SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Avoca Caustic Applicator 75% w/w Cutaneous Stick

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Silver Nitrate

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous stick

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Used for removing granulation tissue, warts (including verrucas), for cautery and as a caustic

4.2 Posology and method of administration

Posology

For topical use only – not to be taken

Paediatric population

No data are available

Method of administration

Precautions to be taken before handling or administering the medicinal product:

Surrounding areas of healthy skin, etc. should be protected from the caustic/staining action of silver nitrate by a suitable barrier such as petroleum jelly, where necessary and practicable

The tip is moistened with suitably clean water and applied topically to the area to be treated.

The recommended dose is 3 applications for a wart and 6 applications for a verruca. Treatment is usually applied daily for three to six days depending on the type of wart.

For instructions on dilution of the medicinal product before administration, see section 6.6

4.3 Contraindications

Hypersensitivity to the silver nitrate or to the excipient potassium nitrate.

Not for use near the eyes or other sensitive areas of the body, due to the corrosive / staining action of the product.

Should not be used for genital warts

4.4 Special warnings and precautions for use

Must be used under medical supervision. The instructions must be followed in view of the caustic/staining nature of the product

Paediatric population

No data are available

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

Paediatric population

No interaction studies have been performed

4.6 Fertility, pregnancy and lactation

Pregnancy

Not known

Breastfeeding

Not known

Fertility

Not known

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Chronic application of silver nitrate or its products to conjunctive, mucous membranes or open wounds may lead to a condition known as argyria, an accumulation of silver metal or compounds in the connective tissues which gives rise to a local or general bluish-black appearance. This is thought to be a completely harmless cosmetic effect only, but it may persist indefinitely or disappear only very slowly.

Absorption of nitrate following reduction of nitrate by certain bacteria in some wounds may cause methaemoglobinaemia. There is a risk of electrolyte disturbances.

Cases of either argyria or methaemoglobinaemia are very rare (<1/10,000) and are likely to arise only under exceptional circumstances of prolonged use of large quantities of silver nitrate.

Paediatric population

No data are available

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Excessive quantities given or incorrect use in topical application may give rise to burning or staining.

Accidental poisoning by ingestion is unlikely with the small quantities involved, but symptoms that do arise are due to the corrosive nature of silver nitrate. There may be pain in the mouth sialorrhoea, diarrhoea, nausea, vomiting, coma or convulsions. Tissues and vomit will be stained black.

Treatment for accidental or intentional poisoning by ingestion should be commenced without delay. This should be by washing out the stomach repeatedly with 1 % sodium chloride solution. After this lavage a purgative should be given, such as 30 g of sodium sulphate in 250 ml of water, to be allowed to remain in the stomach. Demulcents such as egg-white, milk or liquid paraffin may be administered, with pethidine or morphine if necessary. Close attention must be paid to renal function and fluid balance.

Paediatric population

No data are available

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: silver compounds, ATC code: D08AL01

Mechanism of action

Silver nitrate acts as a caustic to remove unwanted tissue and destroy warts, verrucae and other small skin growths

Pharmacodynamic effects

No data are available

Clinical efficacy and safety

No data are available

Paediatric population

No data are available

5.2 Pharmacokinetic properties

Absorption

Absorption of silver nitrate is negligible via intact skin, and poor through most mucus members. It is known to be absorbed more efficiently via the gastrointestinal tract. The nitrate ion, produced in some instances by the action of nitrate-reducing bacteria on the substance from open wounds, etc, may give rise to methaemoglobinaemia, in extreme cases especially if large quantities of the product are used.

Distribution

Silver has no known physiological function. This substance is biologically very refractory and is metabolised with difficulty. Any sizeable quantities that are absorbed later redistribute, mainly as deposits of silver metal and insoluble compounds, about the various organs of the body, principally within the connective tissues. Accumulation is especially predominant within the skin and mucous membranes.

Biotransformation

No data are available

Elimination

Topically applied silver nitrate is generally shed, eventually, externally from the original site of topical administration by desquamation. Systemic excretion is very slow and is reported to be almost exclusively faecal.

Linearity/non-linearity

No data are available

Pharmacokinetic/pharmacodynamic relationship(s)

No data are available

5.3 Preclinical safety data

There are no preclinical safety data of significance to the prescriber which are not already included in the SPC

Environmental Risk Assessment (ERA)

No data are available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium nitrate

6.2 Incompatibilities

Silver nitrate is chemically incompatible with a number of substances such as certain organic chemicals, with which it may present a risk of fire or explosion due to its oxidising properties. Silver nitrate will also form insoluble precipitators with some anions, e.g. chloride, which may for example be present in tap water, and so lose part or all of its activity.

6.3 Shelf life

5 years

6.4 Special precautions for storage

Store in the original package in order to protect from light and moisture

6.5 Nature and contents of container

Box containing 50 or 100 applicators in plastic bags of 10. Each applicator is a 15cm long flexible yellow plastic handle with a treated tip.

6.6 Special precautions for disposal and other handling

The flexible plastic handle may be shaped according to the particular application as required. The tip is moistened with suitably clean water and applied topically to the tissue to be treated for 1 to 2 minutes. Do not moisten the tip using saline solution.

It must be used precisely according to the instructions due to the corrosive and staining nature of the material.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Unused tips can be dissolved in saline solution and the resulting residue can be disposed of in accordance with local requirements. Plastic handles without tips can be disposed of as recyclable plastic in accordance with local requirements.

Use in the paediatric population

No data are available

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 04286/0004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 October 1982

Date of latest renewal: 25 January 1995

10. DATE OF REVISION OF THE TEXT

2 April 2014