

PATIENT INFORMATION LEAFLET

AMETOP® GEL 4% w/w Tetracaine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet

1. What AMETOP Gel is and what it is used for
2. What you need to know before you use AMETOP Gel
3. How to use AMETOP Gel
4. Possible side effects
5. How to store AMETOP Gel
6. Contents of the pack and other information

1. What AMETOP Gel is and what it is used for

AMETOP Gel contains the active substance tetracaine. Tetracaine is a local anaesthetic which numbs the skin.

AMETOP Gel is used:

- to relieve the pain when needles are inserted into a vein for giving an injection or taking a blood sample.
- to relieve the pain of inserting small plastic tubes (cannulae) into veins for putting up drips.

AMETOP Gel is used in adults and infants aged over 1 month.

2. What you need to know before you use AMETOP Gel

Do not use AMETOP Gel:

- if you are allergic (hypersensitive) to tetracaine or any of the other ingredients of AMETOP Gel (see Section 6).
- if you are allergic (hypersensitive) to any other local anaesthetics.
- if you are pregnant or breast-feeding.
- if the patient is less than 1 month old.
- If the patient is a premature baby up until one month after the expected delivery date (44 weeks gestation).
- on wounds
- on broken skin
- on lips, mouth or tongue
- on eyes or ears
- on anal and genital regions.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine

- it may be toxic to the ear, therefore you should not put AMETOP Gel in the ear or use it for any middle ear procedures.
- if you suffer from epilepsy.

Do not swallow AMETOP Gel

Children

Do not use this medicine in infants less than 1 month old or in premature babies up until one month after the expected delivery date (44 weeks gestation).

Other medicines and AMETOP Gel

Tell your doctor or pharmacist if you are taking or have recently taken any medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Do not use if you are pregnant, thinking of becoming pregnant, or breast-feeding.

Ask your doctor or pharmacist before taking or using any medicines.

Driving and using machines

AMETOP Gel is unlikely to affect driving or the use of machines.

AMETOP Gel contains Sodium methyl parahydroxybenzoate (E219) and Sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

3. How to use AMETOP Gel

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults including the elderly:

A maximum of 5 tubes (approximately 5g) can be applied at separate sites at the same time. Application of AMETOP Gel can be repeated after a minimum of 5 hours if necessary. The maximum dose in a 24-hour period should not exceed 7 tubes.

Use in children:

Infants over 1 month of age and children under 5 years of age:

- A maximum of 1 tube (approximately 1g) 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 dose in a 24-hour period should not exceed 2 tubes.
- Do not use if the patient is less than 1 month old or if the patient is a premature baby up until one month after the expected delivery date (44 weeks gestation).

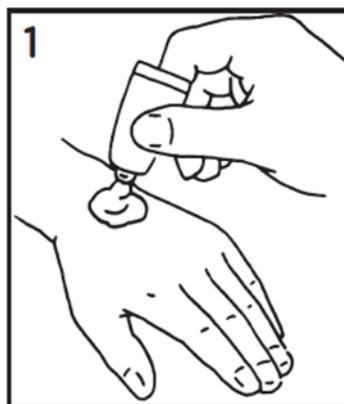
Children over 5 years of age:

A maximum of 5 tubes (approximately 5g) can be applied at separate sites at the same time. Application of AMETOP Gel can be repeated after a minimum of 5 hours if necessary. The maximum dose in a 24-hour period should not exceed 7 tubes.

Your doctor, nurse or pharmacist will tell you where on the skin you need to apply the medicine. One tube of AMETOP Gel can cover an area of up to 30 sq cm (6cm x 5cm or 2½in. x 2in.).

This medicine may be administered by a doctor, nurse or pharmacist. If not, you should carry out the following steps:

- To open the tube, invert the cap and pierce the seal.
- Apply the contents of the tube on the area of the skin to be numbed. **Do not** rub the gel into the skin.
- The mound of gel should then be covered with a plastic film dressing which may be supplied by your doctor or pharmacist.
- Each tube is intended for use on a single occasion only.

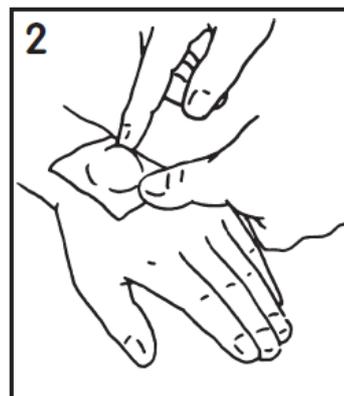


1. Pierce nozzle using spiked cap. Empty tube to form a mound of gel at required site.

How to apply the plastic film dressing

Apply the plastic film dressing as per the manufacturer's instructions.

- Place the dressing over the mound of gel and down around the edges of the gel.
- If no plastic dressing is supplied to you, the mound of gel can be covered by clear plastic kitchen wrap.
- The gel **must** be covered for it to work.
- It will **not** work if you rub it in like an ointment.



2. Smooth down edges of dressing. Record the time of completed application.

After 30-45 minutes, or as recommended by your doctor or pharmacist:

- The dressing should be removed and the gel wiped off the skin with a clean tissue
- Dispose of these carefully out of the reach of children
- AMETOP Gel should not be left on for more than 45 minutes
- The site will remain numb for about 4-6 hours.

Take care to minimise contact with AMETOP Gel (except for the area of skin to be numbed) during application and removal. Allergic reactions to this product can occur, especially following repeated contact. 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.

If the product comes into contact with the eyes, ears, mouth, tongue or nose you should immediately rinse the affected area and contact your doctor or pharmacist for further advice. Only apply to intact, healthy skin.

If you use more AMETOP Gel than you should or if you swallow AMETOP Gel

You may experience intoxication, tingling, numbness in your tongue, ringing in your ears (tinnitus), uncontrolled rapid jerky movement of the eyes, feeling sick or actually being sick, twitching and fitting. You should contact your doctor **immediately**.

4. Possible side effects

Like all medicines AMETOP Gel can cause side effects, although not everyone gets them. The following side effects may happen with this medicine:

Common: may affect up to 1 in 10 people

- redness of the skin at the numbed site (more severe redness has rarely been reported).

Uncommon: may affect up to 1 in 100 people

- itching and swelling of the skin at the numbed site (more severe itching and swelling have rarely been reported).

Very rare: may affect up to 1 in 10,000 people

- blistering of the skin at the numbed site. If blistering occurs remove the AMETOP Gel immediately using a clean tissue and contact your doctor or pharmacist.

The risk of these side effects happening may increase with repeated use.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store AMETOP Gel

- Keep out of the sight and reach of children.
- Use once, then discard.
- Store in a refrigerator at 2-8°C. **Do not** freeze. Protect from heat.
- If not stored in a refrigerator AMETOP Gel must be used within 1 month.

- The expiry date is printed on the base of the tube and on the carton (MM/YYYY). The medicine can be used until the end of the month stated. **Do not** use your medicine after this date.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other Information

What AMETOP Gel contains

- The active substance tetracaine 4% w/w.
- AMETOP Gel: the other ingredients are purified water, sodium chloride, potassium dihydrogen phosphate, xanthan gum (E415), sodium hydroxide (E524) and sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217).

What AMETOP Gel looks like and the contents of the pack

AMETOP Gel is a white semi-transparent gel. Each gram of gel contains 40mg of tetracaine. Each tube contains 1.5g of AMETOP Gel from which 1g (40mg tetracaine) can be squeezed.

Marketing Authorisation Holder

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Manufacturer

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