1.3.2 PATIENT INFORMATION LEAFLET

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 ALDARA CREAM CONTAINS

- 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 CREAM IS USED FOR

ALDARA cream is an immune response modifier.

ALDARA cream is used for the topical treatment of superficial basal cell carcinoma, and of external genital/perianal warts and clinically typical, non hyperkeratotic, nonhypertrophic actinic keratosis on the face or scalp in adult patients

BEFORE YOU USE ALDARA CREAM

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

ALDARA cream has not been evaluated for treatment of internal genital warts and should not be used to treat urethral, intra-vaginal, cervical, rectal or intra-anal warts.

ALDARA cream should be used with caution in patients with autoimmune conditions and in organ transplant patients.

ALDARA cream should not be used immediately following treatment with other applied drugs for the treatment of external genital and perianal warts until the skin has healed from any previous medical or surgical treatment.

Skin colour changes (lighter or darker) following application of **ALDARA** cream may be permanent.

Do not use ALDARA cream:

- if you are hypersensitive (allergic) to imiquimod or any of the other ingredients of **ALDARA** cream

Take special care with ALDARA cream:

- **ALDARA** cream has a potential to exacerbate inflammatory conditions of the skin.

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

Pregnancy and breastfeeding

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

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

Using other medicines with ALDARA cream:

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.

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) actuations of the pump is approximately equivalent to one (1) 250 mg sachet of **ALDARA** cream. The content of the pump should be used 4 weeks after opening and the pump discarded thereafter.

The usual dose is as follows:

Superficial Basal Cell Carcinoma

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

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 there is a clearance of visible genital/perianal warts 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 an occlusive dressing 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 actuations of the pump is sufficient to cover a wart area of 20 cm^2.

Sachets are to be used only once.

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

Information for patients:

Patients 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. It is prudent for patients to minimize or avoid exposure to natural or artificial sunlight.
3. The clinical outcome of therapy can be determined after regeneration of the treated skin, approximately 6 to 12 weeks after the end of treatment.
4. Patients should contact their doctor if they experience any signs or symptom at the application site that restricts or prohibits their daily activity or makes continued application of the cream difficult.

Patients being treated for External/Perianal Warts

1. Sexual (genital, anal, oral) contact should be avoided while the cream is on the skin. It should be washed from the skin before sexual activity.
2. The effect of **ALDARA** cream on the transmission 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 is not a cure.

Patients being treated for Actinic Keratosis

1. During treatment and until healed, affected skin is likely to appear noticeably different from normal skin.
2. It is prudent for patients to 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 sign or symptom 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, talk to your doctor or pharmacist.

If you use more ALDARA cream than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. The following symptoms may be experienced in case of overdosage:

- Severe local skin reactions. Discontinuation of use will be followed by healing of local skin reactions within 2 weeks.
- Following accidental ingestion, nausea, vomiting, headache, fever, 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 take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

ALDARA cream can have the following side effects:

Consult your doctor as soon as possible if any of the following occur:

- More common: Blisters on the skin, itching in genital or other skin areas, open sores or scabs on the skin, redness of skin (severe), scaling
- Symptoms of overdosage: Flu-like symptoms, including diarrhoea, tiredness, fever, headache, or muscle pain

The following side effects usually do not need medical attention. These may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of these continue or are bothersome

- More common: Burning or stinging of skin (mild), flaking of the skin, pain, soreness, or tenderness of the skin (mild), rash, redness of the skin (mild), swelling at place of application.
- Less common: Lightening of the treated skin.

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 moderated.

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 taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

STORING AND DISPOSING OF ALDARA CREAM

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

Store at or below 25 °C.

Do not use 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).

PRESENTATION OF ALDARA CREAM

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.

IDENTIFICATION OF ALDARA CREAM

White to faintly yellow cream with a uniform appearance.

REGISTRATION NUMBER

32/34/0541

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

iNova Pharmaceuticals (Pty) Ltd

15e Riley Road

Bedfordview

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