DATA SHEET

1 PRODUCT NAME

ZAP Topical Anaesthetic Gel (Cool Mint)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Gel containing Benzocaine USP 18.0 % w/w and Tetracaine Hydrochloride USP 2.0% w/w.

For the full list of excipients, see section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Oral topical anaesthetic gel.

ZAP Topical Anesthetic Gel (Cool Mint) is a clear, viscous, green coloured gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

ZAP Topical Anesthetic Gel is indicated to reduce the discomfort of local anaesthetic injected into the mandibular mucobuccal fold and maxillary anterior sites, and to minimise pain in oral mucosal tissue arising from needle punctures, deep scaling procedures, prosthetic adjustments, clamp or crown placement, removal of primary teeth and suture removal. *ZAP Topical Anesthetic Gel* may also be used for the reduction of pharyngeal (gag) reflex associated with the placement of various dental materials into the oral cavity (impression trays, x-ray films).

4.2 Dose and method of administration

The dispenser surface of the *ZAP Topical Anesthetic Gel* "Magic" jar should be depressed and approximately 0.2 - 0.3 mL of gel applied to the desired area using a cotton swab or fingertip. The exact dosage depends on the area to be anaesthetised, the vascularity of the tissues at the application site, and the patient's tolerance. Do not exceed the recommended dosage or apply more than one application per procedure.

The area where the gel is to be applied must be dry prior to application. Removal of the excess saliva with cotton rolls or saliva ejector will minimise dilution of the local anaesthetic.

An appropriate paediatric dosage has not been established. Dosages should be reduced in the elderly, acutely ill, and very young patients.

Care must be taken to avoid cross-contamination between patients.

4.3 Contraindications

ZAP Topical Anesthetic Gel should not be used in patients with a known hypersensitivity to the product or any of its ingredients, or local anaesthetics of the ester type.

ZAP Topical Anesthetic Gel is contraindicated for use outside the oral cavity.

Tetracaine is hydrolysed in the body to p-amino-benzoic acid (PABA) and should not therefore be used in patients being treated with sulphonamides.

4.4 Special warnings and precautions for use

ZAP Topical Anesthetic Gel is intended to be used by a professional dentist.

Absorption is rapid on mucous membranes. Because of the risk of systemic toxicity, *ZAP Topical Anesthetic Gel* should not be applied to traumatised, inflamed or infected, or highly vascular surfaces. The risk of systemic toxicity is greatest in small children and in patients with pre-existing heart disease. Factors that may increase systemic exposure are time and surface area of the exposure.

Caution is advised in paediatric, geriatric, acutely ill or debilitated patients, who may be more susceptible to systemic toxicity of local anaesthetics. Do not use *ZAP Topical Anesthetic Gel* on children younger than 2 years or older patients with cardiac or anaemia problems.

Methaemoglobinaemia has been reported in connection with the use of benzocaine-containing products. Care should be taken not to exceed the maximum recommended dosage. If a patient becomes cyanotic, treat appropriately to counteract (such as with methylene blue, if medically indicated).

Caution is advised in infants and young children because increased absorption of benzocaine may result in methaemoglobinaemia. Monitor for signs of headache, dyspnoea, light-headedness, weakness, confusion, palpitation or chest pain immediately after use.

Repeated and prolonged application may potentiate hypersensitivity.

Tetracaine is associated with a higher incidence of allergic reactions than other anaesthetics, such as lidocaine.

Patients sensitive to PABA, parabens, or paraphenylenediamine may also be sensitive to PABA-derived local anaesthetics such as benzocaine and tetracaine.

Patients should be advised not to eat for one hour following the use of *ZAP Topical Anesthetic Gel*, because swallowing may be impaired, leading to risk of aspiration.

ZAP Topical Anesthetic Gel should not be used under dentures or cotton rolls, because retention under these materials may result in sloughing of tissue.

4.5 Interaction with other medicines and other forms of interaction

Tetracaine may antagonise the antibacterial activity of sulphonamides, and should not be used in patients being treated with sulphonamides (see section 4.3 Contraindications).

Cholinesterase inhibitors inhibit the metabolism of benzocaine, leading to an increased risk of systemic toxicity.

4.6 Fertility, pregnancy and lactation

The safety of benzocaine and tetracaine in pregnancy and lactation has not been fully established.

4.7 Effects on ability to drive and use machines

ZAP Topical Anesthetic Gel is presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

4.8 Undesirable effects

Adverse effects may be due to excessive dosage or rapid absorption, producing high plasma concentrations, as well as to idiosyncrasy, hypersensitivity, or decreased patient tolerance.

Benzocaine and tetracaine are more likely to cause contact sensitisation than other mucosal local anaesthetics.

Tetracaine is more toxic than other mucosal local anaesthetics.

Adverse effects may include allergic contact dermatitis, angioedema and burning, stinging, swelling or tenderness not present before therapy.

Adverse events consistent with high systemic exposures include seizures and cardiac arrhythmias. Specifically, the risks of systemic adverse events from tetracaine include a systemic allergic response to p-aminobenzoic acid (PABA), which at worst could lead to cardiac arrest; or excessive systemic absorption following repetitive or extensive application, which could ultimately lead to convulsions.

Monitor patients for signs and symptoms of methaemoglobinaemia, such as pallor, cyanosis, nausea, muscle weakness, dizziness, confusion, agitation, dyspnoea and tachycardia. Suspected cases should be confirmed by co-oximetry, as standard pulse oximetry readings or arterial blood gas values are not reliable. Clinically significant methaemoglobinaemia requires immediate treatment.

4.9 Overdose

Overdosage is unlikely to occur with *ZAP Topical Anesthetic Gel*. Symptoms of overdosage may include cardiovascular system depression, CNS toxicity and methaemoglobinaemia. Overdoses can lead to severe reactions, including death.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ZAP Topical Anesthetic Gel contains two local anaesthetic agents, which act to minimise pain in oral mucosal tissues.

When applied to intact skin, the gel provides reversible local dermal analgesia by the release of benzocaine and tetracaine into the skin. These active ingredients are used in many over-the-counter analgesic ointments as a topical pain reliever. Both benzocaine and tetracaine are ester-type local anaesthetic agents with rapid onset. The function of both agents is to block sodium ion channels required for conduction of neuronal impulses. These types of topical analgesics are for general use for local anaesthesia, acting to produce temporary loss of sensation by preventing or diminishing the generation of sensory nerve impulses around the site of application.

5.2 Pharmacokinetic properties

Absorption
Benzocaine is minimally absorbed but tetracaine is readily absorbed through mucous membranes into the systemic circulation. The rate of absorption is influenced by the vascularity or rate of blood flow at the site of application, the total dosage administered, and the duration of exposure.

Metabolism
Benzocaine and tetracaine are hydrolysed by esterases in the plasma and, to a lesser extent, in the liver.

Onset and duration of action
Benzocaine rapidly produces topical anaesthesia within 30 seconds of application to mucosal tissue, and tetracaine ensures topical anaesthesia for at least 15 minutes.

5.3 Preclinical safety data

Acute systemic toxic effects of local anaesthetics such as benzocaine include central nervous system depression, convulsive tendency, inhibition of impulse conduction and cardiac contractility, and blood pressure reduction. Systemic availability of benzocaine can trigger methaemoglobinaemia.

The active drug substances in *ZAP Topical Anesthetic Gel* are used in many over-the-counter analgesic ointments as topical pain relievers. Therefore, it is considered to be safe to use if administered following the instructions on the product label.

Animal studies on reproductive toxicity and carcinogenicity are not available.

There are no additional pre-clinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol USP, Polyethylene Glycol 400 NF, Yellow D&C 10, Blue FD&C 1, Sodium Saccharin, Peppermint Oil USP, Carbopol 980 NF, Benzocaine USP, Tetracaine Hydrochloride USP.

6.2 Incompatibilities

In the absence of compatibility studies, *ZAP Topical Anesthetic Gel* must not be mixed with other medicinal products.

6.3 Shelf life

The shelf-life of *ZAP Topical Anesthetic Gel* is 24 months. The expiry date of the product is indicated on the label and packaging. Do not use after the expiry date.

6.4 Special precautions for storage

Store at or below 25°C in the original package. Keep out of reach of children. Use within 30 days of first opening jar.

6.5 Nature and contents of container

ZAP Topical Anesthetic Gel is presented in “Magic” jars containing 30g and 50g. Not all presentations or pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

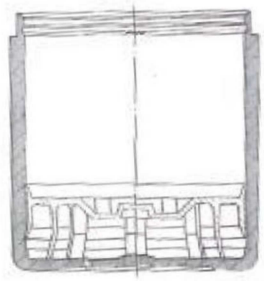
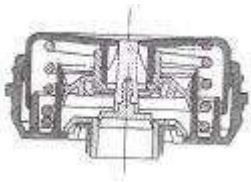
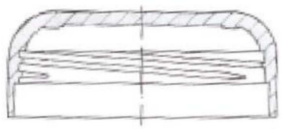
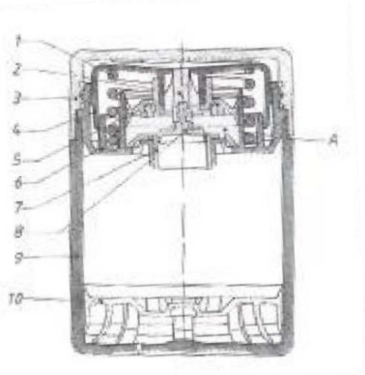
No special requirement for disposal.

The generation of waste should be avoided or minimised wherever possible. Disposal of this product should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

The product should be handled by professionals wearing appropriate personal protective equipment, specifically gloves and avoiding any other skin contact. After administering medications to the individual, gloves must be disposed of, and hands must be washed. Gloves

must not be re-used. Care should be taken when handling emptied containers that contain residue of the product. Empty containers or liners may retain some product residues.

Instructions for use

Container (Jar): 50mL white polypropylene "Magic" jar.	**Pump:** White polypropylene "Magic" jar pump.	**Cap:** White 49mm polypropylene cap.
		
	1. Pressure spring	
	2. Valve pin	
	3. Screw cap	
	4. Pressure plate	
	5. Pressure piston	
	6. Retention ring	
	7. Valve ring	
	8. Valve piston	
	9. Container	
	10. Follower piston	

Dispensing Process: When the pressure plate (4) is pressed downwards the pressure piston (5) moves with it. Due to high pressure in the pump chamber the valve pin (2) in the pressure plate (4) opens. The product in the pump chamber is displaced by the pressure piston (5) and carried to the orifice. The pressure which is formed in the pump chamber closes the valve ring (7), sealing the container (9).

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

DE Healthcare Limited
23 William Pickering Drive
Albany
Auckland 0632

Phone: +64 21 035 1588

Manufacturer

Germiphene Corporation
1379 Colborne Street
Brantford
Ontario N3T 5M1
CANADA

9 DATE OF FIRST APPROVAL

21 October 2010

10 DATE OF REVISION OF THE TEXT

Version 4: 15 March 2023

SUMMARY TABLE OF CHANGES

Version number	Section changed	Summary of new information
4 (15 March 2023)	4.4	Change of age restriction from 6 months to 2 years of age