# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Bazuka Gel

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 12.0 % w/w
Lactic Acid 4.0 % w/w

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Gel

Clear, colourless, collodion-like wart GEL

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the topical treatment of warts, verrucas, corns and calluses.

### 4.2 Posology and method of administration

For adults, children and the elderly. For cutaneous use only.

Bazuka Gel should be applied once daily. The gel should be applied once every night. Treatment can take up to twelve (12) weeks for resistant lesions to disappear, and it is necessary to persevere with the treatment.

1. Every night, soak the affected site in warm water for 2 to 3 minutes.
2. Dry thoroughly with the patient's own towel.
3. Carefully apply one or two drops of the gel to the lesion and allow to dry over its surface. Take care to avoid spreading on to surrounding normal skin. No adhesive plaster is necessary.
4. The following evening, carefully remove and discard the elastic film formed from the previous application, and reapply the gel. Occasionally, if removal of the elastic film proves difficult, carefully reapply the gel directly over it and allow to dry. This should help thicken the film to assist removal. If necessary, such re-application may be made on two or three successive days.
5. Once a week, gently rub away the treated surface using an emery board, as provided, or pumice stone used only for this purpose, before re-applying the gel.
6. The wart, verruca, corn or callus may take up to twelve (12) weeks to disappear and it is important to persevere with the treatment.
7. At the end of treatment, if the elastic film is difficult to remove, it may be allowed to remain on the skin until it sheds.

## 4.3 Contraindications

Not to be used on or near the face, intertriginous or anogenital regions, or by diabetics or individuals with impaired peripheral blood circulation.
Not to be used on moles or on any other skin lesions for which the gel is not indicated.
Not to be used in cases of sensitivity to any of the ingredients.

## 4.4 Special warnings and precautions for use

Keep away from the eyes, mucous membranes and from cuts and grazes.

The gel should be applied carefully to the wart, verruca, corn or callus only, to avoid possible irritation of surrounding normal skin.

Do not use excessively.

Some mild, transient irritation may be expected, but in cases of more severe or persistent pain/irritation, the treatment should be suspended and/or discontinued. See also Section 4.8.

Avoid inhaling vapour, and keep cap firmly closed when not in use.

Contact with clothing, fabrics, plastics and other materials may cause damage, and should be avoided.

For external use only.

Keep all medicines out of the sight and reach of children.

## 4.5 Interaction with other medicinal products and other forms of interaction

None known

## 4.6 Fertility, pregnancy and lactation

There are no or limited amount of data from the use of Bazuka Gel during pregnancy.

Bazuka Gel should not be used during pregnancy, except for short-term treatment of a small single wart, verruca, corn or callus.

It is not known if the systemic Bazuka Gel exposure reached after topical administration can be harmful to an embryo/fetus.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Bazuka Gel may be irritant in certain patients, which in rare instances may appear as a temporary blemish on the skin. See also Section 4.4.

**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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

Any excessive use of the product could cause irritation of the skin. If this occurs, the gel should be used more sparingly or applied less frequently.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

The active ingredients, salicylic acid and lactic acid, are well-established pharmacopoeial substances. In combination, they are routinely used in the treatment of warts, verrucas, corns and calluses for their keratolytic properties. When applied topically, and in high enough concentrations, salicylic acid acts by achieving a slow, painless destruction of the thickened stratum corneum. It softens and destroys the stratum corneum of the affected tissue by reducing the adhesiveness of the corneocytes while causing the cornified epithelium to swell, soften, macerate and finally desquamate. In the treatment of warts, a mild irritant reaction, which may render the virus more prone to immunologic stimulation or response, may add to the mechanical removal of infected cells. The other active ingredient, lactic acid, enhances the availability of the salicylic acid from the dried collodion, in addition to having antiseptic and caustic properties.

### 5.2 Pharmacokinetic properties

The product presents 12% salicylic acid and 4% lactic acid in an evaporative collodion-like gel which forms a cohesive and adhesive film on the skin.
The formulation is presented in a collapsible aluminium tube fitted with a special applicator nozzle allowing the formulation to be dispensed precisely to the affected areas only. This minimises the spread of the preparation onto the surrounding healthy skin, which could otherwise lead to inflammation, irritation and poor patient compliance.

The film-forming characteristics of the collodion-like gel vehicle also offer distinct advantages in clinical usage. The gel quickly forms a surface film, well before it dries completely, thereby prolonging the period during which the keratolytic solution can properly infiltrate and achieve intimate contact with the surface layers of the thickened stratum corneum.
Furthermore, even when the film appears to have dried completely, the inclusion of the non-evaporative lactic acid ensures that a proportion of the salicylic acid remains in solution within the vehicle, thus permitting continued release of the keratolytic, which may otherwise be entrapped within the collodion-like film.
Systemic absorption of salicylic acid or lactic acid after application of the recommended daily dose of one or two drops of the preparation to small, circumscribed areas is exceedingly unlikely.

### 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Camphor

Pyroxylin (contains isopropyl alcohol as a damping solvent)

Ethanol (96%)

Ethyl Acetate

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

36 months in unopened container

### 6.4 Special precautions for storage

Highly flammable - keep away from flames.
Do not store above 25˚C.

### 6.5 Nature and contents of container

5 g and 8 g membrane sealed, internally lacquered, collapsible aluminium tubes with flower pot cap and/or HDPE nozzle applicator and over cap, as appropriate.

### 6.6 Special precautions for disposal

Not applicable

## 7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited
T/A Dermal Laboratories
Tatmore Place, Gosmore
Hitchin, Herts, SG4 7QR, UK

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 00173/0400

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/11/2024

## 10 DATE OF REVISION OF THE TEXT

13/08/2025