

Bettamousse Betamethasone Valerate 0.12% w/w PATIENT INFORMATION LEAFLET

This leaflet provides a summary of the information available on your medicine. Please read this leaflet carefully BEFORE you use your medicine. If you have any questions about this medicine, ask your doctor or pharmacist. If the patient is a child aged 6-12 years, please read "your child" instead of "you" throughout this leaflet, and read the leaflet before the child uses the medicine.

♦ What is your medicine?

Bettamousse contains 0.12%w/w Betamethasone Valerate BP as the active ingredient It also contains cetyl alcohol, stearyl alcohol, polysorbate 60, ethanol, purified water, propylene glycol, citric acid anhydrous, potassium citrate with a propane and butane mixture as the propellant. The container consists of an aluminium can with a valve and a clear cap. The can contains 1009 of the mousse. Betamethasone valerate belongs to a group of medicines known as corticosteroids (or steroids). These reduce inflammation (redness, itchiness and soreness) and should not be confused with the anabolic steroids misused by some athletes.

Product Licence Holder: Evans Medical Ltd, Kingston Road, Leatherhead, Surrey, England, KT22 7PQ Manufacturer: CCL Industries Ltd, Runcorn, England

♦ What is your medicine used for?

Your medicine is used to treat some skin disorders of the scalp that respond to steroid treatment ("steroid responsive dermatoses").

• Before using this medicine.

- Have you used this medicine before and suffered a reaction to it, or are you allergic to any of the ingredients?
- Are you pregnant, planning to become pregnant or breastfeeding?
- · Do you have any infection on your scalp?
- Is the patient under the age of six years?
 (This medicine is not recommended for children under 6 years of age)

If the answer to any of these questions is **YES**, then tell your doctor (or pharmacist) before taking this medicine, so they can advise you what to do

♦ How to use this medicine.

The mousse should be massaged into the skin of the scalp, and left during the day or evening to take effect The mousse should be applied to the affected areas twice a day, each time using no more than a golf-ball sized amount in total. Once the condition is controlled, this can be reduced to once a day or less Bettamousse should always be used sparingly so use as little as possible when covering the affected areas.

As with all steroid preparations, your doctor will want you to use as little as possible to control the problem, for the shortest possible time You may find that once the condition is controlled, you need only use it every few days to keep it in check.

Adults, the elderly and children over six years of age:



1 - Remove the cap



2 – Turn the can upside down and squirt a golf-ball sized amount on to a saucer. The mousse melts when it is in contact with skin, so do not squirt it on to the palm of your hand. If the patient is a child you may need to use less that a golf-ball sized amount – your doctor can advise you about this.



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



4 – Wash your hands straight after using the mousse.



- 5 Do not wash your hair straight after applying the mousse, let the mousse work overnight or throughout the day.
- 6 Repeat this procedure every evening, or as directed by your doctor.

You can wash and dry your hair immediately before applying the mousse. **Take care to keep the mousse away from your eyes**, as this product will sting. If the mousse gets into your eyes, rinse well with cold water and if the pain continues, contact your doctor



Keep the medicine well away from fire or direct heat and take special note of the warnings in the "Storage" section of this leaflet whilst using the mousse.

DO NOT EXCEED THE STATED DOSE

Keep using your medicine for as long as your doctor tells you to. If you stop using it suddenly, your condition may get worse. Your doctor will check your progress, probably monthly, to make sure your condition is improving and that you do not use the medicine for too long.

Children using this mousse to treat seborrhoeic dermatitis should only use it for 5-7 days.

• What to do if you use too much.

If too much mousse is put onto your scalp, wash your scalp straight away and start again. It would be unlikely that you would suffer side-effects from overuse of the product on a single occasion, but if you suffer any effects that you do not understand, tell your doctor. If the medicine is used for a longer time than recommended, or in a higher dose, side-effects may occur throughout the body (See 'Are there any side-effects to this medicine?')

♦ What to do if you miss a dose.

If you forget to use the mousse, use it as soon as you remember, then go on as before. If you only remember at the time of your next dose, use a single dose and go on as before. If you miss several doses, tell your doctor at your next appointment.

◆ Are there any side-effects to this medicine?

Most people find that using this medicine causes no problems. However, if any of the below apply to you

TELL YOUR DOCTOR AS SOON AS POSSIBLE.

- If your skin stings and itches more than usual when you use the mousse, and this does not calm down after a couple of minutes
- If your condition feels worse after using the mousse.
- If you notice any other unusual effects which you do not understand.
- If the mousse does not seem to be working after using it for a week.
- If you develop a scalp infection, or a herpes infection of the eye as this medicine may make the condition worse.

If the mousse is used for many weeks or months, or in a higher dosage than recommended, the following may occur: extra hair growth, changes in skin colour, irregular periods in women, water retention (bloated feeling), mood changes, sleep problems, stomach upsets or discomfort, blurred vision or pain in the eye, or headaches. If any of these apply to you, or you experience any discomfort which you do not understand, tell your doctor immediately (see "What to do if you take too much").

◆ Storage of your medicine

Store below 25°C, and protect from sunlight as this is a pressurised container. **Keep away from fire or direct heat as this product is extremely flammable**. Do not spray on a naked flame or any incandescent material. Do not smoke whilst using or holding this can, and keep the can away from all sources of ignition.

Do not pierce or burn the can, even when empty.

KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Do not use this medicine after the expiry date shown on the base of the can.

♦ What to do with any unused medicine

When you have finished your treatment, dispose of the can safely.

NEVER THROW THE CAN IN A FIRE, EVEN IF IT IS EMPTY

Do not give Bettamousse to anyone else, even if their symptoms seem the same as yours. Your doctor has prescribed this medicine for you only. Date of preparation: September 1995

♦ Further information.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor (or pharmacist) who will have the information you need and will advise you.

Pharmaceutical Companies are not allowed to provide information or advice about personal medical problems.

YOU MAY WANT TO READ THIS LEAFLET AGAIN PLEASE DO NOT THROW IT AWAY UNTIL YOU HAVE FINISHED YOUR MEDICINE

This information only applies to Bettamousse. Bettamousse is a trade mark.