

5. How to store Audavate

Keep this medicine out of the sight and reach of children.

Do not store above 30°C.

Once opened, do not use this medicine for more than 3 months.

Do not use this medicine after the expiry date which is stated on the tube or carton. The expiry date refers to the last day of that month.

Do not throw away 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 Audavate contains:

The active ingredient is betamethasone valerate.

Each 1g contains 1mg of betamethasone (0.1% w/w) as betamethasone valerate.

The other ingredients are liquid paraffin and white soft paraffin.

What Audavate looks like and contents of the pack:

Audavate Ointment is an opaque ointment.

Within each carton is a tube with a plastic screw cap, which contains 30g or 100g of ointment.

Not all pack sizes may be marketed.

Marketing authorisation holder:

Accord, Barnstaple, EX32 8NS, UK

Manufacturer:

Tiofarma B.V.,
Benjamin Franklinstraat 5-10,
3261 LW Oud-Beijerland,
The Netherlands

More Information

If you have any questions or are not sure about anything, ask your doctor or pharmacist who will advise you. Other sources of information are:

- National Eczema Society, Hill House, Highgate Hill, London N19 5NA
- The Psoriasis Association, 2 Queensbridge, Northampton, NN4 7BF
- You may also be able to find out more from books in public libraries.

This leaflet was last revised in July 2019

**For information in large print, on tape, on CD or in Braille,
phone 01271 385257.**

PATIENT INFORMATION LEAFLET

Audavate™ 0.1% w/w Ointment (Betamethasone Valerate)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What is Audavate and what is it used for?

Audavate contains a medicine called betamethasone valerate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

Audavate is used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, psoriasis and dermatitis.

2. What you need to know before you use Audavate

Do not use Audavate:

- if you are allergic to betamethasone valerate or any of the other ingredients of this medicine (listed in Section 6)
- on a child under 1 year old
- to treat any of the following skin problems, it could make them worse:
 - acne
 - severe flushing of skin on and around your nose (rosacea)
 - spotty red rash around your mouth (perioral dermatitis)
 - circular to oval red plaques found over the body and the scalp (plaque psoriasis)
 - itching around your back passage or private parts - unless your doctor has told you to do so
 - itchy skin which is not inflamed
 - viral infections, such as cold sores, herpes or chicken pox
 - fungal infections, such as ringworm, athlete's foot or thrush
 - skin blisters or sores that are caused by bacterial infections, such as impetigo.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Audavate.

Warnings and precautions

Talk to your doctor or pharmacist before using Audavate if:

- you have previously had an allergic reaction with another steroid
- you are applying the ointment under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much.
- you have psoriasis, your doctor will want to see you more often.
- using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying to a large surface area
- you are applying the ointment on broken skin or within the skin folds.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the ointment repeatedly enters the eye.
- you are applying to thin skin such as the face or on children as their skin is thinner than adults and as a result may absorb larger amounts

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Contact your doctor if you experience blurred vision or other visual disturbances.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents

Dressing or bandages should not be used on children or on the face where the ointment is applied. Use on children or on the face should be limited to 5 days

Other medicines and Audavate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

3. How to use Audavate

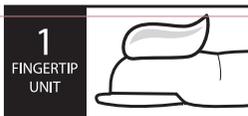
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

- You usually apply Audavate 1 to 3 times a day. This may be reduced as your skin begins to get better, or stopped when it is better.
- This ointment is for use on your skin only.
- Do not use more than the amount prescribed for you.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months), unless your doctor tells you to.
- The germs that cause infections like warm and moist conditions under bandages or dressings, so always clean the skin before a fresh dressing is put on.
- If you are applying the ointment on someone else make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem **does not improve in 2 to 4 weeks**, talk to your doctor.

Guidance on how to apply the ointment

1. Wash your hands.
2. Gently rub the correct amount of ointment into the skin until it has all disappeared. You can measure how much Audavate to use with your fingertip.



This picture shows one fingertip unit.

3. Unless you are meant to apply the ointment to your hands as a part of the treatment, wash them again after using the ointment.

For an adult:

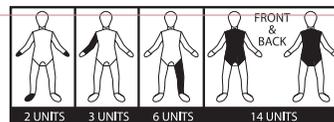
You should find that:

- two fingertips of ointment will cover both hands or one foot
- three fingertips of ointment will cover one arm
- six fingertips of ointment will cover one leg
- fourteen fingertips of ointment will cover the front and back of the body.

Do not worry if you find you need a little more or a little less than this. It is only a rough guide.

For a child:

- Do not use it on children under 1 year of age.
- The smaller the child the less you will need to use.
- A child of 4 years needs about a third of the adult amount.
- A course of treatment for a child should not normally last more than 5 days - unless your doctor has told you to use it for longer.



If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the ointment under an airtight dressing. It will only be at night to help the ointment to start working. After a short period of time you will then apply the ointment as normal.

If you apply Audavate to your face

You should only apply the ointment to your face if your doctor tells you to. It should not be used for more than 5 days, as the skin on your face thins easily. **Do not let the ointment get into your eyes.** If it does, wash it out with plenty of water.

If you use more Audavate than you should

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or if a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you forget to use Audavate

If you forget to apply your ointment, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time.

If you stop using Audavate

If you use Audavate regularly make sure you talk to your doctor before you stop using it.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Audavate and tell your doctor as soon as possible if:

- you develop a generalized rash on your skin
- you find that your skin problem gets worse or become swollen during treatment. You may be allergic to the ointment, have an infection or need other treatment.
- you have psoriasis. You may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

Other side effects you may notice when using Audavate include:

Common (may affect up to 1 in 10 people)

- A feeling of burning, pain, irritation or itching where the ointment is applied.

Very Rare (may affect up to 1 in 10,000 people)

- An increased risk of infection
- An allergic skin reaction
- Rash, itchy bumpy skin or redness of the skin
- Thinning and dryness of your skin and it may also damage or wrinkle more easily
- Stretch marks may develop.
- Veins under the surface of your skin may become more noticeable.
- Increased hair growth or reduction in hair growth or hair loss and changes in skin colour.
- Thinning of your skin that may also damage more easily.
- Weight gain, rounding of the face and high blood pressure. These are more likely to happen in infants and children.
- Bones can become thin, weak and break easily
- Cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- Increased blood sugar levels or sugar in the urine
- High blood pressure
- Slow growth in children

Not known (frequency cannot be estimated from the available data):

- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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. By reporting side effects you can help provide more information on the safety of this medicine.