Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lassar's Cream.Zinc Oxide 23% w/w & Salicylic Acid 2% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Zinc Oxide 23% $^{w}/_{w}$ & Salicylic Acid 2% $^{w}/_{w}$
Also contains Wool Fat (Lanolin).
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A smooth white odourless cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Lassar's Cream is for topical use as an emollient and protective agent.

4.2 Posology and method of administration

Lassar's Cream is applied topically and is for external use only.

Adults: Apply Lassar's Cream to the affected area twice daily. No more than 4 fingertip units should be used at any one time unless directed to do so by a doctor. One fingertip unit should be enough to cover twice the area of an adult hand. Four fingertip units should be enough to cover an adult arm and both sides of the hand.
Children under 3 years of age: Do not use on children under 3 years of age unless directed to do so by your doctor.
Children between 3 and 10 years of age: Apply one fingertip unit to the affected area twice a day. Do not exceed this dose unless directed to do so by your doctor.
Children between 10 years of age and 16 years of age: Apply up to two fingertip units to the affected area twice a day. Do not exceed this dose unless directed to do so by your doctor.
One fingertip unit should be enough to cover twice the area of an adult hand on your child's body.

4.3 Contraindications

Lassar's Cream is contra-indicated in patients displaying salicylate hypersensitivity or in patients with a known sensitivity to its ingredients. It should not be used in the presence of infection.

4.4 Special warnings and precautions for use

Avoid contact with broken or inflamed skin. Salicylate toxicity may occur if applied at a higher does than recommended.

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
This preparation may make skin and surfaces slippery.

4.5 Interaction with other medicinal products and other forms of interactions

There are no known interactions when used as indicated.. However, topical salicylic acid may increase the absorption of other topically applied medicines. Concomitant use of Lassar's Paste and other topical medicines on the same area of skin should therefore be avoided.

4.6 Fertility, pregnancy and lactation

Whilst there are no known contra-indications to the use of Lassar's Cream during pregnancy and lactation, the safety has not been established. Lassar's Cream should therefore be used with caution or following professional advice

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

Salicylic Acid is a mild irritant, and application of preparations containing salicylic acid to the skin may cause dermatitis. Salicylate poisoning has been reported after the application of salicylic acid to large areas of skin and for prolonged periods.

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

Symptoms of systemic salicylate poisoning (tinnitus, dizziness and deafness) have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested. Salicylism is unlikely to occur if Lassar's Cream is used as indicated.
Salicylate poisoning is usually associated with plasma concentrations >350mg/L (2.5mmol/L). Most adult deaths occur in patients whose concentrations exceed 700mg/L (5.1mmol/L). Single doses less than 100mg/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, 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
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

ATC code D02 AB Emollients and protective AB Zinc Product I

Zinc Oxide

Zinc Oxide is widely used as a component of many dusting powders, lotions, ointments, creams and pastes. It has covering and protective properties, gives consistency to topical products and is said to have cooling and slightly astringent properties. It is also widely used as a complete sun block due to its UV reflecting properties.

Salicylic Acid
Salicylic Acid is bacteriostatic and fungicidal. It also possesses keratolytic properties and may exert a solubilising effect on the stratum corneum, with dissolution of the intracellular cement.

5.2 Pharmacokinetic properties

Zinc Oxide
It is unlikely that any Zinc Oxide is absorbed through the skin. Zinc salts are poorly absorbed from the gastro-intestinal tract. Only a small proportion of dietary zinc is absorbed. Zinc is widely distributed throughout the body and is excreted in the faeces with only traces appearing in the urine.

Salicylic Acid
Salicylic acid is rapidly distributed to all the body tissues if absorbed. The rate of excretion in the urine is dependent on the pH.

The human no observable adverse effect level (NOAEL) for topical Salicylic acid is 1.5mg/kg/day. The directions stated give a margin of safety of greater than 100 with respect to this NOAEL.

5.3 Preclinical safety data

No further information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch,
Paraffin, White Soft,
Paraffin, Liquid,
Wool fat.

6.2 Incompatibilities

Zinc Oxide is incompatible with benzylpenicillin.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep container tightly closed.

6.5 Nature and contents of container

120g and 500g clear polystyrene containers with polypropylene screw cap.
Not all pack sizes may be marketed.

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.

7 MARKETING AUTHORISATION HOLDER

Ovelle Limited
Industrial Estate
Coe's Road
Dundalk
Co. Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0206/014/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st April 1983.

Date of last renewal: 1st April 2008.

10 DATE OF REVISION OF THE TEXT

June 2019