1. Name of the medicinal product
Avrobalm Ointment

2. Qualitative and quantitative composition
Each jar contains:

Methyl Salicylate 50%w/w

For the full list of excipients, see section 6.1

3. Pharmaceutical form
Ointment

Pale yellow-coloured ointment.

4. Clinical particulars
4.1 Therapeutic indications
Avrobalm is indicated for the relief of:

- Muscular aches
- Lumbago
- Arthritic and rheumatic pains
- Sprains
- Strains

4.2 Posology and method of administration
Posology

Adult and children over 2 years: Apply to the affected area not more than 3 or 4 times daily.

Children under 2 years: Consult a physician.

Method of administration
Topical administration only.

4.3 Contraindications
Avrobalm is contra-indicated in patients with known hypersensitivity to Methyl salicylate or other Non-steroidal Anti-inflammatory Drugs (NSAID).

It is contraindicated in children less than 2 years.

Because percutaneous absorption may occur, the product should be used with caution in individuals who are sensitive to aspirin and other NSAIDs or who suffer from severe asthma or nasal polyps, conditions associated with aspirin sensitivity.

4.4 Special warnings and precautions for use
For external use only on unbroken skin. Do not apply to large areas of the body, on inflamed or broken skin and with an occlusive dressing.
Avoid contact with the eyes and sensitive areas of the skin.
If irritation or sensitisation develops with the use of Avrobalm, treatment should be discontinued and appropriate therapy instituted.
Not to be used on children under 2 years.
Wash hands thoroughly after use.
Keep all medicines out of the reach of Children.

4.5 Interaction with other medicinal products and other forms of interaction
The low systemic bioavailability of methyl salicylate from Avrobalm means that interaction with other medicines is unlikely.

4.6 Fertility, pregnancy and lactation
Systemic absorption of methyl salicylate after topical administration at recommended dosage is negligible and thus not likely to be excreted in breast milk or through the placenta.

4.7 Effects on ability to drive and use machines
Avrobalm has no influence on the ability to drive and use machines.

4.8 Undesirable effects
Side effects are mild and transient and may include hypersensitivity reactions like skin rashes and contact dermatitis. Local burning, irritation and itching at the site of application may also occur.

Mild chronic Salicylate intoxication or salicylism usually occurs following excessive topical application of salicylates. Symptoms include dizziness, tinnitus, deafness, sweating, nausea, and vomiting, headache, and confusion and may be controlled by reducing the dosage.

Some persons especially those with chronic asthma, chronic urticaria, or chronic rhinitis exhibit notable hypersensitivity reactions which may provoke various reactions including urticaria and other skin eruptions, angioedema, rhinitis and severe, even fatal paroxysmal bronchospasm and dyspnoea.

4.9 Overdose
Over dosage is unlikely to occur with topical application but in case of accidental ingestion, gastric lavage should be carried out and symptomatic treatment should be given.

Application of large amounts especially on excoriated skin or application over large skin areas can cause systemic effects. Mild chronic Salicylate intoxication or salicylism usually occurs following excessive topical application of salicylates. Symptoms include dizziness, tinnitus, deafness, sweating, nausea, and vomiting, headache, and confusion and may be controlled by reducing the dosage.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacodynamic category: Topical products for joints and muscular pain. ATC code: M02AC.

Methyl salicylate is hydrolysed to salicylic acid. Its pharmacological actions are considered to be those of salicylic acid, and its mechanism of action is due to an inhibitory effect on prostaglandin biosynthesis. Methyl salicylate is also considered to have a counterirritant or ruberfacient effect.

Methyl salicylate can be applied topically in effective concentrations, but with very low plasma concentrations of drug. Therapeutic levels in the affected tissues provide relief from pain and inflammation.

5.2 Pharmacokinetic properties
Studies have shown methyl salicylate is absorbed through the skin and is extensively metabolised to salicylic acid after topical application where it exerts its therapeutic action and small amounts are absorbed systemically where the salicylic acid is excreted renally, primarily as salicylic acid but also related metabolites.

5.3 Preclinical safety data
There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

6. Pharmaceutical particulars
6.1 List of excipients
Methyl Salicylate
White Soft Paraffin
Hard Paraffin Wax
Microcrystalline Wax
Yellow Colour (Oil Soluble)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Do not store above 30°C.

6.5 Nature and contents of container
Polyethylene terphthalate (PET) jar with cap.

Pack sizes: 25g, 80g and 500g.

6.6 Special precautions for disposal and other handling
No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder
Avro Pharma Limited
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