SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Bazuka Extra Strength Treatment 26% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic acid 26.0% w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

Clear, pale amber, collodion-like gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the topical treatment of warts and verrucas.

4.2 Posology and method of administration

For adults, the elderly and children over 2 years. Children under 12 years should be treated by an adult, and treatment of infants less than 2 years is not recommended.

Bazuka Extra Strength Treatment Gel should be applied once daily. The gel should be applied once every night. Treatment can take up to 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; this towel should be used for the affected site(s) only.
3. Carefully apply one or two drops of the gel to the lesion and allow to dry over its surface. Take care to avoid 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 re-apply the gel (repeat steps 1 to 3). Occasionally, if removal of the elastic film proves difficult, carefully re-apply the gel 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. Hands should be washed after touching warts or verrucas.
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 or verruca may take up to 12 weeks to disappear and it is important to persevere with the treatment.
7. If the wart or verruca has not disappeared after 12 weeks of treatment, further advice should be sought from a doctor or pharmacist.
8. 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, neck, intertriginous or anogenital regions, or by people with diabetes or individuals with impaired peripheral blood circulation.
Not to be used on moles, birthmarks, hairy warts 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 or verruca only, to avoid possible irritation of surrounding normal skin.

Not to be used for the treatment of corns and calluses.

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 reach and sight of children

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

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

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

It is not known if the systemic Bazuka Extra Strength Treatment 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

The product 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.

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: wart and anti-corn preparations, ATC code: D11AF.
The active ingredient, salicylic acid, is a well-established pharmacopoeial substance, which has been used extensively in dermatological therapy for its 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 thickened 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 and verrucas, a mild inflammatory reaction, which may render the virus more prone to immunologic attack, may assist resolution of the condition.
The use of topical salicylic acid formulated in simple dosage forms at high concentrations and in evaporative vehicles designed to concentrate in use, thereby localising the keratolytic precisely over circumscribed small areas of skin, is commonplace. It has become exceedingly popular with doctors and patients alike, where its safety and efficacy have been very well established through widespread use over many decades.

5.2 Pharmacokinetic properties

Bazuka Extra Strength Treatment Gel presents 26% salicylic acid in an evaporative collodion-like gel application which dries to form a cohesive and adhesive film on the skin.
The formulation offers the highest concentration of salicylic acid commensurate with presenting it in a convenient collapsible aluminium tube fitted with a special applicator nozzle, allowing it to be dispensed precisely to the affected area(s). 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 dry completely, 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 dried collodion-like film. The gel yields a robust flexible film which is firmly anchored to the skin, and can therefore be used, even on the sole of the foot, without the added protection of a plaster.
The availability of salicylic acid has been demonstrated by applying the gel to the normal skin of human volunteers, whereupon the salicylic acid produced a marked irritant effect similar to that of existing preparations. In clinical use, its application will, of course, be restricted to the hyperkeratotic lesions.

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

Povidone

Pyroxylin

Ethanol (100%)

Acetone

Isopropyl alcohol

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Highly flammable - keep away from flames

6.5 Nature and contents of container

Latex-ended, membrane-sealed, internally lacquered collapsible aluminium tubes, containing 5, 6 or 8 g, closed with saddle fold. Spiked HDPE flower-pot screw cap and/or HDPE nozzle applicator assembly with over-cap, as appropriate.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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21/10/2024

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25/10/2024