

Bettamousse® 0.1% w/w cutaneous foam/ Betamethasone 0.1% w/w cutaneous foam

(betamethasone valerate)

Your medicine is known by either of the above names, but will be referred to as Bettamousse throughout this:

Patient Information Leaflet

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.

Corticosteroid creams, ointments and other topical preparations come in four different strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent corticosteroid has a much stronger effect than a mild corticosteroid. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Betamethasone is classed as a potent corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

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).
 - 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 experience blurred vision or any other visual disturbances

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

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the foam without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

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, have recently taken or might take any other medicines.

Some medicines may affect how Bettamousse works or make it more likely you will have side effects.

Examples of these medicines include:

- ritonavir (treatment for HIV)
- itraconazole (for the treatment of infections caused by fungus)

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. You should not use this medicine if you are pregnant or breast-feeding unless your doctor has recommended it.

Driving and using machines

There are no known effects on driving or using machines.

Bettamousse contains Cetyl Alcohol and Stearyl Alcohol

May cause local skin reactions (e.g. contact dermatitis)

Bettamousse contains propylene glycol

This medicine contains 70 mg of propylene glycol in each "golf-ball" sized amount of mousse (approx. 3.5g) which is equivalent to 2% w/w.

Bettamousse contains alcohol (ethanol)

This medicine contains 2022 mg alcohol (ethanol) in each "golf-ball" sized amount of mousse (approx. 3.5g), which is equivalent to 57.79% w/w. It may cause burning sensation on damaged skin. Do not use near an open flame, lit cigarette or some devices (e.g. hairdryers).

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

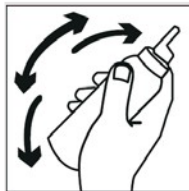
Whilst you have an infection, your doctor may tell you to stop using Bettamousse.

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

Instructions for use:

Attention: for proper dispensing of foam, it is important to hold the container upside down!

1. Shake the can well before use.



2. Remove the cap.



3. 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 into your hand.



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



5. Wash your hands immediately after using the mousse.



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



7. 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 on 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 tell your doctor as soon as possible if:

- you find that your skin condition gets worse or becomes swollen during treatment. You may be allergic to the Bettamousse, have an infection or need other treatment.
- you have psoriasis and you 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 Bettamousse include:

Common: may affect up to 1 in 10 people

- local skin burning or pain
- itchy skin

Very rare: may affect up to 1 in 10,000 people

Use of Bettamousse for a long period of time may cause the following symptoms:

- increased weight
- rounding of the face/moon face
- obesity
- thinning of your skin, this may cause stretch marks and it may also damage more easily
- skin wrinkling
- skin dryness
- the appearance of blood vessels under the surface of your skin
- changes to the colour of your skin
- increased body hair
- hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation / pain
- redness
- rash or hives
- skin infection

In children also look out for the following symptoms:

- delayed weight gain
- slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition

Not Known: frequency cannot be estimated from the available data

- blurred vision

Steroid withdrawal reaction: If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Reporting of side effects

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Bettamousse

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

- Do not use Bettamousse after the expiry date printed on the can and carton label. The expiry date refers to the last day of that 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.
- If the medicine becomes discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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 to protect the environment.

6. Contents of the pack and other information

What Bettamousse contains

Bettamousse contains as the active ingredient 0.1% w/w betamethasone (as betamethasone valerate).

It also contains cetyl alcohol, stearyl alcohol, polysorbate 60, anhydrous ethanol, purified water, propylene glycol, citric acid anhydrous, potassium citrate with a propane and butane mixture as the propellant.

What Bettamousse looks and contents of the pack

The container consists of aluminium can with a valve and a clear cap. The can contains 100g of white foam.

PL 46420/0321

Bettamousse 0.1% w/w cutaneous foam/
Betamethasone 0.1% w/w cutaneous foam

POM

Product Licence Holder and Manufacturer

Your medicine is manufactured by Pharmasol Limited, North Way, Walworth Industrial Estate, Andover, Hampshire SP10 5AZ, United Kingdom, or Farmol Health Care S.r.l. Via del Maglio, 6, 23868 Valmadrera Italy or Recipharm Ltd, Ashton-under-Lyne, Lancashire, OL79RR, United Kingdom and is procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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Bettamousse is a registered trademark of RPH Pharmaceuticals AB, Sweden.

For any information about the medicine, or to request for a copy of this leaflet in Braille, large print or audio, please call the PL holder Suerte Pharma Limited on 020 8839 3000.