ALDARA (Imiquimod 5 %
cream)

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ALDARA Cream

Each 250 mg cream sachet contains Imiquimod 12,5 mg (5 %).

Each 2,0 g cream pump contains 100 mg Imiquimod (5 %).

Read all of this leaflet carefully before you start using ALDARA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ALDARA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ALDARA is and what it is used for
2. What you need to know before you use ALDARA
3. How to use ALDARA
4. Possible side effects
5. How to store ALDARA
6. Contents of the pack and other information

1. What ALDARA is and what it is used for

ALDARA cream modifies the body's immune responses.

ALDARA cream is used for the topical treatment of superficial basal cell carcinoma (a type of skin cancer), and of external genital/perianal warts and clinically typical, non-hyperkeratotic,

non-hypertrophic actinic keratosis (rough scaly patches on your skin that develops from years of exposure to the sun) on the face or scalp in adult patients.

2. What you need to know before your use ALDARA

Do not use ALDARA cream:

- if you are hypersensitive (allergic) to imiquimod or any of the other ingredients of ALDARA cream
- on warts inside the vagina or inside the anus or inside the urethra (where you pass urine). The use of ALDARA cream on these areas has not been studied.

Warnings and precautions

- Tell your doctor if you have problems with your immune system.
- ALDARA cream has a potential to make inflammatory conditions of the skin worse.

Superficial basal cell carcinoma and Actinic keratosis:

- Minimise or avoid exposure to natural or artificial sunlight

External genital/perianal Warts:

- If you are an uncircumcised male with warts under the foreskin, retract the foreskin and wash the area daily.
- Wash ALDARA cream from the skin before sexual activity.
- ALDARA cream may weaken condoms and diaphragms, therefore concurrent use with ALDARA cream is not recommended.

Paediatric use: Safety and effectiveness in patients below the age of 18 years has not been established.

Other medicines and ALDARA

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are using other medicines on a regular basis, the use of ALDARA cream with these medicines may cause undesirable interactions. ALDARA should be used with caution in patients who are receiving immunosuppressive medication. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Pregnancy, breastfeeding and fertility

ALDARA cream is not recommended for use during pregnancy or lactation.

If you are pregnant or breastfeeding your baby while using this medicine, please consult your doctor, pharmacist or other health-care professional for advice.

Driving and using machines

The effects of this medicine on a person's ability to drive and use machines were not assessed.

It is not always possible to predict to what extent ALDARA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ALDARA affects them.

ALDARA contains methyl hydroxybenzoate and propyl hydroxybenzoate.

Methyl hydroxybenzoate and propyl hydroxybenzoate may cause allergic reactions (possibly delayed).

3. HOW TO USE ALDARA CREAM

Do not share medicines prescribed for you with any other person.

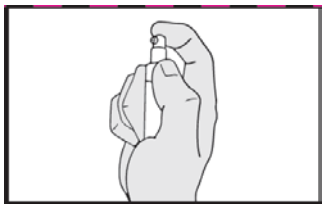
Always use ALDARA cream exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

ALDARA cream is provided in a pump or in single use sachets. Four (4) pump actions of the pump is approximately equivalent to one (1) 250 mg sachet of ALDARA cream. The content of the pump should be used within 4 weeks after opening and the pump discarded thereafter.

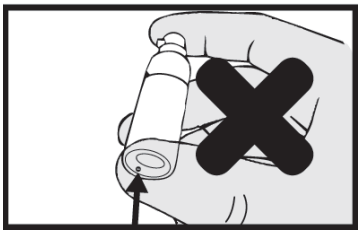
Sachets are to be used only once.

Priming the pump before use

1. Remove the cap by pulling it.
2. To prime the pump; hold the bottle up-right and fully press the top of the actuator several times until the cream appears at the dispenser nozzle. This could take up to 10 presses on the actuator.



3. Do not obstruct the hole under the bottle during the pump activation.



4. The pump is now ready to use. You will not need to prime it again.

The usual dose is as follows:

Superficial Basal Cell Carcinoma (A type of skin cancer)

Apply ALDARA cream once daily for 5 consecutive days per week and the treatment should continue for 6 weeks. Enough cream should be applied to cover the treatment area, including one centimetre of skin surrounding the tumour.

External Genital/Perianal Warts

Apply ALDARA cream once daily 3 times per week (every other day followed by a 2-day treatment-free interval) prior to normal sleeping hours, and should remain on the skin for 8 (6 to 10) hours. Treatment should continue until genital/perianal warts are no longer visible or for a maximum of 16 weeks.

ALDARA cream should be applied in a thin layer and rubbed on the clean wart area until the cream vanishes. The use of a dressing to cover the area is not recommended with ALDARA therapy. During the 6 to 10 hours treatment period, showering or bathing should be avoided. After this period ALDARA cream should be removed with mild soap and water.

Actinic Keratosis

Apply ALDARA cream 3 times per week (example: Monday, Wednesday and Friday) prior to normal sleeping hours, and leave on the skin for approximately 8 hours. Continue treatment for 4 weeks.

The cream in a single-use sachet or four pump actions of the pump is enough to cover a wart area of 20 cm^2.

Sachets should be used only once.

Higher than recommended doses may lead to increased local skin reactions.

Information for patients:

If you are being treated for Superficial Basal Cell Carcinoma

1. During treatment and until healed, affected skin is likely to appear noticeably different from normal skin.
2. You should preferably minimize or completely avoid exposure to natural or artificial sunlight.
3. The effectiveness of therapy can be determined after regeneration of the treated skin, approximately 6 to 12 weeks after the end of treatment.
4. You should contact your doctor if you experience any signs or symptoms at the application site that restricts or prohibits your daily activity or makes continued application of the cream difficult.

If you are being treated for External/Perianal Warts

1. You should avoid sexual (genital, anal, oral) contact while the cream is on your skin. It should be washed from the skin before sexual activity.
2. The effect of ALDARA cream on the transmission (spreading) of genital/perianal warts is unknown. ALDARA cream may weaken condoms and vaginal diaphragms. Therefore, concurrent use is not recommended.
3. Uncircumcised males treating warts under the foreskin should retract the foreskin and clean the area daily.
4. Patients should be aware that new warts may develop during the therapy, as ALDARA cream does not cure this condition.

If you are being treated for Actinic Keratosis

1. During treatment and until healed, affected skin is likely to appear noticeably different from normal skin.
2. You should preferably minimise or avoid exposure to natural or artificial sunlight.
3. During treatment, sub-clinical Actinic Keratosis lesions may appear in the treatment area.

4. You should contact your doctor if you experience any signs or symptoms at the application site that restricts or prohibits your daily activity or makes continued application of the cream difficult.

If you have the impression that the effect of ALDARA cream is too strong or too weak for you, tell your doctor or pharmacist.

If you use more ALDARA cream than you should:

In the event of overdosage, consult your doctor or pharmacist. The following symptoms may be experienced in case of overdosage:

- Severe local skin reactions. If you stop using ALDARA, local skin reactions should heal within 2 weeks.
- Nausea, vomiting, headache, fever, and pain in muscles could occur after taking the contents of approximately 16 sachets or 3 pumps.

If you forget to use ALDARA cream:

Do not use a double dose to make up for a forgotten individual dose.

4. POSSIBLE SIDE EFFECTS

Aldara can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ALDARA, please consult your doctor, pharmacist or other health care professional for advice.

ALDARA cream can have the following side effects:

Tell your doctor if you notice any of the following:

If you are being treated for external genital warts:

Frequent side effects:

- skin infections,
- headache,
- nausea (feeling sick),
- burning, stinging, irritation and itching of the treated skin,
- lightening of the treated skin,
- pain of the treated skin,
- rash at the treatment site,
- muscle pain,
- sensitivity or tenderness of the treated skin.

Less frequent side effects:

- infections of the skin,
- genital thrush,
- infections and inflammation of the nose and throat,
- rash and bumps on the skin,
- swelling of the lymph nodes,
- eating disorder (anorexia),
- feeling depressed and irritable,
- insomnia (not being able to sleep),
- dizziness,
- migraine (severe headache),
- tingling feeling of the skin,
- sleepiness or drowsiness,
- ringing in the ears (tinnitus),
- blushing of the skin (redness),

- abdominal pain,
- diarrhoea,
- cramping of discomfort of the rectum,
- vomiting,
- increasing in sweating,
- joint and back pain,
- difficulty urinating,
- genital pain and discomfort,
- feeling weak,
- flu-like symptoms,
- fever,
- feeling cold.

If you are being treated for superficial basal cell carcinoma (a type of skin cancer):

Frequent side effects:

- skin infections,
- bumps or rash on the skin,
- swelling of the lymph nodes,
- headache,
- back pain,
- bleeding and redness of the treated skin,
- burning and irritation of the treated skin,
- pain of the treated skin,
- tingling sensation of the treated skin,
- general itching of the skin,
- tenderness of the treated skin,

- fatigue,
- fever.

Less frequent side effects:

- irritability,
- dry mouth,
- nausea (feeling sick),
- inflammation and swelling of the skin and treated area,
- swelling of the treated skin,
- discharge of the treated skin,
- scabbing or flaking of the skin,
- flu-like symptoms,
- feeling tired.

If you are being treated for actinic keratosis (rough scaly patches on your skin that develops from years of exposure to the sun):

Frequent side effects:

- eating disorder or loss of appetite (anorexia),
- headache,
- nausea (feeling sick),
- joint and muscle pain,
- burning of the treated skin,
- irritation, redness and itching of the treated skin,
- pain of the treated skin,
- fatigue.

Less frequent side effects:

- infections of the skin,
- bumps and sores on the skin.
- inflammation of the nasal cavity,
- swelling of the lymph nodes,
- feeling depressed,
- irritation and swelling of the eyes,
- blocked nose,
- pain of the throat,
- redness of the skin,
- swelling of the face,
- general itching, pain and inflammation of the skin,
- pain,
- bleeding and discharge of the treated skin,
- swelling of the treated skin,
- tingling sensation of the treated skin,
- scabbing and scarring of the treated skin,
- heat sensation of the treated skin,
- lack of energy,
- fever,
- feeling cold.

Should an intolerable reaction occur, the cream should be removed by washing the area with mild soap and water. Treatment with ALDARA cream can be resumed after the skin reaction has improved.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form"** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information about the safety of ALDARA.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000.

Website: www.inovapharma.co.za.

5. How to store ALDARA

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

Store at or below 25 °C.

Do not use ALDARA after the expiry date stated on the sachet, pump or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

- The active substance is imiquimod.
- The other ingredients are methyl hydroxybenzoate, propyl hydroxybenzoate, benzyl alcohol 2 % *m/m*, isostearic acid, cetyl alcohol, stearyl alcohol, white soft paraffin, polysorbate, sorbitan monostearate, glycerol, xanthan gum and purified water.

What ALDARA looks like and contents of the pack

White to faintly yellow cream with a uniform appearance.

ALDARA cream is available in boxes containing 3 and 12 single use polyester/aluminium foil sachets or in a pack containing 1 or 2 Pumps.

Holder of the Certificate of Registration

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