

KEY INFORMATION

Doublebase™ Emollient Gel

1 NAME OF THE PRODUCT

Doublebase™ Emollient Gel

2 PRODUCT TYPE

Emollient, class I medical device.

3 FORMULATION

White opaque gel.

The therapeutic ingredients in this product are isopropyl myristate 15% w/w and liquid paraffin 15% w/w. (For a full list of ingredients see Section 6.1)

4 PRODUCT PARTICULARS

4.1 Uses

A highly moisturising and protective hydrating gel for regular and frequent use in the management of dry or chapped skin conditions such as eczema, psoriasis or ichthyosis.

Doublebase Emollient Gel may also be used as an adjunct to other topical treatments.

4.2 Directions for Use

Only for application to the skin.

For use by adults, the elderly, infants and children. Apply to the affected areas as often as necessary, even when the skin appears normal. It may also be applied before washing, showering or bathing to prevent further drying of the skin.

Gently smooth Doublebase Emollient Gel over and around all dry and/or inflamed skin areas. For best results, use a few gentle strokes to smooth the gel across the skin in the same direction as hair growth. If necessary, allow time for any excess to soak in. Do not rub the skin vigorously.

If applying another treatment to the same areas of skin as Doublebase Emollient Gel, do not mix the two products. This can be achieved by applying the treatments alternately, leaving sufficient time to allow the previous application to soak in.

4.3 Contra-indications

Do not use in cases of known sensitivity to any of the ingredients.

4.4 Special Warnings and Precautions for Use

Accidental oral ingestion may cause diarrhoea, owing to the oily ingredients, which should be treated symptomatically without attempting to induce vomiting.

Care should be taken as emollients which soak into medical dressings or fabrics (clothing, pyjamas, bed linen, etc.) can increase the flammability of these items. Patients using emollients (and their parents/carers) should take particular care to avoid these materials coming into contact with naked flames or lit cigarettes, etc. As a precaution, dressings and clothing, etc., should be changed frequently and laundered thoroughly.

4.5 Interaction with other Products and other forms of Interaction

This product is not known to affect, or be affected by, medicines taken orally at the same time. If using other topically applied products, allow sufficient time for absorption after each application before applying Doublebase Emollient Gel.

4.6 Pregnancy and Lactation

This product can be used during pregnancy and by breast-feeding mothers. The ingredients have been in widespread use in this and similar preparations for many years, without reports of problems. However, safety trials have not been conducted.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable Effects

Like all treatments, side effects can occur although not everybody gets them.

Although this product has been specially designed for use on dry, problem or sensitive skin local skin reactions can occur in rare cases. In this event, treatment should be discontinued.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the product. Healthcare professionals and patients are asked to report any suspected adverse reactions directly to the manufacturer (see section 7 below).

4.9 Overdose/abuse/misuse

Not applicable

5 MODE OF ACTION

The oily ingredients, isopropyl myristate and liquid paraffin, help rehydration and softening of dry skin by forming an occlusive barrier within the skin surface, reducing drying from evaporation of water that diffuses from the underlying layers, and thus restoring the normal protective function of the skin. Glycerol is a humectant which also helps retain moisture. Doublebase Emollient Gel is designed to deliver the emollient ingredients into the stratum corneum when applied gently for the indicated conditions and offers patients the advantage of being relatively non-greasy despite the high oil content.

6 QUALITY PARTICULARS

6.1 Ingredients

The ingredients are isopropyl myristate, liquid paraffin, glycerol, carbomer, sorbitan laurate, trolamine, phenoxyethanol, and purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Do not store above 25°C. Do not freeze.

6.5 Nature and Contents of Container

250g plastic bottle with pump dispenser

100g plastic laminate tube with screw cap.

(25g packs are also available to the medical and allied professionals).

Individual sales packs comprise a unit carton containing one bottle/tube of gel and a package leaflet.

6.6 Special Instructions for Use, Handling and Disposal

No special requirements.

7 MANUFACTURER / HOLDER OF TECHNICAL FILE

Dermal Laboratories Limited

Tatmore Place

Gosmore

Hitchin

Herts

UK

SG4 7QR

8 DATE OF PREPARATION / UPDATE

December 2017

9 BASIS FOR MARKETING

Class I medical device