Front of leaflet - 148.5mm

Patient Information Leaflet

Balmosa Cream

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 need more information or advice, please ask your doctor or pharmacist.
- You must contact a doctor if your symptoms get worse or do not improve.
- If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What Balmosa Cream is and what it is used for
- 2. Before you use Balmosa Cream
- 3. How to use Balmosa Cream
- 4. Possible side effects
- 5. How to store Balmosa Cream
- 6. Further information

1. What Balmosa Cream is and what it is used for

This medicine contains four active ingredients: menthol, camphor, methyl salicylate and capsicum oleoresin. They work together to soothe and relieve:

- unbroken chilblains
- muscular pain and stiffness in backache
- sciatica (irritation of the sciatic nerve causing pain down the leg)
- lumbago (lower back pain)
- fibrositis (pain, stiffness or tenderness in muscles, tendons and joints)
- rheumatic pain (pain, swelling, stiffness and limited movement in joints, muscles and ligaments) and other related conditions.

2. Before you use Balmosa Cream

Do not use Balmosa Cream and tell your doctor if you:

- are allergic (hypersensitive) to Aspirin or any other non-steroidal anti-inflammatory drugs (NSAIDs) such as Ibuprofen
- are allergic (hypersensitive) to any of the ingredients in Balmosa Cream (see section 6).

Pregnancy and breastfeeding

 If you are pregnant, think you may be pregnant or you are breastfeeding, you should check with your doctor before using this cream. You should only use it if your doctor says it is safe to do so.

Important information about some of the ingredients in Balmosa Cream

This medicinal product contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217), which may cause allergic reactions (possibly delayed).

Also contains lanolin which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Balmosa Cream

For external use only.

Do not use if:

- you have broken skin or skin which is sore (inflamed)
- you have had a skin reaction to the cream. You may need to stop using the cream.

Check that the seal is not broken before first use. Break seal by reversing the cap and pushing pointed end into the tube nozzle.

• Adults, elderly and children of 12 years and above Squeeze some cream onto the affected area and gently massage into the skin. Wash hands immediately after use.

Use the cream as frequently as required.

After using the cream, avoid exposing the affected area to too much sunlight.

• Children under 12

Not recommended

Do not apply near or on the eye or any other mucosal membrane such as inside the nose.

Do not use with air and water tight dressings.

If you accidentally swallow Balmosa Cream

You should contact your doctor or go to your nearest hospital casualty department immediately. Take the pack with you so that the doctor knows what you have swallowed.

4. Possible side effects

Most people will not have problems, however if used in large quantities some people may get side effects: If you get any of these stop using the cream immediately and tell your doctor or pharmacist.

- Allergic reaction. This may be mild with just itching or redness of the skin but sometimes severe allergic reactions can occur. Symptoms could include dizziness or fainting, faster heart rate, swelling of the face, tongue and throat.
- Worsening of asthma and wheezing or difficulty breathing.

If you notice any side effect not listed here, please tell your pharmacist or doctor.

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 Balmosa Cream

- · Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not use Balmosa Cream after the expiry date stated on the carton and tube. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Return all unwanted medicines to your pharmacist for disposal. These measures will help to protect the environment.

6. Further information

Ingredients

The cream contains the active ingredients camphor 4% w/w, methyl salicylate 4% w/w, menthol 2% w/w and capsicum oleoresin 0.035% w/w.

It also contains methylcellulose, white soft paraffin, emulsifying wax, liquid paraffin, wool fat (lanolin), phenoxyethanol, methyl parahydroxybenzoate (E219), propyl parahydroxybenzoate (E217) and purified water.

What the medicine looks like

The medicine is a white cream. It is available in 40g tubes.

Marketing Authorisation holder and manufacturer

The Marketing Authorisation for Balmosa Cream is held by Selsdon Healthcare Ltd., Selsdon House, South Croydon, Surrey CR2 8LD.

Manufactured by Beltapharm SpA, Milan, Italy

Product Licence Number:

PL 19863/0001

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