

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Zerolatum Plus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Light liquid paraffin 51.66% w/w.

Benzalkonium chloride solution (50% w/v) 12.0% w/w equivalent to Benzalkonium chloride 6% w/w.

Irgasan PG 60 3.34% w/w equivalent to Triclosan 2.0% w/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

ATC Code: DO2A

For the prophylactic treatment of eczemas at risk from infection.

4.2 Posology and method of administration

Topical as a bath additive.

Zerolatum Plus should always be diluted with water. It is an effective cleanser and should not be used with soap.

Adults and children over one year:

In an eight inch bath add 40ml (3 capfuls)

Alternatively, in a four inch bath add 20ml (1 ½ capfuls).

Infants 6 - 12 months: Add 1ml (just sufficient to cover the bottom of the cap) and mix well with water.

Do not use for babies younger than six months.

4.3 Contraindications

Patients with a known hypersensitivity to any of the ingredients should not use the product.

4.4 Special warnings and precautions for use

Ingredients with specified warnings

This medicine contains 6% w/w Benzalkonium chloride which may irritate the skin. You should not apply this medicine to the breasts if you are breast-feeding because the baby may take it in your milk.

This medicine contains wool fat (lanolin) which may cause local skin reactions (e.g. contact dermatitis).

Other warnings

Avoid contact of the undiluted product with the eyes. If the undiluted product comes into contact with the eye, reddening may occur. Eye irrigation should be performed for 15 minutes and then the eye examined under fluorescein stain. If there is persistent irritation or any uptake of fluorescein, the patient should be referred for ophthalmological opinion.

Instruct patients not to 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.

The product should not be used with soap

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

No restrictions on the use of the product in pregnancy and lactation are proposed.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

None known.

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 at www.mhra.gov.uk/yellowcard or search **MHRA Yellow Card** in the [Google Play](#) or [Apple App Store](#).

4.9 Overdose

The product is intended for topical use only. Accidental ingestion may cause gastrointestinal irritation with vomiting and diarrhoea. Vomiting may result in foam aspiration. In the case of accidental ingestion, give 1 to 2 glasses of milk or water to drink. If a large quantity of the product is ingested, the patient should be observed in hospital and the use of activated charcoal may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzalkonium chloride and triclosan are anti-bacterial agents with proven efficacy against *Staphylococcus aureus*, the principal causative organism in infected eczemas.

Light liquid paraffin is an emollient widely used in the treatment of eczema.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Crodalan AWS (polysorbate 80, cetyl, stearyl and oleyl acetates and acetylated lanolin alcohol)

Isopropyl palmitate

Oleyl alcohol

Macrogol 4-lauryl ether (Laureth - 4)

Polypropylene glycol (E1520) [ingredient of Irgasan PG60 (triclosan)]

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months (unopened).

6 months after first opening container.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

500ml White sloping shoulder High Density Polyethylene bottles with a 24mm polypropylene screw cap.

6.6 Special precautions for disposal

There are no special instructions for use or handling of Zerolatum Plus.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd
Linthwaite
Huddersfield
HD7 5QH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0426

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/07/2025

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