

Package leaflet: Information for the user

Bettamousse® 1mg/g (0.1%) Cutaneous Foam

Betamethasone

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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Bettamousse 1mg/g (0.1%) cutaneous foam will be called Bettamousse.

What is in this leaflet:

1. What Bettamousse is and what it is used 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 used for

Bettamousse contains the active substance Betamethasone as valerate. Bettamousse belongs to a group of medicines called corticosteroids ('steroids' for short). 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. Bettamousse works by reducing inflammation (redness, itching and soreness). 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 or any of the other ingredients of this medicine (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

Talk to your doctor or pharmacist 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

Children and adolescents

Do not give this medicine to children under the age of 6 years.

Other medicines and Bettamousse

Tell your doctor or pharmacist if you are taking, using, have recently taken or might take or use any other medicines.

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 taking this medicine.

Driving and using machines

There are no known effects on driving or using machines.

Bettamousse contains Cetyl Alcohol and Stearyl Alcohol which may cause local skin reactions (e.g. contact dermatitis)

Bettamousse contains propylene glycol which may cause skin irritation

3. How to use Bettamousse

Always use this medicine exactly as your doctor or pharmacist has told you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. Check with your doctor or pharmacist if you are not sure. Remember:

- **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.

The recommended dose is

Adults:

- 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**

Use in 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 forgotten 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 (may affect up to 1 in 100 people):

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

Rare (may affect up to 1 in 1,000 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.

Not known: frequency cannot be estimated from the available data

- 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 (bloated 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. The frequency of these effects on prolonged use is unknown.

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.

5. How to store Bettamousse

Keep this medicine 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 the month. Do not store above 25° C. Do not refrigerate. Protect from sunlight and any other sources of direct heat as this product is very flammable. Do not pierce or burn the can, even when empty. 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 Bettamousse contains

The active substance is betamethasone (as valerate) 1mg/g (0.1%).

The other ingredients are cetyl alcohol, stearyl alcohol, polysorbate 60, ethanol, purified water, propylene glycol, citric acid anhydrous, potassium citrate and butane/propane.

What Bettamousse looks like and contents of the pack

Bettamousse is a white cutaneous foam mousse. The container consists of an aluminium can with a valve and a clear cap. The can contains 100g of the mousse.

Parallel Product Authorisation Number:

Bettamousse 1mg/g (0.1% w/w) Cutaneous Foam – PPA 465/209/1

Manufacturers:

Pharmasol Limited, North Way, Walworth Industrial Estate, Andover, Hampshire SP10 5AZ, United Kingdom or Aerosol Service Italiana S.r.l. - Via del Maglio N° 6 – Valmadrera, 23868 LECCO, Italy or Recipharm Ltd., Ashton-under-Lyne, Lancashire, OL79RR, United Kingdom.

Product procured from within the EU, repackaged and distributed by the PPA holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Bettamousse is a registered trademark of RPH Pharmaceuticals AB

Date of leaflet preparation by PCO Manufacturing: October 2015