Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Wasp-eze Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzocaine	1.0% w/w
Mepyramine maleate	0.5% w/w
Excipients:	Propylene glycol (E1520) 2.2% w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.
Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of all insect bites and stings, nettle stings and jellyfish stings.

4.2 Posology and method of administration

Route of administration: For cutaneous use.

Adults, the elderly and children:
Hold nozzle approximately five inches from the skin and spray once for 2-3 seconds. Stop spraying immediately if a white deposit or ‘frost’ appears. Repeat once after 15 minutes if necessary. If pain persists, seek medical advice.

4.3 Contraindications

Do not apply to large areas of skin, eczematous, sunburnt, infected or broken skin.
Do not use the spray on the face.
Do not use if you are sensitive to benzocaine, any chemically related anaesthetics (butylcaine and tetracaline) or mepyramine maleate.
Do not use if you are sensitive to any of the excipients or to PABA, parabens or paraphenylenediamine or to commercial hair dyes as there is cross-sensitivity between these products.

4.4 Special warnings and precautions for use

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

Not for repeated or prolonged use.

For external use only. Keep out of the reach and sight of children.
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.
Methaemoglobinaemia has been reported with benzocaine use.

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 (less than 300 pregnancy outcomes) from the use of benzocaine in pregnant women. 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 women.

Fertility:
There is no known effect on fertility.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

May cause allergic dermatitis in sensitive individuals.
Hypersensitivity reactions are rare and generally limited to local anaesthetics of the ester type.
There appears to be no cross-sensitivity between ester-and amide type local anaesthetics. Idiosyncrasy to local anaesthetics has been reported.
There is a risk of sensitization including skin rash with antihistamines such as mepyramine maleate

4.9 Overdose

Overdose is unlikely with this dosage form. There are no known effects and no specific treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: Benzocaine (D04 AB04)
Mepyramine maleate (D04 AA02)

Pharmacotherapeutic group: Antihistamines, Anesthetics, etc. ATC code:D04A
The active ingredients, benzocaine and mepyramine maleate, reduce pain and histamine responses to stings. The physical effects of the cooling propellants help reduce pain.
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

Not applicable.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol (E1520)
Ethanol, denatured
Iso-butane
N-pentane
Dimethyl ether

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

6.5 Nature and contents of container

Aluminium cans internally coated with epoxyphenolic lacquer fitted with valve assembly and actuator button, protected by a polypropylene plastic cap containing 30 ml or 60 ml of solution.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GR Lane Health Products Ltd
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8 MARKETING AUTHORISATION NUMBER

PA00257/071/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 July 1996

Date of last renewal: 09 July 2006

10 DATE OF REVISION OF THE TEXT

February 2015