



Module 1 Administrative and Product Information

BARI DEEP RELIEF CREAM

Menthol, Methyl Salicylate, Eucalyptus Oil and Turpentine Oil Cream

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

Menthol, Methyl Salicylate, Eucalyptus Oil and Turpentine Oil Cream

2. Qualitative and Quantitative Composition

Composition:

Each gram contains:

Menthol BP 5.91 % w/w

Eucalyptus Oil BP 1.97 % w/w

Methyl Salicylate BP 12.80 % w/w

Turpentine Oil BP 1.47 % w/w

Cream Base Q.S.

3. Pharmaceutical Form

Ointment.

	Module 1 Administrative and Product Information
	BARI DEEP RELIEF CREAM
	Menthol, Methyl Salicylate, Eucalyptus Oil and Turpentine Oil Cream

4. Clinical Particulars

4.1 Therapeutic Indications

In the local management of the symptoms of fibrositis, muscle strains and arthroses.

4.2 Posology and Method of Administration

For adults and children over 5 years.

Directions for use: Apply a thin layer to the affected part with gentle massage 2 to 3 times daily.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in

Hypersensitivity to aspirin or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma.

4.4 Special Warnings and Precautions for Use

Do not use if you are allergic to any of the ingredients or medicines like aspirin. Consult your doctor before use if you are pregnant, breast-feeding, asthmatic or on any prescribed medicines. For external use and only on unbroken skin. Avoid contact with the eyes and sensitive areas of skin. Always try on a small area first. Some people may experience discomfort particularly those with sensitive skin or if used in hot weather or after a bath. Wash hands immediately after use. This medicine contains 1mg propylene glycol in each 100mg which is equivalent to 10mg in 1g of cream. Propylene glycol may cause skin irritation. This medicine contains wool fat (lanolin) and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Discontinue use if excessive irritation or other unwanted effects occur. If symptoms persist consult your doctor. Not to be used on children under 5 years of age. Keep all medicines out of the sight and reach of children.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Although no adequately controlled interaction studies have been undertaken, it is possible that excessive use of topical salicylates may increase the effect of coumarin

	Module 1 Administrative and Product Information
	BARI DEEP RELIEF CREAM
	Menthol, Methyl Salicylate, Eucalyptus Oil and Turpentine Oil Cream

anticoagulants and anti-platelet medications. It is therefore advisable that caution be exercised with patients who are on coumarin anticoagulants or antiplatelet medications, including aspirin.

4.6 Pregnancy and Lactation

There are no adequate data for the use of this product during pregnancy or breast-feeding upon which to base specific advice. Safety has not been established during pregnancy and lactation. Patients should seek advice from their doctor before using the product. Salicylates are aspirin-like substances; therefore similar cautions as appropriate for aspirin are advised. As with all medicinal products, use during pregnancy or breast-feeding should be avoided unless considered necessary.

4.7 Effects on Ability to Drive and Use Machines

Not known.

4.8 Undesirable Effects

Irritation of the skin (redness, burning, swelling, blistering) may occur. Burns at application site: not known (frequency cannot be estimated from the available data). There may also be more severe allergy reported (urticaria etc).

Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance.

4.9 Overdose

Not applicable.

	Module 1 Administrative and Product Information
	BARI DEEP RELIEF CREAM
	Menthol, Methyl Salicylate, Eucalyptus Oil and Turpentine Oil Cream

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: -

ATC Code: - M02A

Methyl salicylate is absorbed through the skin and is used for the relief of pain in rheumatic condition.

Turpentine oil when applied topically acts as a rubefacient.

Eucalyptus oil when applied topically acts as a rubefacient and may also be used by inhalation in combination with menthol to relieve nasal congestion.

5.2 Pharmacokinetic Properties

The product is for topical administration. No absorption studies have been carried out with this product. Like other salicylates, methyl salicylate may be absorbed through intact skin.

5.3 Preclinical Safety Data

The ingredients are subject to monographs in the British and European Pharmacopoeias and are documented in Martindale, The Extra Pharmacopoeia. Therefore no pre-clinical data are included with this application.

	Module 1 Administrative and Product Information
	BARI DEEP RELIEF CREAM
	Menthol, Methyl Salicylate, Eucalyptus Oil and Turpentine Oil Cream

6. Pharmaceutical Particulars

6.1 List of Excipients

Sodium Metabisulfite, Carbomer-940, Triethanolamine, Methyl Salicylate, Menthol, Linseed Oil, Iso Propyl Myristate, Capsaicin, Benzyl Alcohol, Butylated Hydroxy Toluene, Propylene Glycol, Iso Propyl Alcohol, Polysorbate 80 & Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30⁰ C Protect form heat & moisture.

6.5 Nature and Contents of Container

1 CREAM (30 gm Lamitube) packed in inner carton.

6.6 Special Precautions for Disposal and Other Handling

Not applicable.