

ARTWORK INFORMATION:

PRODUCT: Audaval 0.1% w/w Ointment

LICENCE: PA 1352/20/2

ITEM / SIZE: Generic package leaflet / 218 mm (h) x 297 mm (w) [flat]

ID CODE: A1000201/1

ITERATION: Version 4; 17/11/2014

INK: Black

APPROVED FOR
SUBMISSION:

APPROVED BY
HEALTH AUTHORITY:

5. Storing Audaval

Keep all medicines out of the reach and sight of children.

Do not store above 30 °C.

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

6. Further Information

What Audaval contains:
The active ingredient is betamethasone valerate.

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

The other ingredients are liquid paraffin and white soft paraffin.

What Audaval looks like and contents of the pack:
Audaval Ointment is an opaque ointment.

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

Not all pack sizes may be marketed.

Marketing authorisation holder:
Auden Mckenzie (Pharma Division) Ltd., Mckenzie House, Bury Street, Ruislip, Middlesex, HA4 7TL, UK

Manufacturer:
Tiofarma B.V., Benjamin Franklinstraat 7-9, 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.

These medicinal products are authorised in the Member States of the EEA under the following names:
United Kingdom:

- Audavate 0.1% w/w Ointment

Ireland:

- Audaval 0.1% w/w Ointment

This leaflet was last revised in July 2014.

For information in large print, on tape, on CD or in Braille, phone +44 (0) 1895 627 420.



A1000201/1

Patient Information Leaflet

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

Read all of this leaflet carefully 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- In this leaflet:**
1. What is Audaval and what is it used for?
 2. Before you use Audaval
 3. How to use Audaval
 4. Possible side effects
 5. Storing Audaval
 6. Further information

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

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

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

2. Before you use Audaval

Do not use Audaval:

- if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of Audaval (listed in Section 6)
- on a child under 1 years 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, athletes 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 Audaval.

Take special care with Audaval:
Check with your doctor or pharmacist before using Audaval 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

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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

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

Other medicines and Audaval

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:

Talk to your doctor or pharmacist before using this medicine if you are pregnant, might become pregnant or are breast-feeding.

3. How to use Audaval

Always use Audaval exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Using this medicine

- You usually apply Audaval 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

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



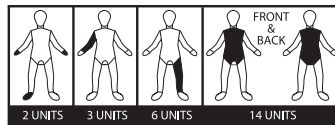
This picture shows one fingertip unit.

- 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 years 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 Audaval 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 Audaval 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 Audaval

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 Audaval

If you use Audaval 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, Audaval can cause side effects, although not everybody gets them.

Stop using Audaval 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 Audaval include:

Common (affects less than 1 in 10 people)

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

Side effects if you use Audaval for a long time, or you use a lot each time you apply it, or you apply it under an airtight dressing or a nappy:

Very Rare (affects less than 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.

If any of the above side effects are troublesome or last more than a few days or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;

Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

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