

طريقة الاستعمال:

يُرجى العمل بموجب تعليمات الطبيب فيما يتعلّق بتكرارية ومدة العلاج.

١. قبل النوم اغسل/ي يديك وافتح/ي كيساً جديداً. أضغط/ي على الكيس وضع/ي كريم الدار على طرف اصبعك.
٢. ادهن/ي طبقة رقيقة من كريم الدار على المنطقة المُعدّة للعلاج وهي نظيفة وجافة. حسب تعليمات الطبيب. افرك/ي بلطف الي داخل الجلد حتى اختفاء الكريم.
٣. كل كيس مخصّص للاستعمال مرة واحدة فقط. تخلّص/ي من الكيس المفتوح بانتهاء الاستعمال. اغسل/ي يديك بالماء والصابون.
٤. اترك/ي كريم الدار على المنطقة المعالجة حسب توصية الطبيب. لا يجوز الاستحمام خلال وجود الكريم على الجلد.
٥. يجب شطف المنطقة التي دهنت كريم الدار عليها بانتهاء العلاج اليومي وذلك بواسطة صابون ناعم وبالماء.

يرجى الانتباه:

ليس للابتلاع! هذا الدواء مخصّص لاستعمال خارجي فقط. ممنوع وضع الكريم في الفم، داخل المهبل، داخل الشرج، داخل أو بالقرب من العينين، الشفتين أو المنخرين.

ممنوع تضييد أو تغطية المنطقة المعالجة. ممنوع استعمال الكريم أكثر من الوقت، الكمية والتكرارية الموصى بها.

في حالة علاج الكاثليل التناسلية: إذا وجدت كاثليل تحت جلدة القضيب التناسلي، فيجب شد الجلدة الي الوراء وغسل المنطقة المتواجدة خلفها كل يوم (انظر/ي فقرة التحذيرات اعلاه). إذا قررت القيام بعلاقات جنسية أثناء وجود الكاثليل، فادمن/ي كريم الدار بعد القيام بالجماع الجنسي وليس قبله. إن كريم الدار قد يضعف من نجاعة الكوندوم والحجاب الحاجز النسائي، ولذلك لا يجوز ترك الكريم أثناء المضاجعة الجنسية. عليك التذكّر أن كريم الدار لا يحمي من انتقال الفيروسات لشخص آخر.

إذا كان كريم الدار مخصّص لعلاج التقران الأكتيني أو لعلاج سرطان الخلايا القاعدية السطحي للجلد فيجب الامتناع عن استعمال مصابيح التسمّع أو أسرة التسمّع والامتناع قدر الإمكان عن التعرّض لأشعة الشمس أثناء الخروج من البيت أثناء ساعات النهار واستعمال كريم الوقاية والملابس الواقية.

في حالة علاج التقران الأكتيني – يجب إعلام الطبيب إذا استعملت سابقاً كريم الدار في المكان المعدّ للعلاج.

على مرضى سرطان الخلايا القاعدية السطحي للجلد إعلام الطبيب إذا كانت الأعراض الجانبية تمنع نشاطهم اليومي العادي أو إذا كانت تصعب على استمرار العلاج بهذا المستحضر. كما، يوصى لهؤلاء المرضى أن يكونوا تحت المتابعة الدائمة لدى الطبيب.

كيف بإمكانك أن تساعد/ي على نجاح العلاج؟

يجب استيفاء العلاج الموصى به من قبل الطبيب بأكمله.

ممنوع إيقاف العلاج بالدواء حتى إذا طرأ التحسّن على حالتك الصحية، بدون استشارة الطبيب. إذا حدث ونسيت دهن الكريم في الموعد المقرر، فيجب دهنها فور التذكّر بذلك وثم الاستمرار بالعلاج كالعادة.

امنع/ي التسمم!

يجب حفظ هذا الدواء واي دواء آخر في مكان مغلق، بعيداً عن متناول ايدي اطفال و/أو رضع و/أو حيوانات مدللة. لمنع اصابتهم بتسمم. اذا تناولت جرعة زائدة او اذا ابتلع ولد سهواً من هذا الدواء، فيجب مراجعة اقرب غرفة طوارئ للمستشفى فوراً ومعك عبوة الدواء.

يمنع تسبب التقيؤ بدون تعليمات واضحة من الطبيب!

هذا الدواء وصف لعلاج مرضك انت وقد يضر مريضاً غيرك. يُمنع اعطاء اقربائك، جيرائك، او معارفك هذا الدواء.

ممنوع تناول أيوية في الظلام! يجب فحص رقعة الدواء والجرعة كلما تتناوله.

استعمل/ي النظارات إذا كنت بحاجة اليها.

التخزين: في درجة حرارة الغرفة (تحت ٢٥ درجة مئوية).

حتى عند مراعاة تعليمات التعبئة/التخزين الموصى بها، فإن الادوية تبقى صالحة لمدة محدودة فقط. يرجى الإنتباه الى تاريخ انتهاء مدة صلاحية الدواء! في أية حالة من الشك، عليك استشارة الصيدلي الذي صرف لك الدواء. يُمنع حفظ ادوية مختلفة في نفس الوعاء.

رقم تسجيل الدواء: ١١٤٤٤٢٩٦٧٥٠٠

المنتج: 3M هيلث كير م.ض. لوفيبورو، إنجلترا.

المستورد: فارماتيم للتسويق ٢٠٠٠ م.ض. ص.ب. ٤٠٥، القدس ٩١٠٠٣.

حُدّت صيغة هذه النشرة من قبل وزارة الصحة وفُحص مضمونها وأقرّ في كانون الثاني نوفمبر ٢٠٠٥.

Patient Package Insert In Accordance With The Pharmacists' Regulations (Preparations) - 1986

This medicine requires a physician's prescription

Read this package insert carefully in its entirety before using this medicine

Aldara 5% Cream

Composition:

Imiquimod 5 mg/100 mg

Inactive Ingredients:

Isostearic acid, Cetyl alcohol, Srearyl alcohol, White soft paraffin, Polysorbate 60, Sorbitan stearate, Benzyl alcohol, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Glycerol, Xanthan gum, Purified water

Therapeutic class: Anti viral, anti cancerous.

Therapeutic Activity:

Aldara cream is indicated:

1. For the topical treatment of external genital and perianal warts (condyloma acuminata) in adult patients.
2. For the treatment of Actinic Keratosis (Solar Keratosis) in adults with normal immune systems.
3. For the treatment of superficial Basal Cell Carcinoma in adults with normal immune systems when surgical methods are less appropriate.

NOTE: Aldara cream is used in different ways for the three different skin conditions it is used to treat. It is very important that you follow the physician's instructions for your skin condition.

When should this medicine not be used?

Do not use this medicine if you are sensitive to any of its ingredients.

Do not use this medicine without consulting a physician before starting treatment:

If you are pregnant or breastfeeding.

Warnings:

If you are sensitive to any type of food or medicine, inform your physician before commencing treatment with this medication.

Do not use on open wounds or irritated skin. Inform your physician if you have tendency for dermal inflammations that the use of Aldara Cream may aggravate.

Aldara cream administration is not recommended until the skin is healed from any previous drug or surgical treatment.

The product intended only for external use. Do not take by mouth in the vagina or anus or use in/near your eyes, lips or nostrils. Before using Aldara cream inform your physician if you have had other treatments for Actinic Keratosis on the intended to treat area. When the treatment is intended for Actinic Keratosis or for Basal Cell Carcinoma do not use sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with Aldara Cream. Use sunscreen and wear protective clothing if you go outside during daylight.

When the treatment is intended for condyloma acuminata avoid sexual contact (genital, oral, and anal) while the cream is present on the skin or alternatively you may rinse the cream off the skin.

Uncircumcised patients who are being treated for warts under the foreskin - expose the crown and clean the area daily.

Genital warts are contagious. Make sure that a physician checks your partner. Aldara cream may weaken the efficacy of condoms and vaginal diaphragms, therefore, the patient should consider using additional contraceptive measures.

Patients should be aware that new warts might develop during therapy.

Drug interactions:

If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending physician, in order to prevent hazards or lack of efficacy arising from drug interactions.

Side effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of using this medicine. The most common side effects after using Aldara cream seems to be local skin effects as: stinging, itching, burning or pain at the treatment site, skin rash, redness, skin peeling, edema, scabbing, skin that becomes hard or thickened, blisters, ulcers, changes in skin color that do not disappear.

In the case of irritation or acute reaction the cream should be removed by washing the area thoroughly with mild soap and water and after than consult your physician.

In any event that you experience side effects not mentioned in this leaflet, or if there is any change in your general feeling you should consult your physician immediately. In case of Actinic Keratosis in addition to the side effects mentioned above, during treatment and until the skin has healed, the skin in the treated area is likely to appear noticeably different from normal skin. Sub-clinical lesions may become apparent in area not seen before, but during treatment they may subsequently disappear. In the case of Basal Cell Carcinoma, in addition to the above mentioned adverse reactions, an infection may develop at the treated area. If this occurs, rest period and antibiotic treatment is required until recovery from the infection.

Dosage:

Dosage is according to physician's instructions only.

For the indication of genital and perianal warts this medication is not intended for patients under 12 years old.

For the indications of Actinic Keratosis and Basal Cell Carcinoma this medication is not intended for use in patients under 18 years of age.

Directions of use:

Please follow your physicians advise on when to use Aldara cream.

1. Before going to bed, wash your hands and open a new sachet. Squeeze Aldara cream onto your fingertip.
2. Apply a thin layer of Aldara cream onto clean, dry intended area according the physicians instructions. Rub gently into the skin until the cream vanishes.
3. After application of the cream, throw away the opened sachet and wash hands with soap and water.
4. Leave Aldara cream on the treated area according physician's instruction. Do not shower or bathe during this time.
5. After treatment, the area where Aldara cream was applied should be washed with soap and water.

Pay attention:

Do not swallow! This medicine is intended for external use only.

Do not take by mouth or in the vagina or anus, in or near your eyes, lips or nostrils.

Do not bandage or occlude the treated area.

Do not use the cream beyond the recommended period, quantity and frequency.

In the case of condilioma acuminata: men with warts under the foreskin should pull the foreskin back and wash underneath every day (see section "Warnings").

If you decide to have sexual relations while you still have warts, apply Aldara cream after – not before – sexual activity. Aldara cream may weaken condoms and diaphragms, therefore the cream should not be left on during sexual activity. Remember, Aldara cream does not protect against passing the virus to someone else.

In case of Actinic Keratosis or Basal Cell Carcinoma: it is recommended to avoid usage of sunlamps or tanning beds, and avoid sunlight as much as possible during treatment with Aldara Cream.

Use sunscreen and wear protective clothing if you go outside during daylight.

Actinic Keratosis patients should notify their physician if they already used Aldara cream on the same area in the past.

Basal Cell Carcinoma patients should be under regular supervision by physician.

They should notify their physician if the adverse reactions prevent them from daily activity or make it difficult to continue the treatment with the product.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the physician. Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your physician. If you forgot to apply Aldara cream, apply the missed dose of cream as soon as you remember and then continue on the regular sceduale.

Avoid Poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting unless explicitly instructed to do so by a physician!

This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. Do not give this medicine to your relatives, neighbors or acquaintances.

Do not take medicines in the dark! Check the label and the dose **each time** you take your medicine. Wear glasses if you need them.

Storage:

At room temperature (25°C or below).

Even if kept in the original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you. Do not store different medicines in the same package.

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