Aldara™ Cream prescribing information

**Presentation:** Aldara™ cream contains 5mg imiquimod per 100mg of cream. The cream is in a sachet that contains 250 mg of a white to slightly yellow cream.

**Indications:** Clinically typical, nonhyperkeratotic and nonhypertrrophic actinic keratoses (AKs) on the face or scalp in immunocompetent adult patients when size/number of lesions limit the efficacy/acceptability of cryotherapy and other topical treatments are contraindicated or less appropriate.

**Action:** Imiquimod is an immune response modifier.

**Dosage:** Apply 3 times per week, for 4 weeks, prior to sleep. Rub the cream on the affected area until the cream vanishes. Leave for approximately 8 hours before removing with mild soap and water. Recommended maximum dose is one sachet, each sachet is to be used once only. Assess response to therapy after 4 weeks treatment free. If any lesions remain, repeat treatment for a further 4 weeks. If lesions persist after a further treatment free period of 4-8 weeks a different therapy should be used.

**Contraindications:** Patients with known hypersensitivity to imiquimod or any of the excipients.

**Precautions:** Avoid contact with the eyes, lips and nostrils. Protect treatment area from solar exposure. Imiquimod cream therapy is not recommended until the skin has healed after any previous drug or surgical treatment. Imiquimod cream has the potential to exacerbate inflammatory conditions of the skin. Imiquimod cream should be used with caution in patients with autoimmune conditions, organ transplant recipients or reduced hematologic reserve. No clinical experience exists with the use of imiquimod cream for the treatment of AK in immunocompromised patients. The use of an occlusive dressing is not recommended with imiquimod therapy. Biopsy clinically atypical AK lesions or lesions suspicious for malignancy to determine appropriate treatment. Data on the use of imiquimod for AK on areas other than the scalp or face is limited. Available data does not support efficacy for lesions on the forearms or hands therefore use of imiquimod is not recommended. No clinical experience exists in patients whose lesions have recurred following treatment with imiquimod, therefore repeat treatment is not recommended. Data from an open label clinical trial suggests that complete clearance rates are decreased in patients with > 8 lesions compared with patients with < 8 lesions. Local skin reactions are common but generally decrease in intensity during therapy or resolve after cessation of therapy. A rest period of several days may be taken if required. An association exists between complete clearance rate and intensity of local skin reactions. These local skin reactions may be related to the stimulation of local immune response. Imiquimod has not been evaluated for the treatment of AK on the eyelids or in the nostrils, ears or inside the vermilion border of the lip. Clinical outcome can be determined approximately 4-8 weeks after the end of treatment.

**Interactions:** Use with caution in patients receiving immunosuppressants.

**Pregnancy and lactation:** No clinical data on exposed pregnancies is available. Exercise caution when prescribing to pregnant women. No advice can be given on use in lactating mothers.

**Undesirable effects:** Severe erythema, scabbing and crusting are very common during imiquimod therapy. Application site reactions such as pain, burning and irritation have also been commonly, and pruritus very commonly, reported in clinical trials. Systemic side effects such as headache, nausea and myalgia have been commonly reported. Alopecia at the treatment site or surrounding area has been detected at a frequency of 0.4%. Skin infections during treatment with imiquimod have been observed. While serious sequelae have not resulted, the possibility of infection in broken skin should be considered. Localised hypo and hyperpigmentation has been reported in patients who have used imiquimod. This may be permanent in some patients. Reductions in blood cell counts have been seen in clinical trials although these are not considered to be clinically significant in patients with normal hematologic reserve. Rare reports of exacerbation of autoimmune disease and remote site dermatologic drug reactions, including erythema multiforme, have been received. There have been postmarketing reports of elevated liver enzymes. Prescribers should consult the Summary of Product
Characteristics for a complete listing of side-effects.

**Special precautions for storage:** Do not store above 25°C. Do not re-use opened sachets.

**Basic price (UK):** Carton of 12 sachets £48.60.

**Legal category:** POM

**Marketing authorisation number:** EU/1/98/080/001

**Further information available from:** Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishops Stortford, CM22 6PU. Tel: 0845 460 0000. Fax: 0845 460 0002. Aldara is a trademark of Meda AB.

**Date of revision:** January 2013

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**Adverse events should be reported. Reporting forms and information can be found at** [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

**Adverse events should also be reported to Meda Pharmaceuticals Ltd.**
**Aldara™ Cream prescribing information**

**Presentation:** Aldara cream contains 5mg imiquimod per 100mg of cream. The cream is in a sachet that contains 250 mg of a white to slightly yellow cream.

**Indications:** For the topical treatment of external genital and perianal warts (condylomata acuminata) in adult patients.

**Action:** Imiquimod is an immune response modifier.

**Dosage:** Apply 3 times per week on non-consecutive days prior to sleep. Rub in a thin layer of cream on the clean wart area until the cream vanishes and leave for 6 to 10 hours. Then remove with mild soap and water. Each single-use sachet covers a wart area of 20 cm². Uncircumcised males treating warts under the foreskin should retract the foreskin and wash the area daily. Imiquimod cream treatment should continue until there is clearance of visible genital or perianal warts or for a maximum of 16 weeks per episode of warts.

**Contraindications:** Patients with known hypersensitivity to imiquimod or any of the excipients.

**Precautions:** Avoid contact with the eyes, lips and nostrils. Imiquimod cream therapy is not recommended until the skin has healed after any previous drug or surgical treatment. It should be used with caution in patients with autoimmune conditions, organ transplant recipients or reduced haematologic reserve. Based on current knowledge, treating urethral, intra-vaginal, cervical, rectal or intra-anal warts is not recommended. Imiquimod cream therapy should not be initiated in tissues where open sores or wounds exist until after the area has healed. Imiquimod cream has the potential to exacerbate inflammatory conditions of the skin. Use of an occlusive dressing is not recommended during imiquimod therapy. Repeat treatment with imiquimod cream is not recommended in immunocompromised individuals. Imiquimod cream should be washed from the skin before sexual activity. It may weaken condoms and diaphragms, therefore concurrent use is not recommended.

**Interactions:** Use with caution in patients receiving immunosuppressants.

**Pregnancy and lactation:** No clinical data on exposed pregnancies is available. Exercise caution when prescribing to pregnant women. No advice can be given on use in lactating mothers.

**Undesirable effects:** Local skin reactions including erythema, erosion, excoriation, flaking and oedema were common in controlled clinical trials with imiquimod cream. Application site pruritus and pain were very common. Most skin reactions were mild to moderate in severity and resolved within 2 weeks of treatment discontinuation. Systemic side effects such as headache and influenza-like symptoms have been commonly observed in clinical trials. Infection at the treatment site has also been commonly reported. Reports have been received of localised hypopigmentation and hyperpigmentation following imiquimod cream use. This may be permanent in some patients. Reductions in blood cell counts have been seen in clinical trials although these are not considered to be clinically significant in patients with normal haematologic reserve. Rare reports of exacerbation of autoimmune disease and remote site dermatologic drug reactions, including erythema multiforme, have been received. Post marketing reports of suspected alopecia during treatment of EGW have been received. There have been post marketing reports of elevated liver enzymes. Prescribers should consult the Summary of Product Characteristics for a complete listing of side-effects.

**Special precautions for storage:** Do not store above 25°C.

**Basic price (UK):** Carton of 12 sachets £48.60.

**Legal category:** POM.

**Marketing authorisation number:** EU/1/98/080/001.

**Further information available from:** Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop Stortford, CM22 6PU. Tel: 0845 460 0000. Fax: 0845 4600002. Aldara is a trademark of Meda AB.

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Adverse events should also be reported to Meda Pharmaceuticals Ltd.
Aldara™ Cream prescribing information

**Presentation:** Aldara cream contains 5mg imiquimod per 100mg of cream. The cream is in a sachet that contains 250 mg of a white to slightly yellow cream.

**Indications:** For the topical treatment of small superficial basal cell carcinomas (sBCCs) in adult patients.

**Action:** Imiquimod is an immune response modifier.

**Dosage:** Apply 5 times per week, for 6 weeks, prior to sleep. Rub the cream on the tumour and 1 cm around until the cream vanishes. Leave for approximately 8 hours. Then it must be removed with mild soap and water. A rest period of several days may be taken if the local skin reaction to imiquimod cream causes excessive discomfort to the patient, or if infection is observed at the treatment site. In this latter case, other appropriate measures should be taken. Assess response to therapy 12 weeks after the end of treatment.

**Contraindications:** Patients with known hypersensitivity to imiquimod or any of the excipients.

**Precautions:** Avoid contact with the eyes, lips and nostrils. Imiquimod cream therapy is not recommended until the skin has healed after any previous drug or surgical treatment. Imiquimod cream has the potential to exacerbate inflammatory conditions of the skin. The use of an occlusive dressing is not recommended with imiquimod therapy. Rarely, intense local inflammatory reactions can occur after a few applications of imiquimod cream. Consider interruption of therapy. Imiquimod cream should be used with caution in patients with autoimmune conditions, organ transplant recipients or reduced haematologic reserve. Imiquimod has not been evaluated for the treatment of basal cell carcinoma (BCC) within 1 cm of the eyelids, nose, lips or hairline. Local skin reactions during treatment are common but generally decrease in intensity during therapy or resolve after cessation of therapy. A rest period of several days may be taken if required. There is an association between the complete clearance rate and the intensity of local skin reactions. No clinical experience exists with the use of imiquimod cream in immunocompromised patients, or in patients with recurrent and previously treated BCCs. Use for previously treated tumours is not recommended. Large tumours (>7.25 cm²) are less likely to respond to imiquimod therapy. Protect treatment area from solar exposure.

**Interactions:** Use with caution in patients receiving immunosuppressants.

**Pregnancy and lactation:** No clinical data on exposed pregnancies is available. Exercise caution when prescribing to pregnant women. No advice can be given on use in lactating mothers.

**Undesirable effects:** Severe erythema, erosion, scabbing and crusting are very common during therapy with imiquimod. Local skin reactions, such as erythema, are probably an extension of the pharmacologic effect of imiquimod cream. Application site reactions such as pain, bleeding, papules, paraesthesia and rash have also been commonly, and pruritus very commonly, reported in clinical trials. Skin infections during treatment with imiquimod have been observed. While serious sequelae have not resulted, the possibility of infection in broken skin should always be considered. Systemic side effects such as back pain and influenza-like symptoms have been commonly reported. Localised hypopigmentation and hyperpigmentation have been reported following imiquimod cream use. This may be permanent in some patients. Reductions in blood cell counts have been seen in clinical trials although these are not considered to be clinically significant in patients with normal haematologic reserve. Rare reports of exacerbation of autoimmune disease and remote site dermatologic drug reactions, including erythema multiforme, have been received. Postmarketing reports of suspected alopecia during treatment of sBCC have been received. There have been postmarketing reports of elevated liver enzymes. Prescribers should consult the Summary of Product Characteristics for a complete listing of side-effects.

**Special precautions for storage:** Do not store above 25°C. Do not re-use opened sachets.

**Basic price (UK):** Carton of 12 sachets £48.60.

**Legal category:** POM.

**Marketing authorisation number:** EU/1/98/080/001.
Further information available from:
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