

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Burneze Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzocaine 1% w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Aerosol spray.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of pain from minor superficial burns and scalds where the skin is unbroken.

4.2 Posology and method of administration

Method of administration: For cutaneous application

Adults, the elderly and children aged over 12 years:

To reduce the pain and blistering use Burneze Spray as quickly as possible.

Hold nozzle five inches from the skin and spray once for 2-3 seconds. Stop spraying immediately if a white deposit or 'frost' appears. If necessary, the application may be repeated once only after 15 minutes. If pain persists, seek medical advice.

4.3 Contraindications

Do not use if you are sensitive to benzocaine or any chemically related anaesthetics (butylcaine and tetracaine).

Do not use if you are sensitive to any of the excipients or to para-amino benzoic acid (PABA), parabens or paraphenylenediamine or to commercial hair dyes as there is cross-sensitivity between these products.

Do not apply to large areas of skin, eczematous, infected or broken skin.

Do not use the spray on the face.

Not for use in children under 12 years of age.

4.4 Special warnings and precautions for use

Patients with any known allergy should seek medical advice. Do not use in or near the mouth or eyes or under conditions in which significant inhalation is likely.

Avoid freezing the skin by repeated or prolonged use. Seek medical advice immediately if burns are extensive (particularly in young children or if they affect fingers, toes or sensitive areas).

For external use only. Keep out of the sight and reach of children.

Not for repeated or prolonged use.

Flammable. Do not use near fire or flame. Pressurised container. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material. Do not use near or place container on polished or painted surfaces.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

Pregnancy:

There are no or limited amount of data from the use of benzocaine in pregnant woman. As a precautionary measure, it is preferable to avoid the use of benzocaine during pregnancy.

Lactation:

There is insufficient information on the excretion of benzocaine or its metabolites in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from benzocaine therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility:

There is no known effect on fertility.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Blood and lymphatic system disorders

Methaemoglobinaemia (frequency not known)

Immune System Disorders

Hypersensitivity (frequency not known)

Skin and Subcutaneous Tissue Disorders

Dermatitis allergic (frequency not known)

4.9 Overdose

An overdose is extremely unlikely with this type of preparation.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antipruritics, incl. Antihistamines, Anesthetics, etc.,
ATC code: D04AB04.

The active ingredient, benzocaine, is a local anaesthetic which relieves pain. The physical effects of the cooling propellants help reduce pain and blistering.

Benzocaine causes a reversible blockade of nerve conduction by decreasing nerve membrane permeability to sodium, which notably increases the recovery period following repolarisation.

5.2 Pharmacokinetic properties

Burneze Spray is applied topically to the affected area.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol denatured

Iso-butane

N-pentane

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium cans (60ml and 200ml) internally coated with epoxyphenolic lacquer fitted with valve assembly and actuator button, protected by a plastic cap.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Seton Products Ltd

Tubiton House

Oldham

OLI 3HS

8 MARKETING AUTHORISATION NUMBER(S)

PL 11314/0038

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

16/09/2005

10 DATE OF REVISION OF THE TEXT

20/01/2014