Module 1 – Administrative and Prescribing Information Module 1.3 – Product Information

Text to appear on the patient information leaflet

WASP-EZE SPRAY

Benzocaine 1.0% w/w and Mepyramine maleate 0.5% w/w

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using Wasp-Eze Spray.

- Keep this leaflet, you may wish to read it again.
- Ask your pharmacist if you need more information or advice.

What is this spray used for?

This cutaneous spray solution is used to treat insect bites and stings, and nettle and jellyfish stings.

Before using this spray

Do not use...

- If you are sensitivie or allergic to any of the ingredients in this product or any chemically related anaesthetics (butylcaine and tetracaine) or mepyramine maleate or para-aminobenzoic acid, parabens or paraphenylenediamine or to commercial hair dyes. See 'what this spray contains' for the full list of ingredients.
- If you are pregnant or breast feeding, except on medical advice.
- On broken skin or eczematous (A skin inflammation characterized chiefly by redness, itching, and the outbreak of lesions that may discharge serous matter and become encrusted and scaly), sunburnt, infected skin. Do not use the spray on the face.
- Near to the eyes or mouth.

Talk to your doctor or pharmacist...

• If you are allergic or sensitive to insect bites or stings, please call your doctor or local hospital immediately.

How to use this spray

Adults, the elderly and children:

- Hold the nozzle 12.5 cm (5 inches) from the bite or sting.
- Press the nozzle down firmly and spray once for 2 to 3 seconds. Stop spraying immediately if a white deposit or 'frost' appears.
- If the bite or sting still hurts, you can use the spray once more after 15 minutes

If the bite or sting is still painful, please tell your doctor or pharmacist.

If you accidentally swallow the spray or get it into your eyes...

The spray is for external use only – do not spray in your mouth or eyes. If accidentally swallowed or sprayed into your eyes or mouth, wash out with plenty of lukewarm water and contact your doctor or local hospital immediately.

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Possible side effects

As with all medicines, this spray can have side effects in some people.

- A blood condition called methaemoglobinaemia which can cause headache, breathlessness and blue-tinged skin, may occur rarely, especially in infants and children. If you suffer this serious side effect, stop using the spray and call your doctor or local hospital immediately.
- You may experience a skin rash, allergic skin reactions or other allergic reactions. If you feel you are reacting badly to this medicine in any way, or notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

How to store this spray

- Keep out of the sight and reach of children.
- Do not store above 25°C and keep away from heat and sunlight.
- Caution 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 use near or place container on polished or painted surfaces.
- There is an expiry date on the label. For example. EXP 03/06 means that you should not use the spray after the end of March 2006.
- If you find that you still have this medicine after its expiry date, return it to your local pharmacist who will dispose of it properly.

What this spray contains

Wasp-Eze contains the active ingredients 1% by weight of the active ingredient benzocaine and 0.5% by weight of mepyramine maleate.

Benzocaine belongs to a group of medicines called local anaesthetics (pain-killers that work on the area where they are applied) and mepyramine to a group called antihistamines. Both help to reduce pain and swelling.

The spray also contains ethanol, propylene glycol, n-pentane, iso-butane and dimethyl ether. In each can there is either 30ml or 60ml of spray.

Marketing Authorisation Holder: LanesHealth (Ireland) Ltd, Suite 7, The Courtyard, Carmanhall Road, Sandyford, Dublin, D18 NW62 Ireland.

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Manufactured by: ColepCCL Rapid-Spray GmbH & Co. KG, Fockestrasse 12, 88471 Laupheim, Germany.

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Wasp-Eze is a trade mark of the G.R. Lane Health Products Ltd, UK.