Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Glutarol 10% w/v Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glutaraldehyde 10.0% w/v

For the full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
A clear, colourless, evaporative, cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of warts, especially plantar warts.

4.2 Posology and method of administration

For adults, children and the elderly.

1.Gently rub the surface of the wart with a piece of pumice stone or manicure emery board, or pare down any hard skin.
2.Using the applicator provided, carefully apply a few drops of the paint to the wart, taking care to localise the application to the affected area. Allow each drop to dry before the next is applied.
3.Repeat twice daily.
4.On subsequent days, repeat steps 1-3.

It is not necessary to cover the treated wart(s) with an adhesive plaster.

4.3 Contraindications

Not to be used in cases of sensitivity to any of the ingredients.
Not to be used on the face, anal or perineal region.
Not to be used on moles or on any other skin lesion for which it is not indicated.

4.4 Special warnings and precautions for use

Keep away from the eyes and mucous membranes.
Avoid spreading onto surrounding uninvolved skin.
Avoid spillage.
Avoid inhaling vapour.
Replace cap tightly after use.
For external use only.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Undesirable effects occur very occasionally and mostly involve mild local skin rashes and irritation. Very rarely, a severe reaction may occur particularly on the hands or when the product is used excessively and allowed to spread onto surrounding normal skin.

If mild irritation should occur, apply a reduced amount (taking special care to avoid spreading beyond the wart or verruca) and apply less often. If the irritation is severe, patients should stop treatment immediately and seek medical advice.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Accidental oral ingestion should be treated immediately by gastric lavage with 2 to 5% aqueous sodium bicarbonate solution. Fluid and electrolyte balance should be monitored and appropriate supportive measures should be provided. Symptoms include headache, nausea, vomiting, diarrhoea and respiratory depression.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Glutaraldehyde is virucidal and thus inactivates the wart virus. On the skin, it also acts as an anhidrotic, drying the warts and surrounding skin, thus reducing the spread of lesions and simplifying the removal of persistent warts by curettage.

As glutaraldehyde stains the outer layers of the skin brown, treatment can be seen to be carried out. This stain soon disappears after cessation of treatment.

5.2 Pharmacokinetic properties

Addition of ethanol to the formulation stabilises the glutaraldehyde against irreversible polymerisation during storage but at the same time diminishes its activity. However, when the aqueous ethanolic solution is applied to the skin, the alcohol rapidly evaporates leaving a concentrated aqueous solution of glutaraldehyde which is highly reactive and attacks the wart before it has time to polymerise. Thus, the ethanolic formulation is stable in storage, as confirmed by stability tests, but is immediately activated when applied to the skin and the alcohol is allowed to evaporate.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Industrial methylated spirit

6.2 Incompatibilities

None known.

6.3 Shelf life

4 years in unopened container.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Amber glass bottle, with black HDPE screw cap and specially designed spatula containing 10 ml of solution.

This is supplied as an original pack (OP).

6.6 Special precautions for disposal and other handling

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Dermal Laboratories (Ireland) Limited
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 December 1980

Date of last renewal: 15 December 2005

10 DATE OF REVISION OF THE TEXT

December 2020