

Cream, 5%
Aldara[®]
(IMIQUIMOD)



Treatment
with Aldara[®]

QUESTIONS & ANSWERS

This brochure is for patients who have been prescribed Aldara for the treatment of superficial basal cell carcinoma (sBCC) or solar keratoses (SK).

Individuals pictured are models and are used for illustrative purposes only.

Why has my doctor prescribed Aldara?

Your doctor has prescribed Aldara (imiquimod) because you have been diagnosed with a skin condition called superficial basal cell carcinoma (sBCC) and/or solar keratoses (SK). This leaflet helps explain what to expect during your treatment with Aldara and how to use the medication most effectively.

What is superficial basal cell carcinoma (sBCC)?

Basal cell carcinomas are the most common type of skin cancer. Superficial basal cell carcinomas are one type of basal cell carcinomas, they are confined to the top layer of the skin and often appear as shiny, pink or red raised patches on the skin.

What are solar keratoses (SK)?

Solar keratoses are pre-cancerous lesions. They are more common in people with fair skin and occur from repeated exposure of the skin over many years to ultraviolet (UV) radiation in sunlight.

Solar keratoses usually appears as thickened, scaly patches of skin or pink/brown spots on the face and scalp. It is important to treat sunspots because, in a small number of cases, they can lead to some types of serious skin cancers.¹

How does Aldara work?

Aldara is a topical treatment. Although the exact way that Aldara works is unknown, there is evidence it is due to its effects on the immune system.

Aldara contains the active ingredient imiquimod. Imiquimod is an immune response modifier – it activates immune cells in the body. The immune cells then recognise and destroy the diseased skin cells.

What can I expect to happen during treatment with Aldara cream?

During treatment the skin in the treatment area is likely to appear noticeably different from normal skin.

Redness and itching of the treatment area are common and are signs that Aldara is working. Because Aldara stimulates the body's own defences, the reactions experienced vary from patient to patient.

You may also experience other skin reactions such as; small open sores, swelling, small bubbles under the skin, burning, flaking and scabbing at the site where Aldara is applied. Some users may even experience flu-like symptoms.

How does superficial BCC respond to Aldara treatment?

These photographs give you an indication of how your superficial BCC is likely to respond to Aldara treatment. The actual response may vary from patient to patient.

**BEFORE
TREATMENT**



**DURING
TREATMENT**



**AFTER
TREATMENT**



Photographs courtesy of Dr. Sue McCoy, General Practitioner, Adelaide, SA.

How does solar keratoses respond to Aldara treatment?

Solar keratoses that were not visible before you started your treatment may appear. They may clear up as your treatment progresses. So, don't worry if your skin looks worse before it gets better. These photographs give you an indication of how your solar keratoses are likely to respond to Aldara treatment. The actual response may vary from patient to patient.

BEFORE TREATMENT

A couple of visible lesions



WEEK 2

21 lesions



2 WEEKS POST TREATMENT

2 lesions



4 WEEKS POST TREATMENT

Lesions gone



Photographs courtesy of Prof. Stuart Salasche, USA.

When and how should I apply Aldara for superficial BCC?

Aldara should be applied to the affected area once a day at bedtime for five consecutive days per week (e.g. Monday to Friday) for a 6-week period – or as recommended by your doctor.

When and how should I apply Aldara for solar keratoses?

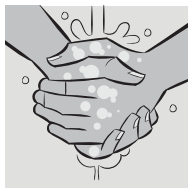
Aldara for solar keratoses may be applied to the affected area using ONE of two treatment regimens. Your doctor will advise which treatment regimen to use. The treatment regimens are:

1. Aldara should be applied once a day at bedtime, 3 times per week (e.g. Mon, Wed, Fri) for 4 weeks, followed by a period of 4 weeks without any treatment. Your doctor will then check your skin condition. If any solar keratoses lesions remain, the treatment should be repeated for another 4 weeks.
2. Aldara should be applied once a day at bedtime, 3 times per week (e.g. Mon, Wed, Fri) for up to 16 weeks continuously. Treatment should continue for no more than 16 weeks at a time. Your doctor will advise for how long to use Aldara for.

Applying Aldara Cream

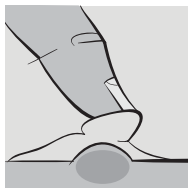
1

Before applying Aldara, wash your hands and treatment area with mild soap and water and allow it to dry thoroughly.



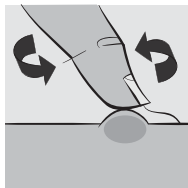
2

Apply a thin layer of Aldara onto the treatment area and rub it gently into the skin until the cream vanishes. For sBCC lesions enough cream should be applied to cover the lesion and about 1cm of surrounding skin.



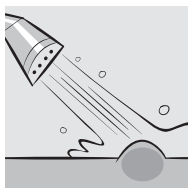
3

Wash your hands with mild soap and water.



4

Leave Aldara on the affected area for 6 to 10 hours. Do not shower or bathe during this time.



5

After 6-10 hours, the area where Aldara was applied should be washed with mild soap and water.

What should I do if I experience troublesome local skin reactions?

If you do experience uncomfortable local skin reactions which you find troublesome, or have any concerns, speak to your doctor.

If you experience discomfort or if redness becomes excessive, your doctor may advise you take a short break from treatment. When these local skin reactions have settled down, your doctor may advise you to resume your treatment.

It is not necessary to prolong the treatment period in order to make up for the doses you missed.

Once opened, can I reuse an Aldara sachet or pump?

Aldara cream is packaged in single use sachets and in a multi-dose pump pack.



If you are using an Aldara single sachet, it is recommended that any remaining unused cream be discarded after each use. Carefully dispose of the unused Aldara cream in the sachet where children cannot reach it.

If you are using an Aldara Pump, after applying the cream, replace the protective cap back on the pump dispenser.

Write the date on the label the first day you use the Aldara Pump and carefully store the pump pack where children cannot reach it. Once opened, the contents of the pump are to be used within 4 weeks.

Can I use cosmetics with Aldara?

Unless instructed by your doctor, it is advised not to use cosmetics or any other skin products, including creams, lotions, and medications, on the area of treatment while on Aldara therapy.

Can I use sunscreen with Aldara?

You should avoid sun exposure or other UV light (such as tanning booths) during and immediately following treatment with Aldara.

The potential therapeutic effects of using sunscreen simultaneously with Aldara have not been examined in clinical trials. If going outside during daylight, wear a wide-brimmed hat, long sleeves and trousers (or a long skirt) to protect your skin. Apply a broad-spectrum sunscreen (SPF 30 or higher) before going outdoors and reapply regularly during the day. **Do not apply sunscreen directly on the treatment area.**

After your treatment with Aldara is completed be sure to use sunscreen to protect your skin from future exposure to UV light.

When using Aldara:

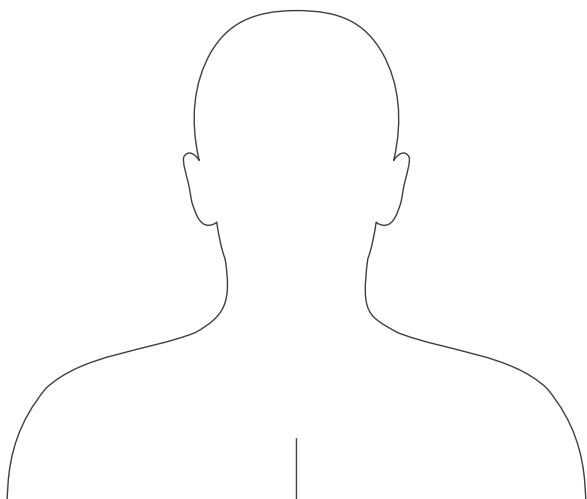
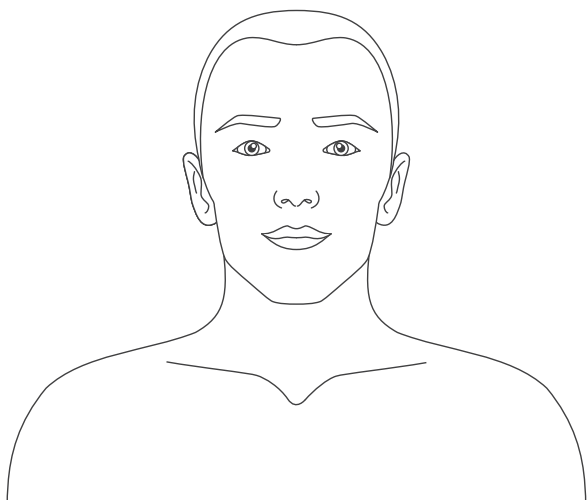
- Do not apply Aldara in or near the eyes, lips and nostrils.
- Do not use sunlamps or tanning beds during treatment.
- Avoid excessive sun exposure.
- Aldara has been prescribed for your use only. Do not share this medicine with others even if they seem to have the same condition as you.

Before using Aldara, read the Consumer Medicine Information that comes with the pack. Use only as directed by your healthcare professional.

This leaflet does not contain all the available information and it does not take the place of talking to your doctor or pharmacist.

Applying your Aldara in a way that will provide the best results

Treat the areas indicated by your doctor.



Your personal treatment record for superficial BCC

I will apply Aldara on the following days;
Choose the same 5 consecutive days each week.

Apply at bedtime for 5 consecutive days, for 6 weeks

WEEK	MON	TUE	WED	THUR	FRI	SAT	SUN
1-6							

The total treatment period is 6 weeks – or as recommended by your doctor.

YOUR NEXT APPOINTMENT

DATE

TIME

NOTES

Your personal treatment record for solar keratoses

Aldara for solar keratoses may be applied to the affected area using ONE of two treatment regimens. Your doctor will advise which treatment regimen to use.

REGIMEN 1

I will apply Aldara on the following days;
Choose the same 3 days each week.

<i>Apply at bedtime, 3 times a week for 4 weeks</i>							
WEEK 1-4	MON	TUE	WED	THUR	FRI	SAT	SUN
<i>Allow a 4-week treatment free rest period</i>							
WEEK 5-8	Rest period – review with your doctor at 8 weeks						
<i>If solar keratoses lesions remain, your treatment should be repeated for another 4 weeks</i>							
WEEK 9-12							

Each treatment period should not be extended beyond 4 weeks due to missed doses or rest periods.

REGIMEN 2

I will apply Aldara on the following days;
Choose the same 3 days each week.

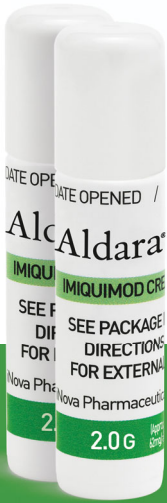
<i>Apply at bedtime, 3 times a week for 16 weeks</i>							
WEEK 1-16	MON	TUE	WED	THUR	FRI	SAT	SUN

The treatment should not be extended beyond 16 weeks due to missed doses or rest periods.

YOUR NEXT APPOINTMENT

DATE

TIME



Aldara[®] (IMIQUIMOD)

Cream, 5%

inova
pharmaceuticals

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1. Dodson JM et al. Arch Dermatol 1991; 127: 1029–31.
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