Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Menthol & Wintergreen Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients % w/w
Methyl salicylate 5.00
Oleoresin capsicum 0.2
Levo Menthol 2.00
Turpentine oil 13.18

Excipients:
Cetostearyl alcohol is present at 4.50% w/w.
E487 sodium laurilsulfate is present at 0.47 % w/w
Sunset Yellow (E110) is present at 0.004%w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
A pale peach-coloured topical 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

Topical to the affected area. Massage into affected part until absorbed. Repeat several times daily for continued relief. This product should not be applied to neonates, infants or children under 16 years of age.

4.3 Contraindications

Not to be applied to mucous membranes or broken skin or children under 16 years of age.

4.4 Special warnings and precautions for use

For external use only.

Wash hands thoroughly after applying. Avoid contact with the eyes, broken skin or mucous membranes. If the condition is aggravated or there is no improvement, consult the doctor. E110 may cause allergic reactions.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Sodium laurilsulfate (E 487) may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

Sensitivity to Sodium laurilsulfate (SLS) can vary according to body site, age and patient population as well as other factors such as hydration level, skin colour and disease. Patient populations with decreased skin barrier functions such as in atopic dermatitis are more sensitive to the irritant properties of SLS.
Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions observed or reported with this product.

4.6 Fertility, pregnancy and lactation

There is no evidence of contra-indication in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Menthol may give rise to hypersensitivity reactions including contact dermatitis. In the event of an allergic reaction, the product should be washed off the skin with soap and water.

Post-marketing Data:
Adverse drug reactions (ADRs) identified during post-marketing experience with methyl salicylate / Levomenthol are included in table below. The frequencies are provided according to the following convention: Very common (1/10); Common (1/100 and < 1/10); Uncommon (1/1,000 and < 1/100); Rare (1/10,000, <1/1,000); Very rare (<1/10,000); Not known (cannot be estimated from the available data).

Body System (SOC)	Frequency	Adverse Drug Reaction
Skin and Subcutaneous Tissue Disorders	Not known	Burns at application site

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No information.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Counter irritant.
Mild local rubefacient and anodyne action.

ATC Code M02AC Preparations with salicylic acid derivatives.

5.2 Pharmacokinetic properties

(a) General characteristics
While local absorption of the active ingredients may occur, the amount applied relative to the total body mass is small. Thus, systemic pharmacological activity is unlikely and the action of the product is restricted to its local action.

(b) Characteristics in patients
No information available.

5.3 Preclinical safety data

No information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid paraffin
Cetostearyl alcohol
Sodium laurilsulfate (E487)
Sunset yellow (E110)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Keep the cap tightly closed. Store in the original carton in order to protect from light.

6.5 Nature and contents of container

125ml polyethylene terphthalate (PET) clear bottle with cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ovelle Ltd
Industrial Estate
Coe’s Rd
Dundalk
Co. Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0206/022/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 1988

Date of last renewal: 01 September 2008

10 DATE OF REVISION OF THE TEXT

July 2018