Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

After Bite 3.5% w/v Cutaneous Emulsion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ammonia 3.5 % w/v.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Emulsion
Opaque, milky emulsion having a characteristic ammoniacal odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For fast relief from insect bites and stings and relief from nettle stings.

4.2 Posology and method of administration

For cutaneous use only.
Apply as required.
For adults and children over 2 years old.
Rub applicator on affected area. Prompt use gives maximum relief. If itching persists repeat the application. Do not bandage or cover tightly until dry.

4.3 Contraindications

After bite is contraindicated in individuals with known hypersensitivity to ammonia. For external use only.

4.4 Special warnings and precautions for use

Keep out of reach of children.
Avoid mouth or eyes. If this should occur rinse well with water.
If swallowed do not induce vomiting. Drink milk and citrus juices and consult a doctor.
If rash, redness, irritation, swelling or pain increases discontinue use and consult the doctor.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

None known.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Frequency not known: rash, redness, irritation, swelling or pain may increase following application of this product (see section 4.4).

4.9 Overdose

None known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ammonia – neutraliser (dilute).

5.2 Pharmacokinetic properties

Topical preparation.

5.3 Preclinical safety data

After Bite contains strong ammonia solution which is a known counter-irritant. Specific toxicology studies have not been conducted to demonstrate the safety of this product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alcohol ethoxylate
Mineral Oil
Dimeticone
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High Density polyethylene vial having a low density polyethylene friction fit applicator tip with a screw cap moulded of polypropylene, with a fill capacity of 14.8ml and filled to contain 14ml.

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

Zenview Limited
26 Fitzwilliam Street Upper
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22919/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 10 June 1991

Date of last renewal: 10 June 2006

10 DATE OF REVISION OF THE TEXT

December 2019