SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Odour Free Lloyds Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Diethylamine salicylate BP 10%w/w

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

As an analgesic massage cream for the relief of rheumatic pains. For the relief of pain and fibrositis or soft tissue rheumatism, lumbago, sciatica and allied complaints. For the relief of inflammatory pains in muscles, ligaments, joints and sprains, caused by injury or over-use and stiffness after exercise.

4.2. Posology and Method of Administration

For topical administration

Apply sufficient cream to the painful area, massaging until the cream has been fully absorbed into the skin. The application may be repeated two or three times a day.

The Elderly
No special precautions are required for the elderly.

Children
Should be used in children under the age of six only on medical advice.

4.3 Contraindications

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

Odour Free Lloyds Cream is contraindicated where there is known hypersensitivity to aspirin, other salicylates, or other non-steroidal anti-inflammatory drugs (including when taken by mouth) especially where associated with a history of asthma. The cream should not be used on cut, abraded or broken skin.

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. If symptoms persist consult your doctor.

The excipients methyl p-hydroxybenzoate and propyl p-hydroxybenzoate may cause allergic reactions (possibly delayed) and cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Odour Free Lloyds Cream should be kept out of the sight and reach of children.

Do not 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.

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 Fertility, pregnancy and lactation

Pregnancy: There is inadequate evidence of safety in human pregnancy, Odour Free Lloyd's Cream 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

None known

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Diethylamine salicylate is a counter-irritant.

5.2 Pharmacokinetic Properties

Not applicable.

5.3 Pre-clinical Safety Data

None state.

6.1 List of excipients

Cetostearyl alcohol
Methyl hydroxybenzoate
Polysorbate 60
Propyl Hydroxybenzoate
Sorbitan Monostearate
Stearic acid flake
Light Liquid Paraffin
Water purified

6.2 Incompatibilities

None known.

6.3 Shelf-Life

36 months unopened

6.4 Special Precautions for Storage

Store in a cool place

6.5 Nature and contents of container

100g amber glass jar with aluminium screw cap fitted with a PVC closure ring.

6.6 Instruction for Use, Handling and Disposal

Not applicable

7. MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00240/0059

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15 January 2003

10 DATE OF REVISION OF THE TEXT

04/12/2019