Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ametop 40 mg/g 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 parahydroxbenzoate (E219) 2 mg/g
Sodium propyl parahydroxybenzoate (E217) 0.2 mg/g

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel
White, opalescent gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Percutaneous local anaesthetic to produce anaesthesia of the skin prior to venepuncture, venous cannulation or non-ablative dermal laser procedures.

Ametop is indicated in adults and infants aged over 1 month.

4.2 Posology and method of administration

Posology
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 and an application time of one to two hours for laser procedures, 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 the above recommended time 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 gel is not recommended before 1 month after the expected delivery date (44 weeks 'gestation').

Hypersensitivity to the active substance, 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 Interaction with other medicinal products and other forms of interactions

None known

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of tetracaine in pregnant women. As no animal studies were performed looking at reproductive toxicity, it is unknown if there could be direct or indirect harmful effect with respect to pregnancy (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 in 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: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: cannot be estimated from the available data

System Organ Class	Adverse drug reactions
General disorders and administration site conditions	*Common* Application site erythema[1,3]
	Uncommon Application site oedema[2,3] Application site pruritus[2,3]
	Very rare Application site vesicles[4]

[1]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.

[2]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.

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

[4]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 medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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.

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 3.33μM (1μg/ml) concentration of was tetracaine 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

Sodium hydroxide (E524)
Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate (E217)
Potassium dihydrogen 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

Refrigerated: 2 years

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 in a refrigerator (2°C to 8°C). 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. The tubes are individually cartoned. 12 individual cartons are also available in a dispenser pack with 24 dressings.

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 MARKETING AUTHORISATION HOLDER

Alliance Pharma (Ireland) Limited
United Drug Distributors, United Drug House
Magna Business Park, Magna Drive
Citywest
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2325/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 May 1996

Date of last renewal: 21 May 2006

10 DATE OF REVISION OF THE TEXT

October 2020