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Product	Aldara	Size	350mmX240mm
Product spec	Cream	Font	Arial 7 pt
		Color	Black
Type	Leflet		
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Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986

This medicine is to be supplied by physician's prescription only

Aldara 5%, Cream

Active Ingredient:

Imiquimod 5%
For Inactive ingredients: See section 6 ('Additional information') in this leaflet.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. What is this medicine intended for?

Aldara cream is used in a different way for each of the indications. The physician may prescribe **Aldara** for the treatment of:

- External genital and perianal warts (condyloma acuminata) in adult patients.
- Actinic Keratosis in adults with normal immune systems.
- Superficial Basal Cell Carcinoma in adults with normal immune systems when surgical methods are less appropriate.

Aldara assists the immune system with the production of natural substances, helping the body to fight cancer cells in actinic keratosis or viruses causing warts.

Therapeutic group: Immunomodulators (agents regulating the immune response).

2. Before using this medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient Imiquimod or to any of the other ingredients that this medicine contains (see section 6-'Additional information' in this leaflet).

Special warnings regarding the use of this medicine

- If you have been previously treated with **Aldara** or similar medicines, tell your physician before starting treatment with **Aldara**.
 - Tell your physician if you know of problems with your immune system.
 - Tell your physician if you know of abnormalities in your blood counts.
 - Avoid using **Aldara** until the skin is healed from any previous drug or surgical treatment.
 - Avoid contact of the cream with your eyes, lips or nostrils.
- In case of contact of the cream with these regions, wash the region with water.
- The medicine is intended for external use only.
 - Do not use this cream beyond the recommended period, quantity and frequency.
 - Do not cover the treated area with clothes or dressing after applying **Aldara**.
 - If you experience intolerable discomfort in the treated area, wash the area on which **Aldara** has been applied with mild soap and water. After the area calms down, you may resume the treatment with **Aldara**.
 - Due to the mechanism of action of **Aldara**, there may be worsening of local inflammatory conditions in the treated area.
 - During the treatment with **Aldara** until complete recovery, appearance of the treated area may be significantly different from normal skin appearance.

If you are treated with Aldara for warts in the genital and anal areas, pay attention to the following additional warnings:

- Men with warts under the foreskin should pull the glans back and wash underneath every day. If this area is not cleaned on a daily basis, the skin in the foreskin area may become tight, swollen and exfoliated. As a result, it will be difficult to expose the glans. If these symptoms appear, stop the treatment and contact a physician.
- Do not use on open wounds. Wait until the wounds heal.
- If you suffer from internal warts, do not apply the cream on internal areas such as urethral orifice, vagina, cervix or anus.
- Tell your physician if you have problems with the immune system due to an illness or medications that you are taking, since **Aldara** should not be used for more than one treatment cycle in such situations.
- Tell your physician if you are HIV positive, since the efficacy of **Aldara** in these patients has not been established.
- If you decide to have sexual relations while you still have warts, apply **Aldara** cream after sexual activity rather than before.
- Aldara** cream may harm the effectiveness of condoms and diaphragms, therefore the cream should be removed before sexual activity.

- Remember, **Aldara** cream does not protect against passing the virus to someone else, transmission of the AIDS virus or other sexually transmitted diseases.

If you are being treated with Aldara for actinic keratosis or superficial skin cancer (basal cell carcinoma), pay attention to the following additional warnings:

- 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 while staying outside during daylight.

If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist. There are no known medicines which should be avoided during the treatment with **Aldara** cream.

Children

Treatment of **Aldara** is not recommended for children and adolescents.

Pregnancy and Breastfeeding

Consult the physician if you are pregnant or planning to become pregnant. The physician will evaluate the benefit versus the risk associated with the use of **Aldara** during pregnancy. Animal studies have not demonstrated any direct or indirect deleterious effect of the medicine during pregnancy.

Do not breastfeed during treatment with **Aldara**, because it is not known whether the active substance Imiquimod is excreted in breast milk or not.

Driving and using machines

Based on the known information, it cannot be concluded that **Aldara** can affect your ability to drive or operate machines.

Important information about some of the medicine's ingredients

- Aldara** contains Methyl hydroxybenzoate and Propyl hydroxybenzoate which may cause an allergic reaction (a delayed reaction may also occur)
- Cetyl alcohol and Stearyl alcohol may cause local skin irritations (such as contact dermatitis).

3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

- Before going to bed, wash your hands and the treated area with mild soap and water. Dry the area.
- Open a new sachet. Squeeze **Aldara** cream onto your fingertip.
- Apply a thin layer of **Aldara** cream onto clean, dry intended area according the physician's instructions. Rub gently into the skin until the cream vanishes.
- Each sachet is for one use only. After application of the cream, throw away the opened sachet and wash your hands with soap and water.
- Leave **Aldara** cream on the treated area according to physician's instruction. Do not shower or bathe during this time.

At the end of daily treatment, the area where **Aldara** cream was applied should be washed with mild soap and water.

The dosage and treatment will be determined only by the physician. The recommended dose is usually:

External topical treatment of warts in the genital and anal areas

- Apply the cream on the warts.
- Continue the treatment with **Aldara** according to physician's instruction until the warts disappear. (Half of the women treated with **Aldara** cream will recover within 8 weeks. Half of the men will recover within 12 weeks, but some patients experience an improvement in their health condition in only 4 weeks).
- Apply the cream once a day, 3 times per week (for example, on Sunday, Tuesday and Thursday). The duration of treatment can be between 4 to 12 weeks.
- Do not use **Aldara** for a period longer than 16 weeks for each relapse of warts.
- Leave **Aldara** cream on the warts for 6-10 hours; do not shower during this period.
- After 6-10 hours, wash the area on which **Aldara** has been applied with mild soap and water.
- One cream sachet is sufficient to cover a wart of 20 cm².

For treatment of superficial basal cell carcinoma

- Apply the cream on the region requiring treatment and about 1 cm around it.
- Apply the cream once a day, 5 times per week (for example, on Sunday, Monday, Tuesday, Wednesday and Thursday), for 6 weeks.
- Leave **Aldara** cream on the skin for 8 hours; do not shower during this period.
- After 8 hours, wash the area on which **Aldara** has been applied with mild soap and water.

For treatment of actinic keratosis

- Apply the cream once a day, 3 times per week (for example, on Sunday, Tuesday and Thursday).

- The duration of treatment is 4 weeks.

3 weeks after the end of treatment, the physician will evaluate the skin condition. If the lesions have not yet disappeared, you need another treatment cycle of 4 weeks.

- Leave **Aldara** cream on the skin for 8 hours; do not shower during this period.
- After 8 hours, wash the area on which **Aldara** has been applied with mild soap and water.
- One sachet contains cream sufficient to cover a lesion of 25 cm².

If you have accidentally applied a higher dose, wash the area with mild soap and water. After the area calms down, you may apply the cream again.

If you or if a child accidentally swallowed the medicine, go immediately to the physician.

If you forgot to apply the medicine at the scheduled time, apply your next dose as soon as you remember. Do not apply the cream more than once a day.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, the use of **Aldara** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them. During treatment with the medicine, the color of the skin in the treatment area may change. In some patients, this is reversible and in some patients it is irreversible.

Some patients experience a decrease in blood count, which may make you more sensitive to infections, cause bruising more easily, and make you feel tired. If you experience these symptoms, contact a physician. If you notice lesions or spots on the skin, which appear as little red spots and are gradually expanding, sometimes accompanied by itching, fever, general feeling of being unwell, pain in the joints, vision problems, burning, local pain or sores in the eyes and in the mouth, stop using **Aldara** and contact a physician immediately.

A few patients have experienced hair loss in the treatment area or around it.

Many side effects associated with the use of **Aldara** are related to the local action of **Aldara** in the affected area, and these effects indicate that the medicine acts appropriately.

Tell the physician or the pharmacist as soon as possible if you do not feel well during the treatment with **Aldara** cream.

If you are treated with Aldara for warts in the genital and anal regions:

Most of the side effects of **Aldara** cream result from its local action in the skin.

Very common side effects:

- Redness, peeling of the skin, scaly skin, swelling, skin thickening, skin ulcers, scabbing and blisters under the skin
- Itching, burning or local pain

Most of these side effects are temporary, not serious and will resolve in about two weeks after treatment completion.

Common side effects:

- Headaches

Uncommon side effects:

- Fever, flu-like symptoms, pain in the muscles and joints
- Uterine prolapsed, pain during sexual intercourse in women, erectile difficulties in men
- Increased sweating, flushing, feeling sick
- Gastrointestinal symptoms

Ringing in the ears

Tiredness, dizziness, migraines, sensation of tingling, sleeplessness, depression, loss of appetite

Swollen glands, bacterial, viral or fungal infections, vaginal infections including vaginal yeast infection

Cough and cold with sore throat

Very rare side effects:

- Severe and painful skin reactions, especially in cases of overdose
- Painful skin reactions in the vaginal opening, which may even cause difficulties urinating; in such cases, seek medical attention

If you are treated with Aldara for superficial basal cell carcinoma

Most of the side effects of **Aldara** cream result from its local action in the skin. Local skin reactions may indicate that the medicine exerts an appropriate effect.

Very common side effects:

- Itching

Common side effects:

- Sensation of tingling, small swollen areas in the skin, local pain, burning, irritation, bleeding, redness or rash (if pus or other signs of infection appear, contact a physician)

If you experience extreme discomfort in the skin during the treatment, consult a physician. The physician may recommend to you to stop using **Aldara** cream for several days, a short rest from the treatment

• Swollen glands, back pain

Uncommon side effects:

- Changes in the treated area such as: peeling of the skin, inflammation, swelling, scabbing of the skin, cracks in the skin, blisters, dermatitis
- Feeling sick, dry mouth, flu-like symptoms, tiredness

If you are treated with Aldara for actinic keratitis

Most of the side effects of **Aldara** cream result from its local action in the skin. Local skin reactions may indicate that the medicine exerts an appropriate effect.

Very common side effects:

- Itching

Common side effects:

- Local pain, burning, irritation, redness (if pus or other signs of infection appear, contact a physician)
- Headache
- Anorexia, nausea
- Muscle pain, joint pain, tiredness

Uncommon side effects:

- Changes in the treated area such as: bleeding, inflammation, peeling of the skin, skin sensitivity, swelling, small swollen areas in the skin, sensation of tingling, scabbing of the skin, scarring, ulcers, sensation of warmth in the area, discomfort

Inflammation of the internal area of the nose, nasal congestion, flu or flu like symptoms, sore throat, pain in the extremities, fever, weakness, tremor

• Depression

• Irritation of the eyes, swelling of the eyelids

• Diarrhea

• Redness

• Swelling of the face, ulcers

If any side effects get worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

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

• Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.

• Do not store at a temperature above 25°C.

• Do not re-use a sachet after it has been opened; destroy the cream leftovers of an open sachet.

6. Additional Information

In addition to the active ingredient, the medicine also contains:

Iosostearic acid, Cetyl alcohol, Stearyl alcohol, Polysorbate 60, White soft paraffin, Sorbitan stearate, Benzyl alcohol, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Glycerol, Xanthan Gum, Purified water.

• What does the medicine look like and what are the contents of the package:

Each sachet contains 250 mg of white to light yellow cream. Each box contains 12 sachets for single use.

• Registration holder and his address: MegaPharm Ltd., P.O.B. 519, Hod Hasharon, 4510501

• Manufacturer and his address: 3M Health Care Ltd., Loughborough, England.

• This leaflet was checked and approved by the Ministry of Health in November 2014.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health: 114-44-29675.

• If you have any questions, please call 114-44-29675.

• If you experience any side effects, please call 114-44-29675.

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