SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) OF VILICIN BALM

1. NAME OF THE MEDICINAL PRODUCT

Villicin Balm

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Methyl salicylate 15% w/w

Menthol crystals 2.62% w/w

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

Smooth homogenous ointment, with characteristic smell of menthol, off-white colour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is used to treat minor aches and pains of the muscles/joints (e.g., arthritis, back ache, sprains.) Menthol and Methyl salicylate are known as couterirritants. They work by causing the skin to feel cool and then warm. This feelings on the skin distract you from feeling the aches/pains deeper in your muscle joint and tendons

4.2 Posology and method of administration

Adults and children over 6

Apply to the affected parts and slowly massage well into the skin. For muscular strains and stiffness.

Elderly

Sufficient quantity is appropriate.

Children

Do not use on children under 6years old

Method of administration

For external use application

4.3 **Contraindications**

Hypersensitivity to the active substance or to any of the excipient listed in section 6.1

Not to be used on children under 6years

Do not apply to skin abrasions

4.4 Special warnings and precautions for use

Keep away from eyes and sensitive areas. If symptoms persist consult a doctor.

Wash hands thoroughly after use.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Keep out of the reach of children.

4.5 **Interaction with other medicinal products and other forms of interaction**

There have been reports that topical salicylates may potentiate the anticoagulant effects of warfarin. Menthol has also been reported to interact with warfarin (when taken orally) decreasing its effectiveness

4.6 **Fertility, pregnancy and lactation**

There is no, or adequate evidence of safety in human pregnancy or lactation. As a precautionary measure, vilicin should be used when there is no safer alternative.

4.7 **Effects on ability to drive and use machines**

Not applicable

4.8 **Undesirable effects**
Use sparingly on tender skin and do not cover immediately after application. If an adverse reaction occurs discontinue medication immediately. Known side effects of menthol – contact dermatitis or eczema, hypersensitivity reactions characterized by urticaria, flushing and headache.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 **Overdose**

When used externally as directed, overdose is unlikely. However, symptoms of systemic salicylate poisoning have been reported after the application of salicylates to large areas of skin or for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested.

Salicylate poisoning

Common features include vomiting, dehydration, tinnitus, vertigo, deafness, and sweating, warm extremities with bounding pulses, increased respiratory rate and hyperventilation. Some degree of acid-base disturbance is present in most cases.

A mixed respiratory alkalosis and metabolic acidosis with normal or high arterial pH (normal or reduced hydrogen ion concentration) is usual in adults and children over the age of four years. In children aged four years or less, a dominant metabolic acidosis with low arterial pH (raised hydrogen ion concentration) is common. Acidosis may increase salicylate transfer across the blood brain barrier.

Uncommon features include haematemesis, hyperpyrexia, hypoglycaemia, hypokalaemia, thrombocytopaenia, increased INR/PTR, intravascular coagulation, renal failure and non-cardiac pulmonary oedema.

Central nervous system features including confusion, disorientation, coma and convulsions are less common in adults than in children.

Management

Activated charcoal may be administered if significant quantities have been ingested within an hour of presentation. The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account. Elimination is increased by urinary alkalinisation, which is achieved by the administration of 1.26% sodium bicarbonate. The urine pH should be monitored. Correct metabolic acidosis with intravenous 8.4% sodium bicarbonate (first check serum potassium). Forced diuresis should not be used since it does not enhance salicylate excretion and may cause pulmonary oedema.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700mg/L (5.1mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under ten years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

Menthol

Ingestion of the product or excessive use may also lead to camphor poisoning, the symptoms of which include nausea, vomiting, epigastric pain, headache, dizziness, oropharyngeal burning, delirium, muscle twitching, epileptiform convulsions, CNS depression and coma. Breathing is difficult and the breath has a characteristic odour; anuria may occur. Death from respiratory failure or status epilepticus may occur; fatalities in children have been recorded from 1g.

Ingestion of significant quantities of menthol is reported to cause symptoms including severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma; they may be managed by supportive care, including anticonvulsant therapy. Gastric lavage may be considered if the patient presents within 1 hour of ingestion; any convulsions must be controlled first. Activated charcoal may be given orally.

5. **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**

Smooth homogenous ointment, with characteristic smell of menthol.

Vilicin is a smooth, white or off-white ointment which incorporates methyl salicylatesand menthol and methyl salicylate as active ingredients

Menthol relieves itching, dilates the vessels causing a sensation of coldness followed by an analgesic effect. Methyl salicylate has the actions of the salicylates. It is readily absorbed through the skin and has counter-irritant properties.

ATC code: M02AC

5.2 **Pharmacokinetic properties**

None available
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.

5.3 **Preclinical safety data**
Not applicable

6. **PHARMACEUTICAL PARTICULARS**
6.1 **List of excipients**

Petroleum jelly

Paraffin wax

6.2 **Incompatibilities**

None known

6.3 **Shelf life**

36 months.

6.4 **Special precautions for storage**

Store below 25 degrees centigrade

6.5 **Nature and contents of container**

Glass containers with blue plastic screw cap

Pack sizes: 25g

6.6 **Special precautions for disposal and other handling**

Not applicable

7. **MARKETING AUTHORISATION HOLDER**
Daily-Need Industries Limited
Plots 9/10 Unity close, Oshodi Scheme Industrial Estate, Lagos
www.dailyneedgroup.com,
info@dailyneedgroup.com

8. **MARKETING AUTHORISATION NUMBER(S)**

04-1707

9. **DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION**

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10. **DATE OF REVISION OF THE TEXT**

Company Contact Details

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