BLISTEX RELIEF CREAM

Summary of Product Characteristics Updated 17-Sep-2018 | Dendron Brands Limited

1. Name of the medicinal product

BLISTEX RELIEF CREAM

2. Qualitative and quantitative composition

Strong ammonia solution	0.100% w/w
Aromatic ammonia solution	6.040% w/w
Liquefied phenol	0.494% w/w

For excipients, see 6.1.

3. Pharmaceutical form

Cream.

Off white smooth cream.

4. Clinical particulars

4.1 Therapeutic indications

For quick relief of occasional cold sores, cracked lips or chapped lips.

4.2 Posology and method of administration

At first symptoms apply every hour. By topical application to the lips.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

If you suffer from recurrent cold sores consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Not contraindicated.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Immune system disorders: Hypersensitivity reactions

General disorders: Application site irritation, swelling or inflammation

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, website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

No known problems associated with overdosage.

5. Pharmacological properties

Pharmacotherapeutic group: Other dermatologicals ATC code: D11 AX

5.1 Pharmacodynamic properties

The product was developed for topical use and is for the relief of occasional cold sores, cracked lips and chapped lips.

Ammonia is incorporated into the formulation for its rubefacient properties.

Phenol is present in the formulation for its disinfectant properties. Phenol is bacteriostatic in concentrations of about 0.02% to 1% bactericidal to some organisms in concentrations as low as 0.4%. Phenol is also reported to be active against certain viruses.

These two actives are present in an emollient emulsion base, comprising largely of lanolin 25.4% w/w and White Soft Paraffin 33% w/w. These oleaginous substances, also known as occlusive agents and humectants, are employed as protectives and as agents for softening the skin and rendering it more pliable, but chiefly as vehicles for the more active drugs above.

Emollients soften the skin by forming an occlusive oil film on the stratum corneum, thus preventing drying from evaporation of the water that diffuses to the surface from the underlying layers of skin.

In this way, Blistex Relief Cream provides an effective treatment for the relief of occasional cold sores, cracked lips and chapped lips.

(References abstracted from Goodman & Gillman and Martindale).

5.2 Pharmacokinetic properties

Approximately 80mg of Blistex Relief Cream is applied to the lips at any one time. Blistex Relief Cream is a topical treatment with locally acting agents.

Any trace quantities of ammonia entering the blood system via Blistex Relief Cream would be so small compared to normal background concentrations of ammonia as to be inconsequential.

Ammonia in the body represents that which is liberated from the deamination of amino acids and the deamination of amides. Portal venous blood contains a high concentration of ammonia. Normally about 20% of the urea produced in the body diffuses into the gut, where it is converted by bacteria to ammonia and carbon dioxide. Intestinal bacteria also produce ammonia from dietary proteins. The ammonia is absorbed and converted back to urea in the liver, by way of the ornithine cycle. Another significant role of ammonia is in the synthesis of glutamine.

Renal excretion – Normal renal venous blood contains a high concentration of ammonia synthesised from glutamine and other amino acids in the kidney. The ammonia that is formed by the kidney is excreted when the urine is acidic, but is largely returned to the systemic circulation if the urine is alkaline. In an acidic urine, NH_3 accepts a proton and exists almost entirely as NH_4^+. Under normal states of metabolism about 70mEq of non-volatile acid is generated per day: about one half of this is excreted in the urine in conjunction with NH_4^+, and the remainder is excreted as titratable acid. Renal production of ammonia is stimulated by acidosis: ammonia buffers urinary acid and allows further secretion of protons into the tabular fluid. Potassium depletion also results in a primary increase in the alkalinization of the urine (Tannen, 1977). This may increase the amount of ammonia that is returned to the circulation via the renal vein and have a deleterious effect when potassium depletion coexists with hepatic failure.

Normal physiological mechanisms are designed to keep the concentration of ammonia in the blood as low as possible. Thus, ammonia added to the venous circulation by the kidney or gastrointestinal tract is converted to urea by the liver.

Phenol – A paper published by JAMA in 1953 showed that phenol readily penetrates the human skin and that detoxification by conjugation is initiated immediately.

The pharmaceutical form of Blistex Relief Cream is similar to the aromatised liquid petrolatum of Camphor phenique. This being so, we would expect that after local application the amount of phenol in blood attributable to Blistex Relief Cream would be of the order of 0.0003 mg/100ml of blood.

According to the Journal of Clinical Pathology 12:129, 1942 the residual phenol content of blood in normal human beings varies from 0.0 to 0.08 mg/100ml free phenol and 0.0 to 0.08 mg/100ml conjugated phenol.

This suggests that residual phenol in normal humans can be anything up to 250 times greater than that which is likely to come from Blistex Relief Cream.

The results of the 1953 paper indicate that phenol from Blistex Relief Cream is rapidly absorbed through the skin and is rapidly detoxified due to its extremely low concentrations.

5.3 Preclinical safety data

N/A

6. Pharmaceutical particulars

6.1 List of excipients

White soft paraffin

Purified water

Modified lanolin

Sorbitan palmitate

Peppermint oil

Polysorbate 40

Ethanol 96%

Cineole

Racemic camphor

Saccharin sodium

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

Keep all medicines out of the reach of children.

6.5 Nature and contents of container

Collapsible printed aluminium tube with elongated nozzle and plastic screw-on cap, containing 3.5 g or 5 g of cream.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements

Administration Details

7. Marketing authorisation holder

DDD limited

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8. Marketing authorisation number(s)

PL 0133/5007

9. Date of first authorisation/renewal of the authorisation

29th July 1999

10. Date of revision of the text

01/02/2016

Company Contact Details

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