

ALDARA™ TURNS OVER A NEW LEAF

iNova Pharmaceuticals (Pty) Limited
 Reg. No. 1952/1001640/07
 15e Riley Road
 Bedfordview 2007
 Private Bag 3115
 Bedfordview 2008
 Republic of South Africa
 Tel: +27 11 087 0000
 Fax: +27 11 455 3873

Dear Healthcare Professional,

As a Doctor, you experience on a daily basis, the difficulties that can be associated with the complexities of dosage and administration of medicines. Patient compliance and the convenience of administration, is critical to the outcomes in the treatment of many conditions.

It is with this in mind that iNova Pharmaceuticals introduces a new Aldara (Imiquimod) delivery system, in the form of the Aldara Pump - a convenient, multi-dose administration system that can be used as directed for a month after opening.

As a market leader in South Africa¹, Aldara is already well established in the fields of therapy it is indicated for. Aldara is a topically active positive immune response modifier,² that enhances the body's immune response against dysplastic cells associated with actinic keratosis and tumour cells of superficial basal cell carcinoma.^{3,4} The activation of the immune response also results in a significant reduction in human papilloma virus viral load in external genital warts.²

TREATMENT FOR ACTINIC KERATOSIS (AK)			TREATMENT FOR SUPERFICIAL BASAL CELL CARCINOMA (sBCC)			TREATMENT FOR EXTERNAL GENITAL WARTS (EGW)		
Treatment Duration	Sachets	Pump	Treatment Duration	Sachets	Pump	Treatment Duration	Sachets	Pump
4 Weeks	1 box (12 sachets)	2 pumps	6 Weeks	2,5 boxes (30 sachets)	5 pumps	16 weeks*	4 boxes (48 sachets)	8 pumps

*Duration: Total Wart clearance or maximum of 16 weeks.

Aldara Pump will be available from 24 May 2017 in conjunction with the current packaging form.

The following product information will be beneficial when ordering Aldara Sachets and/or Aldara Pump:^{5,6}

PROPRIETARY NAME	PACK SIZE AND INGREDIENTS	SCHEDULING STATUS	INDICATIONS	PRODUCT CODES	LIST PRICE (EXCL. VAT)
Aldara Pump	Each 2,0 g cream pump contains 100 mg Imiquimod (5 %)	S4	The topical treatment of: Superficial basal cell carcinoma External genital/perianal warts Actinic keratosis	Barcode: 6009900316604 NAPPI code 722706001 DSV Code 036002	R 520,74
Aldara Sachets	1 box contains 12 sachets. Each 250 mg cream sachet contains 12,5 mg Imiquimod (5 %)	S4	The topical treatment of: Superficial basal cell carcinoma External genital/perianal warts Actinic keratosis	Barcode: 9314057005668 NAPPI code 851884008 DSV Code 036001	R 781,10

We truly believe that the addition of this innovative delivery system to our product offering will add immense value to doctors, pharmacists and patients alike; simplifying the dosage and administration of this novel agent. Should you require any further information, please contact iNova Pharmaceuticals on: (011) 087 0000.

Thank you for your support.

Yours sincerely



Tershia Stevens
 Marketing Manager RX
 t.stevens@inovapharma.co.za



References: 1. Impact Rx data, August 2016. 2. Tyring SK, Arany I, Stanley MA, et al. A Randomized, Controlled, Molecular Study of Condylomata Acuminata Clearance During Treatment with Imiquimod. *J Infect Dis* 1998;178:551-555. 3. Korman N, Moy R, Ling M, et al. Dosing With 5% Imiquimod Cream 3 Times per Week for the Treatment of Actinic Keratosis. Results of Two Phase 3, Randomized, Double-blind, Parallel-Group, Vehicle-Controlled Trials. *Arch Dermatol* 2005;141:467-473. 4. Dauden E, on behalf of the BASALE Study Group. Effectiveness and satisfaction with imiquimod for the treatment of superficial basal cell carcinoma in daily dermatological practice. *J Eur Acad Dermatol Venereol* 2011;25:1304-1310. 5. Aldara approved package insert. 6. South African Medicine Price Registry. [online] 14 November 2016 [cited] 16 November 2016; Available from URL: <http://www.mpr.gov.za/PublishedDocuments.aspx?DocCatId=21>.

Scheduling status: S4 **Proprietary name and dosage form:** Aldara Cream. **Composition:** Each 2,0 g cream pump contains 100 mg Imiquimod (5 %). **Preservatives:** Methyl hydroxybenzoate 0.2 % m/m, Propyl hydroxybenzoate 0.02 % m/m, Benzyl alcohol 2 % m/m. **Pharmacological classification:** A 34 **Other indications:** Aldara Cream is indicated for the topical treatment of superficial basal cell carcinoma (sBCC), and of external genital/perianal warts (condyloma acuminata) and clinically typical, non hyperkeratotic, nonhypertrophic actinic keratosis (AKs) on the face or scalp in adult patients. **Contra-indications:** Hypersensitivity to any of the ingredients. **Warnings:** Safety and efficacy in patients below the age of 18 years have not been established. Should not be used to treat urethral, intra-vaginal, cervical, rectal or intra-anal warts and following treatment with other cutaneously applied drugs until the skin has healed from any previous medical or surgical treatment. Aldara Cream has not been evaluated for the treatment of superficial basal cell carcinoma within 1 cm of the eyelids, nose or lips. Aldara Cream has not been evaluated for the treatment of actinic keratosis on the eyelids, the inside of the nostrils or ears, or the lip area inside the vermilion border. **Interactions:** Due to its immunostimulating properties, Aldara should be used with caution in patients who are receiving immunosuppressive medication. **Pregnancy and lactation:** Aldara Cream is not recommended for use during pregnancy and lactation. **Dosage and directions for use: Superficial Basal Cell Carcinoma:** Aldara Cream is to be applied 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 centimeter of skin surrounding the tumor. The clinical outcome of therapy can be determined after regeneration of the treated skin, approximately 6 to 12 weeks after the end of treatment. **External Genital/Perianal Warts:** Aldara Cream should be applied 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 (6-10) hours. Treatment should continue until there is a clearance of visible genital/perianal warts or for a maximum of 16 weeks. **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 Aldara Cream treatment for 4 weeks. After a 4-week treatment-free period the physician should assess the treated area to determine clearance of AKs. If any AKs persist in the treatment area, apply imiquimod cream 3 times per week for an additional 4 weeks (for a maximum total treatment duration of 8 weeks). **Side effects and special precautions:** Local application site reactions include itching, burning sensation, and pain at the wart treatment site. The most frequently reported local skin reactions are erythema, erosion, excoriation/flaking and oedema. 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. Uncircumcised males with warts under the foreskin should retract the foreskin and wash the area daily. Aldara Cream should be washed from the skin before sexual activity. The concurrent use of condoms and diaphragms with Aldara Cream is not recommended. Aldara has the potential to exacerbate inflammatory conditions of the skin. Registration number: 32/34/0541 [Act 101/1965]. **Name and business address of applicant:** iNova Pharmaceuticals (Pty) Ltd, Co. Reg. No. 1952/001640/07, 15e Riley Road, Bedfordview. Tel. No. 011 087 0000. www.inovapharma.co.za. For full prescribing information, refer to the package insert approved by the medicines regulatory authority. Further information is available on request from iNova Pharmaceuticals. IN2337/16.

