Summary of Product Characteristics

1. **Name of the medicinal product**
   Ametop gel 4% w/w

2. **Qualitative and quantitative composition**
   Tetracaine base 4.0% w/w

3. **Pharmaceutical form**
   Topical, white opalescent gel, each gram containing 40mg of Tetracaine base.

4. **Clinical particulars**

   4.1 **Therapeutic indications**
   Percutaneous local anaesthetic to produce anaesthesia of the skin prior to venepuncture or venous cannulation.

   4.2 **Posology and method of administration**
   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.

   In certain circumstances anaesthesia of more than one site may be necessary (e.g. where cannulation is difficult). In such case the following maximum dosages apply: Adults (including the elderly) and children over 5 years: A maximum of 5 tubes (approximately 5g) can be applied to separate sites at the same time. Children over 1 month of age and under 5 years: No more than 1 tube should be applied at a single time but this may be split over separate sites.

   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. 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 for adults and 2 tubes for children.

**Not recommended for infants under 1 month of age.**

### 4.3 Contra-indications

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 gel is not recommended before 1 month after the expected delivery date (44 weeks gestation).

Known hypersensitivity to any of the ingredients or to local anaesthetics of the ester type.

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.

### 4.5 Interactions with other medicinal products and other forms of interactions

None known

### 4.6 Use during pregnancy and lactation

There is no specific information as to the safety of Tetracaine in pregnancy, although Tetracaine has been in wide use for many years without apparent ill-consequence. The rapid hydrolysis of Tetracaine by plasma pseudocholinesterase
means that it is unlikely to present a significant hazard to the fetus when used as indicated. It is not known whether Tetracaine or its metabolites are secreted in breast milk. Therefore the product is not recommended for use on breast feeding mothers.

4.7 Effects on ability to drive and use machines

No adverse effects on the ability to drive or to use hazardous machinery are expected following use of Ametop gel.

4.8 Undesirable effects

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.

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

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.

4.9 Overdose symptoms, emergency procedures, antidotes

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.

5. Pharmacological properties

5.1 Pharmacodynamic properties

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.

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 3.33µM (1µg/ml) concentration of Tetracaine was fully metabolised in human plasma within 20 seconds.

*In vivo* data has demonstrated that Ametop gel is 15 ± 11% bioavailable when administered to intact normal skin, with a mean absorption and elimination half life of 1.23 ± 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
Sodium methyl-p-hydroxybenzoate
Sodium propyl-p-hydroxybenzoate
Monobasic potassium phosphate
Xanthan gum
Sodium chloride
Purified water

6.2 Major incompatibilities

None Known

6.3 Shelf life

The shelf-life shall not exceed 24 months from date of manufacture. Within the recommended shelf life of 2 years at 2-8°C, the product, following dispensing, may be stored for up to 1 month at 25°C at point of use.
6.4 Special precautions for storage

Store at 2-8°C. Do not freeze. Protect from heat.

6.5 Nature and contents of container

1.5g, internally lacquered, aluminium collapsible tubes, designed to deliver 1.0g of Ametop gel on squeezing.

6.6 Instructions for use and handling

As Tetracaine can cause contact sensitisation reactions, particularly with repeated contact, healthcare professionals should take care to minimise contact with Ametop gel during application and removal.

7. Marketing authorisation holder

Smith & Nephew Healthcare Ltd.
Healthcare House
101 Hessle Road, Hull
HU3 2BN, England

8. Marketing authorisation number

PL 14038/0001

9. Date of the first authorisation or renewal

July 1995

10. Date of revision of the text

January 2011