SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Algesal®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tube of Algesal contains Diethylamine Salicylate 10%w/w

Excipient(s) with known effects:

Lavandin composition (Contains d-limonene & Linalool) 0.10% w/w

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Off white, lavender-scented cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For symptomatic relief of rheumatic and minor musculo-skeletal conditions including lumbago, fibrositis, sciatica, bruises and strains.

4.2 Posology and Method of Administration

Adults (including the elderly) and children 6 years and over:

For cutaneous use. Apply three times daily to the affected area, massaging until cream is fully absorbed.

Children under 6 years:

Not recommended.

4.3 Contra-indications

Hypersensitivity to the active substances or to any of the excipients.

Algesal should not be used if the surface of the skin is broken.

Algesal contains terpene derivatives (ie camphor) as excipients, which can lower the epileptogenic threshold and, at excessive doses, lead to neurological accidents such as convulsions in infants and children. Therefore, Algesal should not be used by children who have a history of convulsions.

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

Consult your doctor before use if you are pregnant, breastfeeding, asthmatic or on any other medicines.

For external use only. Not to be used on broken skin. Avoid contact with eyes and sensitive areas of the skin. Always try on a small area first. Always use sparingly.

Some people may experience discomfort, particularly those with sensitive skin or if used in hot weather/after a hot bath. Temporary skin redness/burning sensation may occur. Discontinue use if excessive irritation or unwanted effects occur. Not to be used on children under 6 years of age. If symptoms persist consult your doctor. Keep all medicines out of the sight and reach of children.

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.

Excipient warnings: "This medicine contains fragrance with d-limonene and linalool, which may cause allergic reactions."

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. It is therefore advisable that caution should be exercised with patients who are on coumarin anticoagulants.

Salicylates (as NSAIDs) may increase blood levels and therefore toxicity of methotrexate by delaying its excretion.

4.6 Pregnancy and Lactation

Pregnancy: There is inadequate evidence of safety in human pregnancy, Algesal should not be used in pregnancy unless there is no safer alternative.

Lactation: Not recommended.

4.7 Effects on Ability to Drive and Use Machines

Not applicable.

4.8 Undesirable effects

Temporary skin reactions (redness, burning sensation and rashes) may occur.

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 the 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

Overdose is unlikely when used as recommended. If applied to a large area of skin, or in the unlikely event of oral ingestion, the product may cause systemic adverse effects depending on the amount absorbed.

Salicylate poisoning is usually associated with plasma concentrations >350 mg/L (2.5 mmol/L). Most adult deaths occur in patients whose concentrations exceed 700 mg/L (5.1 mmol/L). Single doses less than 100 mg/kg are unlikely to cause serious poisoning.

Symptoms
Common features include vomiting, dehydration, tinnitus, vertigo, deafness, 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, thrombocytopenia, 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
Give activated charcoal if an adult presents within one hour of ingestion of more than 250 mg/kg. 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 >700 mg/L (5.1 mmol/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.

If used to excess by elderly patients, there is a risk of terpene-related agitation and confusion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Diethylamine salicylate is a topical analgesic, with the anti-inflammatory properties of salicylates.

5.2 Pharmacokinetic properties

After topical application small amounts of salicylic acid are detectable in the plasma. Elimination in the urine occurs over a period of 48 hours.

5.3 Preclinical safety data

There are no additional preclinical safety data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylene glycol stearate, glycerol monostearate, stearic acid, triethanolamine, petrolatum, light liquid paraffin, microcrystalline wax, lavandin composition (Contains d-limonene & Linalool) and purified water.

6.2 Incompatibilities

Not known.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

50g: Aluminium tube with a white HDPE screw cap.

100g: Aluminium tube with a white HDPE screw cap.

6.6 Instructions for use, handling and disposal

Wash hands well after use.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
HD7 5QH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00240/0342

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/02/2006

10 DATE OF REVISION OF THE TEXT

29/09/2020