# Giving them freedom f confidence to be who they're meant to be.

## BENEFITS OF ELIDEL CREAM FOR PATIENTS<sup>2-5</sup>

ELIDEL

ELIDEL

- Keep patients flare-free longer<sup>2,3</sup>
- Rapid relief in pruritus<sup>4</sup>
- Acceptable safety profile & well tolerated<sup>5</sup>

#### ABBREVIATED MALAYSIAN PRESCRIBING INFORMATION

Indication: Elidel 1% cream is indicated for short-term and intermittent long-term treatment of mild to moderate atopic dermatitis in non-immunocompromised patients aged 2 years and older, in whom the use of alternative, conventional therapies is deemed inadvisable because of potential risks, or in the treatment of people who are not adequately responsive to or intolerant of alternative, conventional therapies. Pack size: Elidel 1% cream is available in tube of 15g. Dosage & administration: Apply a thin layer of Elidel 1% cream to affected skin twice daily. Elidel 1% cream may be used on all skin areas, including head, neck and intertriginous areas. Due to the low level of systemic absorption, there is no restriction either in the extent of the body surface area treated or in the duration of treatment. Dosing recommendation for paediatrics is the same as adults. Contraindications: Known hypersensitivity to pimecrolimus. Special warnings & precautions: Elidel 1% cream should not be applied to areas affected by acute cutaneous viral infections and is not recommended in patients with (1) Netherton's syndrome, (2) severely inflamed or damaged skin or (3) with immunocompromised immune systems. Throughout the course of treatment, it is prudent for patients to avoid natural or artificial sunlight exposure. Adverse reactions: Commons reactions are application site burning, application site reactions intrition, puritus & erythema] and folliculifus. Uncommon to very rare reactions are impetigo, condition aggravated, herpes simplex dermatitis, molluscum contagiosum, rash, pain, paraesthesia, desquamation, dryness, oedema, skin papilloma, furuncle, alcohol intolerance, allergic reactions and skin discoloration. Interactions: Based on its minimal extent of absorption, interaction of Elidel 1% cream with systematically administered drugs are unlikely to occur. Elidel 1% cream to the there with protective immune response to childhood vaccinations. Caution should be exercised when prescribing Elidel 1% cream to the breadst.

#### Full prescribing information would be provided upon request.

#### References

1.Luger T, et al. Recommendations for pimecrolimus 1% cream in the treatment of mild-to-moderate atopic dermatitis: from medical needs to a new treatment algorithm. Eur J Dermatol. 2013;23(6):758-66. Page 763. 2.Sigurgeirsson B, et al. Effectiveness and safety of a prevention-of-flare-progression strategy with pimecrolimus cream 1% in the management of paediatric atopic dermatitis. Journal of the European Academy of Dermatology and Venereology. 2008 Nov 1;22(11):1290-301. 3.Gollnick H, et al. Pimecrolimus cream 1% in the long-term management of adult atopic dermatitis: prevention of flare progression. A randomized controled trial. British Journal of Dermatology. 2008 May 1;158(5):1083-93. 4. Kaufmann R, Bieber T, Helgesen AL, et al. Onset of pruritus relief with pimecrolimus cream 1% in adult patients with atopic dermatitis: a randomized trial. Allergy. 2006 Mar 1;61(3):375-81. 5. Sigurgeirsson B, et al. Safety and efficacy of pimecrolimus in atopic dermatitis: a 5-year randomized trial. Prediatrics. 2015 Apr 1;135(4):597-606.

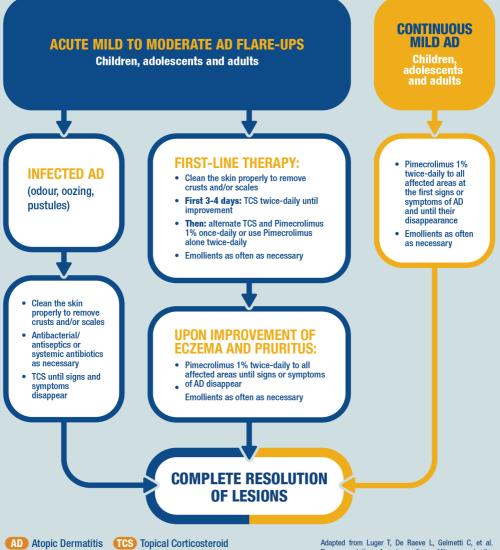
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Mylan Healthcare Sdn. Bhd. meter-m Global Business & Convention Centre, Block A, Level 2, No. 8, Jalan 19/1, 46300 Petaling Jaya, Salangor Darul Ehsan, Malaysia. Phone: +603-7957 5975 Fax: +603-7957 5863 MYELI-2019-05-04



# PIMECROLIMUS 1% CREAM IN THE TREATMENT OF MILD TO MODERATE ATOPIC DERMATITIS: TREATMENT ALGORITHM<sup>1</sup>



- Reserve TCS for the short-term treatment of acute disease flares<sup>1</sup>
- Use Elidel following the treatment of an acute flare with TCS<sup>1</sup>
- · Emollients should be applied as often as necessary to dry skin<sup>1</sup>

Adapted from Luger T, De Raeve L, Gelmetti C, et al. Recommendations for pimecrolimus 1% cream in the treatment of mild-to-moderate atopic dermatitis: from medical needs to a new treatment algorithm. Eur J Dermatol. 2013;23(6):758-66. Page 763; Figure 2, Treatment algorithm for mild-to-moderate AD





## **RECOMMENDATION BY THE EUROPEAN ATOPIC DERMATITIS 2018** GUIDELINES<sup>1</sup>

#### DOI: 10.1111/jdv.14891

**JEADV** 

### GUIDELINES

# Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part I

A. Wollenberg,<sup>1,2,\*</sup> S. Barbarot,<sup>3</sup> T. Bieber,<sup>4</sup> S. Christen-Zaech,<sup>5</sup> M. Deleuran,<sup>6</sup> A. Fink-Wagner,<sup>7</sup> U. Gieler,<sup>8,9</sup> G. Girolomoni,<sup>10</sup> S. Lau,<sup>11</sup> A. Muraro,<sup>12</sup> M. Czarnecka-Operacz,<sup>13</sup> T. Schäfer,<sup>14</sup> P. Schmid-Grendelmeier,<sup>15,16</sup> D. Simon,<sup>17</sup> Z. Szalai,<sup>18</sup> J.C. Szepietowski,<sup>19</sup> A. Taïeb,<sup>20</sup> A. Torrelo,<sup>21</sup> T. Werfel,<sup>22</sup> J. Ring,<sup>16,23</sup> For the European Dermatology Forum (EDF), the European Academy of Dermatology and Venereology (EADV), the European Academy of Allergy and Clinical Immunology (EAACI), the European Task Force on Atopic Dermatitis (ETFAD), European Federation of Allergy and Airways Diseases Patients' Associations (EFA), the European Society for Dermatology and Psychiatry (ESDaP), the European Society of Pediatric Dermatology (ESPD), Global Allergy and Asthma European Network (GA2LEN) and the European Union of Medical Specialists (UEMS)

## **KEY HIGHLIGHTS<sup>1</sup>**



## Suitability & effectiveness of TCI treatment

- The overall recommendation for Pimecrolimus is for treatment of Atopic Dermatitis (AD) in children & for facial lesions. Overall recommendation for Tacrolimus is for long-term maintenance.
- Treating sensitive body areas such as the face with TCI while treating other affected body areas with a TCS may be a useful and cost-effective strategy.



## Safety & tolerability of TCI treatment

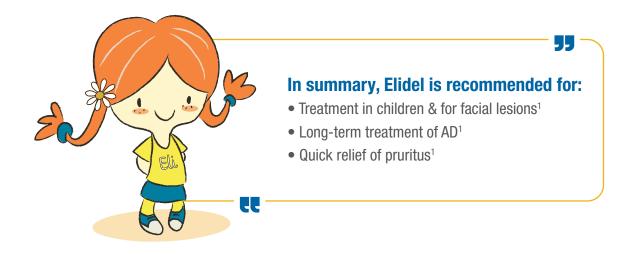
- Both TCIs are suitable for long-term treatment of AD.
- The use of topical calcineurin inhibitors is also not associated with increased risk of non-melanoma skin cancer, other malignancies or photocarcinogenicity.
- Some patients experience a transient worsening of skin conditions. These side-effects are more common with Tacrolimus ointment than with Pimecrolimus cream and when they are applied on acutely inflamed skin.



## Fast relief of pruritus with TCI treatment

 TCIs relieve significantly pruritus in AD. Itch is completely relieved after the first days of treatment in both adults and children\*.

\*Twenty-two RCTs were meta-analysed (16 – pimecrolimus 1% cream, 3 - tacrolimus 0.3% ointment, 1 – tacrolimus 0.1% ointment, 1 – tacrolimus 0.03% and 1 – tacrolimus 0.01% ointment).



For Healthcare Professionals Only TCI: Topical Calcineurin Inhibitor; TCS: Topical Corticosteroids

#### Abbreviated Malaysian Prescribing Information:

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#### **Reference:**

1. Wollenberg A, Barbarot S, Bieber T, Christen-Zaech S, Deleuran M, Fink-Wagner A, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part I. Journal of the European Academy of Dermatology and Venereology. 2018 Jun;32(6): 657–682.

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MY-ELI-2019-05-02

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## Treating Atopic Dermatitis (AD) at sensitive skin area can be challenging.

## WHY CAN IT BE CHALLENGING?

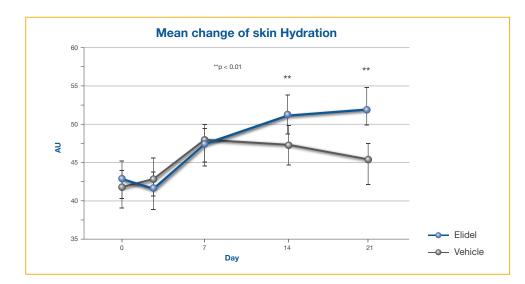
## Here are some characteristics of sensitive skin<sup>1</sup>:

- Sensitive skin has a thinner skin barrier with an imbalance of intercellular lipid of stratum corneum<sup>1</sup>
- Sensitive skin has higher transcutaneous penetration<sup>1</sup>. Skin absorption is increased about twofold in patients with AD compared with patients with normal skin<sup>2</sup>.
- Almost 80% of patients declared their concern about applying some treatments on sensitive skin areas such as the face, neck and flexures<sup>3</sup>.



## **3 REASONS ELIDEL SHOULD BE YOUR PREFERRED TREATMENT FOR AD AT SENSITIVE SKIN AREA**

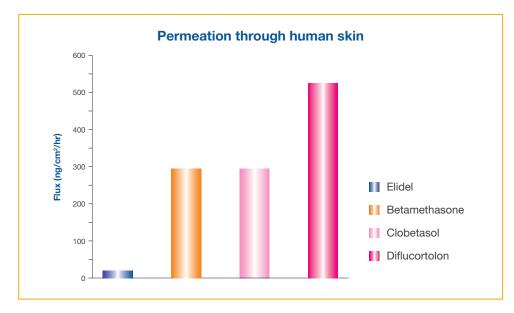
1. Elidel **restores** and **does not damage the skin barrier and lipid bilayer structure**<sup>4</sup>. Treatment with Elidel also provides moisturizing/emollient properties<sup>5</sup>



Adapted from Aschoff R, Schwanebeck U, Bräutigam M, Meurer M. Skin physiological parameters confirm the therapeutic efficacy of pimecrolimus cream 1% in patients with mild-to-moderate atopic dermatitis. Experimental dermatology. 2009 Jan;18(1):24-9.



2. Elidel has negligible systemic bioavailability. Its permeation through the skin is lower compared to Topical Corticosteroids by a factor 70-110<sup>6</sup>. Results indicate that Pimecrolimus has per se a lower risk of lower risk of systemic immunosuppression and may offer a larger safety margin than other topical therapeutic options<sup>6</sup>.



Adapted from Billich A, Aschauer H, Aszódi A, Stuetz A. Percutaneous absorption of drugs used in atopic eczema: pimecrolimus permeates less through skin than corticosteroids and tacrolimus. International journal of pharmaceutics. 2004 Jan 9;269(1):29-35.

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## 3. Proven efficacy and recommended by 2018 JEADV guidelines for use in sensitive skin area.<sup>7,8</sup>

#### Abbreviated Malaysian Prescribing Information:

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#### **References:**

1. Berardesca E, Farage M, Maibach H. Sensitive skin: an overview. International journal of cosmetic science. 2013 Feb;35(1):2-8. 2. Halling-Overgaard AS, Kezic S, Jakasa I, et al. Skin absorption through atopic dermatitis skin: a systematic review. British Journal of Dermatology. 2017 Jul;177(1):84-106. 3. Gollnick H, Luger T, Freytag S, Bräutigam M, STABIEL Study Group. StabiEL: stabilization of skin condition with Elidel–a patients' satisfaction observational study addressing the treatment, with pimecrolimus cream, of atopic dermatitis pretreated with topical corticosteroid. Journal of the European Academy of Dermatology and Venereology. 2008 Nov;22(11):1319-25. 4. Jensen JM, Pfeiffer S, Witt M, et al. Different effects of pimecrolimus and betamethasone on the skin barrier in patients with atopic dermatitis. Journal of Allergy and Clinical Immunology. 2009 May 1;123(5):1124-33. 5. Aschoff R, Schwanebeck U, Bräutigam M, Meurer M. Skin physiological parameters confirm the therapeutic efficacy of pimecrolimus cream 1% in patients with mild-to-moderate atopic dermatitis. Experimental dermatology. 2009 Jan;18(1):24-9. 6. Billich A, Aschauer H, Aszódi A, Stuetz A. Percutaneous absorption of drugs used in atopic eczema: pimecrolimus permeates less through skin than corticosteroids and tacrolimus. International journal of pharmaceutics. 2004 Jan 9;269(1):29-35. 7. Sigurgeirsson B, Boznanski A, Todd G, et al. Safety and efficacy of pimecrolimus in atopic dermatitis: a 5-year randomized trial. Pediatrics. 2015 Apr 1;135(4):597-606. 8. Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part I. Journal of the European Academy of Dermatology and Venereology. 2015 Apr 1;132(6): 657–682.

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MY-ELI-2019-05-03

# **SAY GOODBYE TO WARTS** Endwarts FREEZE

for common warts<sup>1</sup>





The unique technology can be used on adults and children over 4 years old. EndWarts, FREEZE is a medical device. Always read the instructions for use carefully before treatment.

For Healthcare Professionals Only

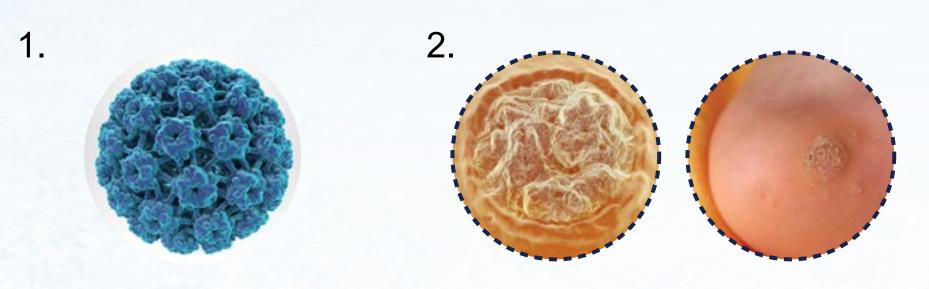
# A Unique Ultra freeze technology device that offers fast, easy & effective solution





# **About Warts**

Warts are contagious disease that is caused by human papillomavirus (HPV).<sup>2</sup>
 It has a rough surface that may look like head of a cauliflower, with black dots inside.<sup>3</sup>



Human Papillomavirus

# High prevalence of warts and patient's insight



Most people will experience asymptomatic infection with HPV at some time in their life.<sup>4</sup>





Affected ~ 10% of population<sup>2</sup>

1 in 3 school-ages children will experience warts<sup>5</sup>

I

CRYOTHERAPY



Families that suffered from warts in the past<sup>6</sup>



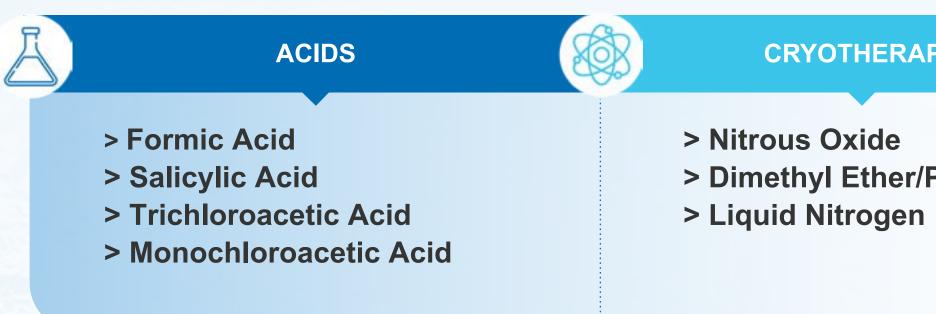
Insights from patients shows that 90% visited a professional for diagnosis<sup>4</sup>





# **Differences in wart treatment options**

# **Acids Treatment & Cryotherapy**



	<b>Acids</b> Keratolytic therapy that slowly destroys virus-infected epidermis. <sup>7</sup>	Cryotherapy Necrotic destruction of HPV-infected keratinocytes through the deepest layer of the warts <sup>7</sup>
Efficacy	Effective on warts treatment.8	Cryotherapy is the most effective for common wart group. <sup>9</sup>
Duration	Results require weeks to months of treatment. <sup>8</sup>	Freeze the warts in only one treatment. <sup>1</sup>
Compliance	The patient must strictly adhere to instructions, generally once daily until resolution. <sup>8</sup>	Once every two weeks. <sup>1</sup>

# CRYOTHERAPY

> Dimethyl Ether/Propane







wart at -80°C and reaches the deepest layer of the wart.

EndWarts<sub>®</sub> FREEZE, is an effective and clinically proven cryotherapy treatment for common warts.<sup>10</sup>



Randomized, Controlled, Investigator-Blinded, Comparative Study between EndWarts<sub>®</sub> FREEZE and two other cryotherapy treatments, Wortie<sup>®</sup> and Wartner<sup>®</sup>.



Study objectives evaluate on:

- Cure rate after one to maximum three treatments
- Efficacy and safety



# **Main findings**

- EndWarts<sub>®</sub> FREEZE shows superior cure rate VS Wartner<sup>®</sup> or Wortie<sup>®</sup>
- 47.4% and Wortie<sup>®</sup> at 52.8% in PP populations

	ITT	
EndWarts <sup>®</sup> FREEZE	70.7%	
Wartner®	46.2%	
Wortie®	47.5%	

> Almost three times more subjects were cured after 1 application by EndWarts<sub>®</sub> FREEZE (34%), versus Wartner<sup>®</sup> (10.5%) and Wortie<sup>®</sup> (13.9%). (PP analysis)

\*A wart was considered cured if surface area measurements were near zero (cm<sup>2</sup>), and if there was no presence of roughness and thickness of the skin.

ITT: Intention-To-Treat; PP: Per-Protocol.

# The only cryotherapy device in market to offer this NEW unique Ultra FREEZE Technology with nitrous oxide, a very cold gas. It freezes the

• After a maximum of three applications was significantly (p = 0.001) higher cure rate for EndWarts<sub>®</sub> FREEZE at 82% compared to with Wartner<sup>®</sup> at

and the second difference of the	and the second second	
PP		
82%		
47.4%		
52.8%		





# How to use $EndWarts_{R}$ FREEZE



# **1. ACTIVATE**

Before the very first use only.

EndWarts<sub>®</sub> FREEZE needs to be activated once. Do not remove the cap yet. Turn the white part of the device minimum one full turn in the direction of the arrow until you notice a loud click. Some force is needed. You may hear some soft clicks before. After you have activated the device successfully, never repeat this step.



# 2. LOAD

**Before each treatment EndWarts**<sub>®</sub> **FREEZE** needs to be loaded with cold gas. Place **EndWarts**<sub>®</sub> **FREEZE upright** on a table, with the transparent cap down. Hold the device with a steady grip. With the other hand, **push** the white part of the device **downward for exactly 2 seconds.** Pushing for longer will waste useful doses. Pushing shorter, reduces the freeze effect.





# 3. CHECK

Remove the transparent cap and **use the product immediately!** Check that you see **ice vapour**. If there is no ice vapour, repeat step 1.

# 4. TREAT

Press the tip firmly against the wart.
For best results - the time is crucial!
15 seconds on thin skin (hands, fingers, toes, side/top of feet and arms).



40 seconds on feet Put the cap back on. DONE!

After use, store in a refrigerator. The wart will slowly disappear after 10 to 14 days. If the wart, or part of it, does not disappear within 14 days repeat steps 1, 2 and 3.

# **O** not use EndWarts<sub>®</sub> FREEZE

- on children under 4 years of age
- on the face, groin, genitals, scalp or mucosa
- on healthy skin (skin without warts)
- on warts located on sensitive skin and take particular care when treating areas of thin skin (e.g. around joints)
- if the wart and/or surrounding skin is bleeding or open, irritated, itchy, infected or red
- if you are not sure the growth is a common wart, consult your doctor before use
- on moles, corns, blisters, other skin defects or anything that might be skin cancer (melanoma)
- on liquid filled vesicles on the skin (called 'molluscum contagiosum') or any other vesicles or blisters
- if pregnant or a nursing mother
- if you are diabetic or a person with blood circulation or blood clotting problems
- on multiple warts at the same time, if they are located close together. Wait 14 days before you treat the next wart

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# CHOOSE EndWarts FREEZE as your choice for treating common warts<sup>1</sup>

- A NEW innovative within Cryotherapy Treatment
- Unique ultra freeze technology, freezes the wart at -80°C with nitrous oxide ( $N_2O$ ) •
- Easy to use Medical Device •
- Proven fast and only one treatment needed
- It is widely available in Europe and one of the fast selling cryotherapy for warts treatment<sup>11</sup>

## **Abbreviated Product Information**

Indication: EndWarts, FREEZE is a rapid home treatment that effectively removes warts on hands, arms and feet. The treatment is suitable for adults and children over 4 years old. Function: It is the first home treatment with nitrous oxide, a very cold gas. Through an Ultra Freeze Technology 1 it freezes the wart at -80°C and reaches the deepest layer of the wart. EndWarts FREEZE is a high tech device that is quick and easy to use. Packaging: One package includes one EndWarts FREEZE device (7,5g nitrous oxide liq.), a set of 7 disposable tips and one Instruction for use. Do not use EndWarts, FREEZE: on children under 4 years of age, on the face, groin, genitals, scalp or mucosa, on healthy skin (skin without warts), on warts located on sensitive skin and take particular care when treating areas of thin skin (e.g. around joints), if the wart and/or surrounding skin is bleeding or open, irritated, itchy, infected or red, if you are not sure the growth is a common wart, consult your doctor before use, on moles, corns, blisters, other skin defects or anything that might be skin cancer (melanoma), on liquid filled vesicles on the skin (called 'molluscum contagiosum') or any other vesicles or blisters, if you are diabetic or a person with blood circulation or blood clotting problems, on warts in a cluster or warts are closer than 3 cm, treat one wart and wait 14 days before you treat the next wart, If you are pregnant or breast-feeding, check with your doctor whether you can use this device. Safety precautions: Do not inhale. For external use only. Keep out of the sight and reach of children. Do not apply for longer than 15 seconds on thin skin (hands, fingers, toes, top/side of feet and arms), or 40 seconds on thick, callous skin (soles of feet). Excessive or incorrect application can cause pain and skin or nerve damage. EndWarts FREEZE should be used by an adult when treating warts on children. Nitrous oxide is a non-toxic, non-flammable gas, but it will support combustion in case of fire. Keep away from heat/sparks/open flames/hot surfaces. Do not smoke or use close to a naked flame. Pressurized container. May burst if heated. Do not pierce or burn the cartridge even after use - the device is under high pressure and cannot be opened. Side effects: Blisters (possible blood blisters) around the treated area, depigmentation (skin losing its colour), minor burns and scar formation, risk of skin/nerve damage (in case of overexposure) and transient disturbed sensation (tingling, prickling feeling). Storage: Dry and cool place (between 5 – 25°C). Protect from sunlight. Product may be refrigerated but do not store in freezer.

Please refer to full product information before using EndWarts, FREEZE.

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1. Endwarts, freeze product insert. 2. Al Aboud AM, Nigam PK. Wart (Plantar, Verruca Vulgaris, Verrucae). InStatPearls [Internet] 2019 May 13. StatPearls Publishing. 3. Hirsch L, editor. Warts (for Teens) – Nemours KidsHealth [Internet]. KidsHealth. The Nemours Foundation; 2019 [cited 2020Dec22]. Available from: https://kidshealth.org/en/teens/warts.html 4. Bruggink SC, Eekhof JAH, Egberts PF, van Blijswijk SC, Assendelft WJ, Gussekloo J. Natural course of cutaneous warts among primary school children: a prospective cohort study. Ann Fam Med. 2013;11(5):437-441. 5. Van Haalen FM, Bruggink SC, Gussekloo J, Assendelft WJ, Eekhof JA. Warts in primary schoolchildren: prevalence and relation with environmental factors. Br J Dermatol. 2009 Jul;161(1):148-52. 6. Customer Journey-warts-The Czech Republic, 2018. (Data on file, 2018). 7. Lipke MM. An armamentarium of wart treatments. Clin Med Res. 2006 Dec 1;4(4):273-93. 8. Sulaiman AA, Muhamad NH. Comparative study between cryotherapy and salicylic acid in the treatment of plantar warts in Erbil-Iraq. Zanco J Med Sci. 2018;22(1):65-72. 9. Bruggink SC, Gussekloo J, Berger MY, Zaaijer K, Assendelft WJ, de Waal MW, et al. Cryotherapy with liquid nitrogen versus topical salicylic acid application for cutaneous warts in primary care: randomized-controlled trial. CMAJ. 2010;182(15):1624–1630. 10. Walczuk I, Eertmans F, Rossel B, Cegielska A, Stockfleth E, Antunes A, et al. Efficacy and safety of three cryotherapy devices for wart treatment: a randomized, controlled, investigator-blinded, comparative study. Dermatol Ther (Heidelb). 2018;8(2):203–216. 11. GfK Customer Journey Warts, Italy, August 2018.

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