

PATIENT INFORMATION LEAFLET

AMETOP® GEL 4% w/w Tetracaine

Read this entire leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use AMETOP Gel carefully to get the best results from it.

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

In this leaflet

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

AMETOP Gel is a local anaesthetic which numbs the skin.

AMETOP Gel is used:

- 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.

2. 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.

Take special care with AMETOP Gel

- if you suffer from epilepsy.

Do not swallow AMETOP Gel

Important information about some of the other ingredients in AMETOP Gel:

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

Using other medicines

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.

3. How to use AMETOP Gel

Adults including the elderly and children over 5 years of age:

- A maximum of 5 tubes (approximately 5g) can be applied at separate sites at the same time

Children over 1 month of age and under 5 years of age:

- No more than 1 tube should be applied at a single time but this may be split over separate sites.
- 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).

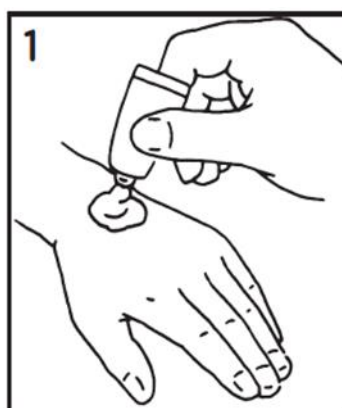
Application of AMETOP Gel can be repeated after a minimum of 5 hours if necessary.

- The maximum dose in a 24-hour period should not exceed 7 tubes for adults and 2 tubes for children.

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.

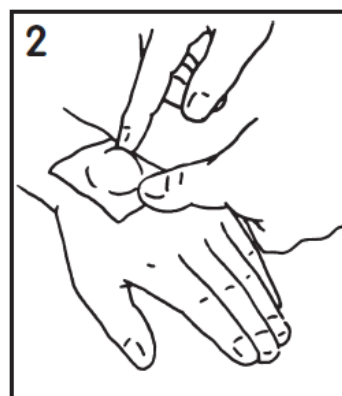


1. Pierce nozzle using spiked cap. Empty tube to form a mound of gel at required site.

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 1 hour
- 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.

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 tingling, numbness in your tongue, ringing in your ears (tinnitus), feeling sick or actually being sick, twitching and fitting if you use more AMETOP Gel than you should or if you swallow AMETOP Gel. 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:

Frequently;

- redness of the skin at the numbed site.

Less Frequently;

- itching and swelling of the skin at the numbed site.

Rarely;

- more severe redness, swelling and/or itching at the numbed site.

Very rare;

- 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

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.

6. Further Information

What AMETOP Gel contains

- The active substance tetracaine.
- 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 containing 4%w/w of tetracaine. 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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UK Product Licence (PL 16853/0150)

Manufacturer

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Date of preparation: July 2018

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