SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Blistex Cold Sore Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 100 mg of docosanol.

Excipient: 50 mg propylene glycol/gram cream.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream.

White cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of early stages (prodrome or erythema phase) of recurrent labial herpes simplex infection (coldsores) in immunocompetent patients.

4.2 Posology and method of administration

Route of Administration: Cutaneous use

Posology

Adults and adolescents aged 12 years and over:
Apply a thin film carefully over the entire cold sore 5 times a day (approximately every 3 hours during waking hours).

Treatment must begin as soon as possible after the first cold sore symptoms or signs appear (pain, burning/itching/tingling or redness) as efficacy has not been demonstrated when the treatment is initiated at the stage of an already developed blister or ulcer.

Treatment should continue until healing has occurred, usually 4 to 6 days, or for a maximum of 10 days.

Elderly:
No special dose recommendation.

Paediatric population:
The safety and efficacy of Blistex Cold Sore Cream in children aged younger than 12 years have not been established.

Dosage in renal failure:
No dose adjustments necessary due to negligible topical absorption.

4.3 Contraindications

Hypersensitivity to the active substance (docosanol) or to any of the excipients.

4.4 Special warnings and precautions for use

Avoid application close to or in the eyes.

Should only be used for cold sores on the mouth and face.

Must not be used to treat genital or ocular herpes infections

Avoid transmitting the virus, particularly when active lesions are present

The cream should not be used in immuno compromised patients.
Treatment with the cream should not be initiated at the stage of an already developed blister or ulcer.
If the recurrent cold sore is particularly severe, consult doctor.
Immunocompromised patients should consult a pharmacist or doctor concerning treatment of any infection, including cold sores.

Pediatric population
There is no treatment experience available for the use in children below the age of 12 years and only limited experience in adolescent(aged12-18years). It is recommended that the cream should not be used in children under 12 years.
This formulation contains propylene glycol and may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Therefore, Blistex Cold Sore Cream should not be used simultaneously with other topical medicinal products at the same application site.

4.6 Fertility, pregnancy and lactation

Pregnancy:

There are no data from the use of docosanol in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or post natal development. Since systemic exposure to docosanol is negligible, docosanol can be used during pregnancy.

Lactation:

There are no data from the use of docosanol in breast feeding women. No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding woman to docosanol is negligible. Docosanol can be used during breast-feeding

4.7 Effects on ability to drive and use machines

Due to its negligible absorption docosanol has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
not known (cannot be estimated from the available data).
Results from clinical trials of the treatment of recurrent labial herpes simplex demonstrate no difference in the frequency or type of undesirable effects in patients treated with Blistex Cold Sore Cream or placebo.

Nervous system disorders

Very common: Headache(10.4%of docosanol-treated patients and 10.7% of placebo-treated patients).

General disorders and administration site conditions

Common: Application site adverse reactions which include dry skin, rashes and skin disorders(2.9% of docosanol-treated patients and 2.3% of placebo-treated patients).
Facial oedema has also been reported but these application site adverse reactions are consistent with normal facial reactions experienced with cold sores.

Reporting of suspected adverse reactions

Reporting suspected adverse actions 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

Adverse reactions related to overdose by topical application of Blistex Cold Sore Cream are unlikely because of negligible percutaneous absorption. Similarly, poor oral absorption makes the occurrence of adverse reactions unlikely following ingestion of docosanol.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Chemotherapeutics for topical use, antivirals
ATC code: D06BB11

The exact mechanism of the antiviral activity of docosanol is unknown. *In vitro* studies indicate that docosanol affects the fusion between the virus and the plasma membrane, which inhibits intracellular uptake and replication of virus. *In vitro* studies demonstrate that docosanol-treated cells resist infection by lipid-enveloped viruses such as HSV-1. Docosanol has no effect against non-enveloped viruses.

Docosanol 10% was compared to placebo (containing poly ethylene glycol) in two randomised, double-blind, controlled clinical trials. In one study, 370 adults were randomised. Subjects started with treatment in the prodrome or erythema phase of an acute recurrence of orofacial herpes. The ITT population consisted of 183 subjects for docosanol and 183 subjects for placebo. The median time to complete healing was 4.0 days in the docosanol group and 4.7 days in the placebo group a difference of 18.9 hours. In the second study, 373 adults were randomised. Subjects started with treatment in the prodrome or erythema phase of an acute recurrence of orofacial herpes. The ITT population consisted of 187 subjects for docosanol and 184 subjects for placebo. The median time to complete healing was 4.3 days in the docosanol group and 4.9 days in the placebo group a difference of 15.9 hours. In studies with treatment initiation at stages later than the prodromal or erythema stage, efficacy was not demonstrated.

5.2 Pharmacokinetic properties

Under conditions reflecting normal clinical use of Blistex Cold Sore Cream, docosanol could not be quantified (limit of quantification, LOQ=10ng/ml) in the plasma of treated patients. Ten women with active labial herpes simplex were treated with Blistex Cold Sore Cream. After a single dose on study day 1 and after multiple doses (five times daily, study days 2-3), blood samples were withdrawn upto 24 hours after treatment and analysed for docosanol. Of the 209 plasma samples analysed, the docosanol level was below the LOQ in 208 and exactly at the LOQ in one sample.

Docosanol is metabolized to docosanoic acid, its major metabolite. Both docosanol and docosanoic acid are endogenous components of cell membranes in man, particularly in erythrocytes, brain, nerve myelin sheath, lung, and kidney.

5.3 Preclinical safety data

Preclinical data revealed no special hazard for humans based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose stearates (mono and distearate)

Light mineral oil

Propylene glycol (E1520)

Benzyl alcohol (E1519)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
After first opening the container: 6 months

6.4 Special precautions for storage

Do not store above 25˚C.

6.5 Nature and contents of container

Epoxy-lined aluminium tubes closed with a polyethylene screw cap.
Pack sizes: 2 g

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Blistex Limited
7 Pilgrim Street,
London,
EC4V 6LB
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 53512/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/09/2025

10 DATE OF REVISION OF THE TEXT

11/09/2025