

Bettamousse® 0.1 % w/w Cutaneous foam

(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. 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 or nurse. This includes any possible side effects not listed in this leaflet.
- In this leaflet, Bettamousse 0.1%w/w cutaneous foam will be called Bettamousse.

What is in this leaflet:

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

1. What Bettamousse is and what it is for

Bettamousse belongs to a group of medicines called corticosteroids ('steroids' for short).

Bettamousse works by reducing inflammation (redness, itching and soreness). Bettamousse is used to treat skin disorders of the scalp such as psoriasis (raised red patches of skin covered in silvery scales) that may feel itchy, tight or sore.

It is important to use this medicine to prevent damage to the skin and infections from developing.

2. What you need to know before you use Bettamousse

Do not use Bettamousse:

- If you are allergic to betamethasone valerate
- If you are allergic to any of the other ingredients of Bettamousse (listed in section 6). Some of these ingredients (stearyl alcohol, cetyl alcohol and propylene glycol) may cause local skin reactions (e.g. contact dermatitis).
- If you have any kind of infection of the scalp, unless this is already being treated
- On a child under 6 years of age.

If any of the above applies to you, talk to your doctor or pharmacist.

Warnings and precautions

Check with your doctor before using Bettamousse if:

- You have any kind of skin infection
- You have open wounds on your scalp
- You are taking any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding ask your doctor or pharmacist for advice before using Bettamousse.

3. How to use Bettamousse

Important:

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Remember:

- **Always use Bettamousse exactly as your doctor has told you**
- **Use as little Bettamousse as possible for the shortest possible time**
- Avoid contact with your eyes. If Bettamousse gets into your eyes, rinse well with cold water. If your eyes continue to sting, contact your doctor
- Avoid contact with the inside of your nose and mouth
- Avoid contact with any open wounds.

How much to use

Adults:

- The usual adult dose is no more than a golfball sized amount of mousse
- Massage into the affected areas of the scalp twice a day (in the morning and evening)
- **If there is no improvement in your condition after 7 days, stop using Bettamousse and see your doctor again.**

Children over 6 years of age:

- The dose depends on their physical size
 - The usual dose for children is less than for adults. For example, for a child half the size of an adult, use no more than half a golf ball sized amount of mousse
 - Massage into the affected area of the scalp twice a day (in the morning and evening)
 - **Do not use Bettamousse for more than 5 to 7 days on children. If the symptoms have not improved see your doctor again**
- Do not use in children under 6 years of age**

As symptoms improve

For adults and children: Where there is some improvement in symptoms, Bettamousse can be applied just once a day. If the condition continues to get better, it may be possible to apply Bettamousse once every few days, to keep the symptoms from coming back.

Infections

If you have a skin infection your doctor will give you another medicine to treat the infection

Whilst you have an infection, your doctor may tell you to stop using Bettamousse.

If you are not sure about how much mousse to use, ask your doctor or pharmacist.

Instructions for use:

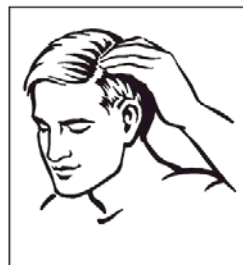
1. Remove the cap.



2. Turn the can upside down and squirt the required amount of mousse onto a clean saucer or something similar. The mousse melts when it touches your skin, so do not squirt it in to your hand.



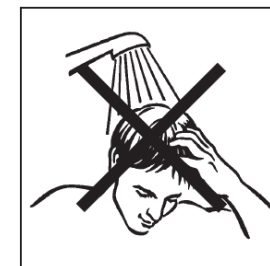
3. Massage the mousse into the affected areas of your scalp, and not your hair. Allow your hair to dry naturally.



4. Wash your hands immediately after using the mousse.



5. Do not wash your hair straight after applying the mousse. Let the mousse work overnight or through the day.



6. You can wash and dry your hair immediately before applying the mousse.
This product is flammable. Do not use Bettamousse near a naked flame or direct source of heat. Do not smoke while using or holding the can.

Medical check-ups

If you use this medicine for a long period of time, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

If you use more Bettamousse than you should

Wash your scalp straight away and start again. It is unlikely that you will suffer side-effects from using too much on one occasion. If you are concerned, contact the nearest hospital casualty department or your doctor.

Using more than the recommended dose of Bettamousse for a long time can lead to a number of side effects (see section 4).

If you forget to use Bettamousse

Do not use a double dose to make up for a missed dose. Simply take the next dose as planned.

If you stop using Bettamousse

Do not stop using Bettamousse without first talking to your doctor. Your condition may return after you stop using Bettamousse. If this happens, talk to your doctor as soon as possible.

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

4. Possible side effects

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

Stop using Bettamousse and seek immediate medical help if you have any of the following symptoms:

- Headache
- Stinging
- Itching.

Uncommon side effects

(affect less than 1 in 100 people):

- Infection of the skin
- Thinning of the skin
- Marking of the skin (such as dark spots or lines)
- Red rash on the face
- Bruising easily.

Rare side effects

(affect less than 1 in 1000 people):

- Sensitivity reactions such as itching, redness and stinging
- Lighter or darker patches of skin
- Hair loss
- Infection of the hair follicles
- Red spots on the skin.

Other side effects:

- Worsening of the scalp condition, causing pus-filled ulcers to form
- Acne
- Purple stained skin
- Rash around the mouth.

Effects of using a high dose of Bettamousse for a long time:

- Extra hair growth
- Changes in skin colour
- Irregular periods in women,
- Water retention (bloating feeling)
- Mood changes or sleep problems
- Blurred vision or pain in the eye
- Stomach upsets or discomfort
- Acne
- Headaches.

These effects are more likely to happen in children, and if dressings are applied to cover the scalp after Bettamousse has been applied.

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

5. How to store Bettamousse

Keep out of the sight and reach of children.

Do not use Bettamousse after the expiry date on the label. The expiry date refers to the last day of that month.

Do not store Bettamousse above 25°C.

Do not refrigerate.

Caution: Extremely Flammable

Pressurised container – Protect from sunlight and do not expose to temperatures above 50°C. Do not pierce or burn even when empty. Do not spray near a naked flame or any heat-generating material, and keep this can away from sources of ignition. Do not smoke when near this can.

If the foam mousse become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Bettamousse contains

The active substance is betamethasone (as valerate)
Each gram of cutaneous foam contains 1 mg betamethasone as valerate.
The other ingredients are cetyl alcohol, stearyl alcohol, polysorbate 60, ethanol, purified water, propylene glycol, citric acid anhydrous, potassium citrate and propane/butane mixture as propellant.

What Bettamousse looks like and contents of the pack

Bettamousse is a white cutaneous foam mousse.

Bettamousse comes in an aluminium can with a valve and a clear cap. It comes in size of 100 g.

Manufacturer and Product License holder

Manufactured by

Pharmasol Ltd., North way, Walworth Industrial Estate, Andover, Hampshire, SP10 5AZ, England. UK.

Procured from within the EU by Product Licence holder
Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharma Ltd.

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