

# NEW ZEALAND DATA SHEET

## 1. PRODUCT NAME

Ametop 4% w/w topical gel

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 40 mg tetracaine (as hydrochloride) equivalent to tetracaine base 4.0% w/w.

### Excipients with known effect:

Sodium methyl parahydroxybenzoate (E219) 2 mg/g

Sodium propyl parahydroxybenzoate (E217) 0.2 mg/g

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Topical gel.

Topical, white opalescent gel.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Used to relieve pain when needles are inserted into a vein for giving an injection or taking a blood sample. It can also be used to relieve pain of inserting cannulae for drips.

### 4.2 Dose and method of administration

#### Dose

Adults (including the elderly): A maximum of 5 tubes (approximately 5g) can be applied at separate sites at a single time. Application of Ametop gel can be repeated after a minimum of 5 hours if necessary. The maximum cumulative dose in a 24-hour period should not exceed 7 tubes.

#### *Paediatric population*

Ametop is contraindicated in premature babies or in full term infants less than 1 month of age (see section 4.3).

Infants over 1 month and children under 5 years of age: A maximum of 1 tube (approximately 1 g) can be applied at separate sites at a single time. Application of Ametop gel can be repeated after a minimum of 5 hours if necessary. The maximum cumulative dose in a 24-hour period should not exceed 2 tubes.

Children over 5 years of age: A maximum of 5 tubes (approximately 5 g) can be applied at separate sites at a single time. Application of Ametop gel can be repeated after a

minimum of 5 hours if necessary. The maximum cumulative dose in a 24-hour period should not exceed 7 tubes.

### **Method of administration**

*Cutaneous route.*

#### *Precautions to be taken before handling or administering the medicinal product*

It may be advisable to use a finger cot or rubber glove during application and removal of Ametop gel. Always wash hands thoroughly after use (see section 6.6).

Apply the contents of the tube to the centre of the area to be anaesthetised and cover with an occlusive dressing. The contents expellable from 1 tube (approximately 1 gram) are sufficient to cover and anaesthetise an area of up to 30 sq.cm. (6x5cm). Smaller areas of anaesthetised skin may be adequate in infants and small children. Each tube is intended for use on a single occasion only.

Adequate anaesthesia can usually be achieved following a thirty minute application time for venepuncture, and a forty-five minute application time for venous cannulation, after which the gel should be removed with a gauze swab and the site prepared with an antiseptic wipe in the normal manner.

It is not necessary to apply Ametop gel for longer than 30-45 minutes and anaesthesia remains for 4-6 hours in most patients after a single application.

### **4.3 Contraindications**

Use in premature babies or in full term infants less than 1 month of age, where the metabolic pathway for Tetracaine may not be fully developed. For premature babies use of Ametop is not recommended before 1 month after the expected delivery date (44 weeks 'gestation').

Hypersensitivity to the active substance, to local anaesthetics of the ester type, or to any of the excipients listed in section 6.1.

Do not apply Ametop gel to broken skin, mucous membranes or to the eyes or ears.

### **4.4 Special warnings and precautions for use**

Only apply to intact, normal skin.

Not to be taken internally.

Ametop gel, like other local anaesthetics may be ototoxic and should not be instilled into the middle ear or used for procedures which might involve penetration into the middle ear.

Repeated exposure to Ametop gel may increase the risk of sensitisation reactions to Tetracaine.

Although the systemic availability of Tetracaine by percutaneous absorption of Ametop gel is low, caution should be exercised in patients with epilepsy.

Ametop contains Sodium methyl-p-hydroxybenzoate (E219) and Sodium propyl-p-hydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

#### **4.5 Interactions with other medicinal products and other forms of interaction**

None known

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

There are no adequate data from the use of Tetracaine in pregnant women. There are no animal studies to indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

The rapid hydrolysis of Tetracaine by plasma pseudocholinesterase means that it is unlikely to present a significant hazard to the foetus when used as indicated.

As a precautionary measure, it is preferable to avoid the use of Ametop during pregnancy.

##### Breast-feeding

It is not known whether Tetracaine or its metabolites are secreted in breast milk. A risk to the new-borns/infants cannot be excluded. Therefore the product is not recommended for use on breast feeding mothers.

##### Fertility

There are no clinical data regarding the potential effect of Ametop gel on fertility.

#### **4.7 Effects on ability to drive and use machines**

Ametop gel has no or negligible influence on the ability to drive or use machines.

#### **4.8 Undesirable effects**

##### Tabulated list of adverse reactions

The following listing of adverse reactions is based on clinical trial experience and/or post-marketing use. The frequency of adverse reactions reported during post-marketing use cannot be determined as they are derived from spontaneous reports. Consequently, the frequency of these adverse events is qualified as "not known".

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common:  $\geq 1/10$

Common:  $\geq 1/100$  to  $< 1/10$

Uncommon:  $\geq 1/1,000$  to  $< 1/100$

Rare:  $\geq 1/10,000$  to  $< 1/1,000$

Very rare:  $< 1/10,000$

Not known: cannot be estimated from the available data

<b>System Organ Class</b>	<b>Adverse drug reactions</b>
General disorders and administration site conditions	<i>Common</i> Application site erythema <sup>1,3</sup>
	<i>Uncommon</i> Application site oedema <sup>2,3</sup> Application site pruritus <sup>2,3</sup>
	<i>Very rare</i> Application site vesicles <sup>4</sup>

<sup>1</sup>Slight erythema is frequently seen at the site of application and is due to the pharmacological action of tetracaine in dilating capillary vessels. This may help delineating the anaesthetised area.

<sup>2</sup>Slight oedema or itching are less frequently seen at the site of application. This may be due to the local release of histamine and 5-HT.

<sup>3</sup>More severe erythema, oedema and/or itching confined to the site of application have rarely been reported.

<sup>4</sup>In very rare instances, blistering of the skin at the site of application may be apparent - in these cases, remove the gel immediately and treat the affected area symptomatically.

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

## **4.9 Overdose**

Overdosage with Ametop gel is unlikely to result from application to intact skin. If accidentally ingested systemic toxicity may occur, and signs will be similar to those observed after administration of other local anaesthetics. These signs have been described as: signs of inebriation, tingling, numbness of the tongue, tinnitus, nystagmus, nausea or vomiting, twitching and ultimately convulsions. Oxygen is recommended as the first line treatment for systemic toxicity.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Anaesthetics, Local, ATC code: N01BA03

### Mechanism of action

Tetracaine is a local anaesthetic and is believed to act by blocking nerve conduction mainly by inhibiting sodium ion flux across the axon membrane. Tetracaine achieves this by acting upon specific receptors that control gating mechanisms responsible for conductance changes in specialised proteinaceous sodium channels.

Blocking sodium ion flux prevents the setting up of an action potential in the nerve axon, thus preventing pain receptors signalling to the central nervous system.

### Pharmacodynamic effects

Tetracaine additionally has vasodilatory effects, which commonly results in a localised erythema.

## **5.2 Pharmacokinetic properties**

The ester type 'caine' anaesthetics are rapidly metabolised in blood mainly by plasma pseudocholinesterase. A 3.33 $\mu$ M (1 $\mu$ g/ml) concentration of Tetracaine was fully metabolised in human plasma within 20 seconds.

*In vivo* data has demonstrated that Ametop gel is 15  $\pm$  11% bioavailable when administered to intact normal skin, with a mean absorption and elimination half life of 1.23  $\pm$  0.28 hours.

Peak plasma levels of p-(n-butylamino) benzoic acid (BABA), the major metabolite of tetracaine are between 3-6 hours post dose.

## **5.3 Preclinical safety data**

None stated.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

In addition to the active ingredient, Ametop gel contains:

Sodium Hydroxide (E524)  
Sodium methyl-p-hydroxybenzoate (E219)  
Sodium propyl-p-hydroxybenzoate (E217)  
Monobasic potassium phosphate  
Xanthan gum (E415)  
Sodium chloride  
Purified water

### **6.2 Incompatibilities**

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### **6.3 Shelf life**

The shelf- life should not exceed 24 months from the date of manufacture when stored at 2° to 8°C.

Within the recommended shelf-life, the product, may be stored for up to 1 month at or below 25°C.

### **6.4 Special precautions for storage**

Store at 2 - 8°C. Refrigerate, do not freeze.

### **6.5 Nature and contents of container**

1.5g, internally lacquered, aluminium collapsible tubes, designed to deliver 1.0g of Ametop gel on squeezing. Each 1.5g tube is presented in a carton.

Pack sizes of 1 tube and 12 tubes. Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal and other handling**

As Tetracaine can cause contact sensitisation reactions, particularly with repeated contact, healthcare professionals are advised to wash their hands thoroughly after use, to avoid contamination of other parts of the body. It may be advisable to use a finger cot or rubber glove during application and removal of Ametop gel.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7. MEDICINE SCHEDULE**

Pharmacy-Only Medicine

## **8. SPONSOR**

Max Health Ltd  
PO Box 44452  
Pt Chevalier, Auckland 1246  
Telephone: (09) 815 2664.

## **9. DATE OF FIRST APPROVAL**

28 October 1999

**10. DATE OF REVISION OF THE TEXT**

31 August 2021

**SUMMARY TABLE OF CHANGES**

<b>Section Changed</b>	<b>Summary of new information</b>
8	Change of sponsor PO Box details.