

KEY INFORMATION – DOUBLEBASE™ ONCE

1 NAME OF THE PRODUCT

Doublebase™ Once

2 PRODUCT TYPE

Emollient, class I (MDD) medical device.

3 FORMULATION

White opaque gel.

(For full list of ingredients see Section 6.1).

4 PRODUCT PARTICULARS

4.1 Uses

Doublebase Once is an advanced, highly moisturising, and protective emollient gel for regular once-daily application. It is used in the management of dry skin conditions such as eczema, psoriasis, or ichthyosis.

Doublebase Once may also be used as an adjunct to any other emollients or treatments.

4.2 Directions for use

Only for application to the skin.

For maximum benefit, gently smooth Doublebase Once over and around all dry skin areas once daily or as often as necessary.

Use a few gentle strokes to smooth the gel across the skin in the same direction as hair growth (like stroking a cat or dog). If necessary, allow time for any excess to soak in. Do not rub the skin vigorously.

When used as a soap substitute for washing, in order to prevent further drying of the skin, use as you would use normal soap.

If applying another treatment to the same areas of skin as Doublebase Once, try to avoid mixing the two products. This can be achieved by applying the treatments alternately, leaving sufficient time to allow the previous application to soak in.

For use by adults, the elderly, infants and children.

4.3 Contraindications

Do not use in cases of known hypersensitivity to any of the ingredients listed in section 6.1.

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.

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 products and other forms of interaction

This product is not known to affect, or be affected by, medicines. If using other topically applied products, allow sufficient time for absorption after each application before applying Doublebase Once.

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.

Doublebase Once has been specially designed for use on dry, problem, or sensitive skin. However, in rare cases it can cause skin irritation (mild rashes) or allergic skin reactions on extremely sensitive skin. These rare effects tend to occur during or soon after the first few uses. 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 users/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 (waterproof) barrier on or within the upper layers of the skin (the stratum corneum), reducing drying from evaporation of water that diffuses from the underlying layers, and thus restoring the normal protective function of the skin. The formulation also contains humectants which also help to retain moisture.

Doublebase Once is designed to deliver the emollient ingredients into the stratum corneum when applied gently for the indicated conditions and offers users/patients the advantage of being relatively non-greasy despite the high oil content.

6 QUALITY PARTICULARS

6.1 Ingredients

Isopropyl myristate
Liquid paraffin
Glycerol
Steareth-21
Macrogol stearyl ether
Ethylhexylglycerin
1,2-hexanediol
Caprylyl glycol
Povidone

Trolamine
Carbomer
Purified water

6.2 Incompatibilities

None known

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

500g 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
Hertfordshire, SG4 7QR
UK

8 DATE OF PREPARATION / UPDATE

June 2023.

9 BASIS FOR MARKETING

Medical Devices Directive (93/42/EEC) class I medical device.