used Do not apply Aldara Cream in our near the eyes, lips, or nostrils Do not use sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with Aldara Cream. IF you go outside during daylight, use sunscreen and wear protective clothing, including a hat What are the possible side effects of Aldara Cream? The most common side effects with Aldara Cream are skin reactions at the treatment site including: Redness Swelling A sore, blister, or ulcer Skin that becomes hard or thickened Changes in skin color that do not always go away Skin peeling Scabbing and crusting Itching Burning During treatment and until the skin has healed, your skin in the treatment area is likely to appear noticeable different from normal skin. Side effects, such as redness, scabbing, itching, and burning are common at the sit where Aldara Cream is applied, and sometimes the side effects go outside of the area where Aldara Cream was applied.

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Swelling, small open sores, and drainage may also be experienced with use of Aldara Cream. You may also experience itching and/or burning. Actinic keratoses that are not seen before may appear during treatment and may alter go away. If you have questions regarding treatment or skin reactions, please talk with your health care provider. You have a higher chance for severe skin reactions if you use too much Aldara Cream or use it the wrong way. Stop Aldara Cream right away and call your health care provider if you get any skin reactions that affect your daily activities, or that do not go away. Sometimes, Aldara Cream must be stopped for awhile to allow your skin to heal. Talk to your health care provider if you have questions about your treatment or skin reactions. Other side effect of Aldara Cream include headache, back pain, muscle aches, tiredness, flu-like symptoms, swollen lymph nodes, diarrhea, and fungal infections. If the reaction seem excessive, if either skin breaks down or sores develop during the first week of treatment, if flu-like symptoms develop or if you being to not feel well at any time, contact your health care provider. These are not all the side effects of Aldara Cream. For more information, ask your health care provider or pharmacist. How do I store Aldara Cream? Store Aldara Cream at temperatures 39-77 degrees Fahrenheit (4-25 degrees Celsius). Do not freeze Safely throw away Aldara Cream that is out of date or that you do not need Keep Aldara Cream and all medicines out of reach of children General Information about Aldara Cream Medicines are sometimes prescribed for conditions that are not mentioned in Patient Information brochures. Do not use Aldara Cream for a condition for which it was not prescribed. Aldara Cream is a prescription-only medicine. Remember these general rules about prescription medicines Always use Aldara Cream as directed by your doctor or other health care provider Discard any unused cream after each application Do not share Aldara Cream with anyone else; it was prescribed only for you Keep Aldara Cream and all medicines out of reach of children What are the ingredients in Aldara Cream? Active Ingredient: imiquimod Inactive ingredients: soteareic acid, cetyl alcohol, stearyl alcohol, white petrolatum, polysorbate 60, sorbitan monosterate, glycerin, xanthan gum, purified water, benzyl alcohol, methylparaben, and propylparaben. If you have other questions about Aldara Cream, call 1-800-328-0255 or visit our Web site at [www.aldara.com](http://www.aldara.com).