

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benzalkonium Chloride Reckitt Benckiser 0.20% w/w Cutaneous Spray solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzalkonium Chloride 0.20% w/w

Contains the excipient propylene glycol Ph Eur 2.080% w/w

For a full list of excipients, see Section 6.1

3 PHARMACEUTICAL FORM

Cutaneous Spray, Solution (Topical Spray)

Product is a clear colourless liquid with slight pine odour

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the antiseptic cleansing of minor wounds

4.2 Posology and method of administration

For Cutaneous use

For adults and children over 12 months of age: For occasional, localised, short-term use only. To be applied to fresh minor wounds to eliminate common bacteria associated with infection of minor wounds. The product should be sprayed to cover the entire wound and can be re-applied if the wound is reopened

For adults and children over 6 years of age:

Spray a full dose (1 to 2 sprays) once **onto** each wound and leave for five minutes. If necessary use a clean tissue or cotton wool to wipe up any excess liquid.

For children aged between 1 and 6 years of age:

Please seek the advice of a pharmacist or healthcare professional prior to use if you have any concerns. Spray once (1 spray) **onto** each wound (**can only be applied to a maximum of 4 wounds at a time**) and leave for five minutes. If necessary use a clean tissue or cotton wool to wipe up any excess liquid.

This medicinal product is for use once in 24hours and for a maximum of 3 – 5 days. It should not be used on a continuous basis

If you have concerns about your symptoms or your symptoms get worse, please contact a healthcare professional

Table. Surface area coverage with a full spray of product.				
Distance (cm)	Weight (mg)	Surface Area (cm ²)	Product Dispensed per Surface Area	Amount of BKC Dispensed per Surface Area

			(mg/cm ²)	(mg)
4	173	13.2	13.1	0.026
6	173	15.1	11.5	0.023
8	173	17.7	9.8	0.020
10	173	19.1	9.1	0.018
12	173	22.4	7.7	0.015

Table. Volume and weight calculations per spray or per ml.			
ml per Spray	Mg Product per Spray	Mg BKC per Spray	Mg BKC per ml of Product
0.1722	172.96	0.3415	1.9837

The product is not intended to improve wound healing or be used to improve wound healing

4.3 Contraindications

Do not use on children of 1 years of age or under.

People with known hypersensitivity to Benzalkonium chloride or any of the excipients should not use Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray solution.

4.4 Special warnings and precautions for use

Label Warning: For external use only. Do not use around the eyes or genitalia or ears, in the mouth or over large areas of the body that exceed 5% of the total body surface area (5% is estimated to reflect minor wounds of both knees and elbows). Do not inhale. In the case of accidental eye contact the eye should be irrigated with copious amounts of cold water.

This medicinal product contains propylene glycol and may cause skin irritation.

Benzalkonium chloride may be deactivated when used with soap or any other surfactants.

4.5 Interaction with other medicinal products and other forms of interaction

No specific drug interaction studies have been undertaken; therefore, we cannot recommend the use of Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray solution with any other topical products.

4.6 Fertility, pregnancy and lactation

For Benzalkonium Chloride no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. The potential risk for humans is unknown.

Use during pregnancy and lactation is not expected to be associated with harmful effects as cutaneous absorption is minimal. In order to avoid ingestion by a breast fed child, application to the breasts during lactation is not advised

4.7 Effects on ability to drive and use machines

Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray solution has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Post-marketing experience shows no adverse experiences specific to the topical application of Benzalkonium Chloride

Reckitt Benckiser 0.20% w/w Cutaneous Spray solution; adverse experiences have been limited to those that are typically reported for topical antiseptics. Additional effects may occur. In general, the adverse reactions rate for topical antiseptics is very rare (<1/10,000).

Skin and subcutaneous tissue disorders:

Very Rare: skin dystrophy, acrodermatitis, exacerbation of eczema, contact dermatitis, alopecia or rash.

General disorders and administration site disorders:

Very Rare: (< 1/10,000) signs and symptoms of systemic allergic reactions, including papular rash, pruritus or rash.

Very Rare: local site reactions including application site fissure, a, skin irritation, skin burning sensation, erythema, skin discoloration or skin exfoliation

4.9 Overdose

Due to Benzalkonium Chloride low absorption into the systemic circulation following both oral and cutaneous application, its acute toxicity is very low and it is unlikely that any toxic effects would be seen in humans following either cutaneous dosing with Benzalkonium Chloride Reckitt Benckiser 0.20% w/w Cutaneous Spray solution as recommended or accidental ingestion. If necessary use a clean tissue or cotton wool to wipe up any excess liquid.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D08 AJ01 Group: Antiseptics and Disinfectants. Quaternary ammonium compounds.

Benzalkonium chloride is a quaternary ammonium compound which has been used for many years as a surfactant and antiseptic/disinfectant. It is known to be bactericidal in low concentrations (typically between 0.1 and 0.2%) to a wide range of Gram-positive and Gram-negative bacteria.

Benzalkonium chloride kills (a log 5 reduction) Staphylococcus aureus and beta-hemolytic Streptococci (e.g., Streptococcus pyogenes) in 1 minute, and Pseudomonas aeruginosa in 5 minutes

Table. In vitro bactericidal effects Benzalkonium Chloride Reckitt Benckiser 0.20% w/w Cutaneous Spray solution.				
Strain	Contact time	Medium	Result	Criteria met
Corynebacterium xerosis Staphylococcus epidermidis Proteus vulgaris Streptococcus pyogenes Staphylococcus aureus (MRSA) Enterococcus faecalis (VRE)	5 min	Full strength in clean (0.3) and dirty (3.0g/l bovine serum albumin)	>5.0 log reduction	EN 1276
Staphylococcus aureus Corynebacterium xerosis		Full strength in clean		

Staphylococcus epidermidis Proteus vulgaris Streptococcus pyogenes Staphylococcus aureus (MRSA) Enterococcus faecalis (VRE)	1 min	(0.3) and dirty (3.0g/l bovine serum albumin)	>5.0 log reduction	EN 1276
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Note: EN 1276 is designed to evaluate the antimicrobial efficacy of disinfectant products intended for use in food, industrial, domestic and institutional areas. It can be used to assess efficacy. A Five log reduction of all organisms in 5 minutes is required to pass the EN1276.

5.2 Pharmacokinetic properties

Quaternary ammonium compounds such as Benzalkonium chloride are only absorbed to a very small extent through human skin.

5.3 Preclinical safety data

The low level of Benzalkonium chloride in the product, coupled with its low level of absorption from intact and broken skin, make it unlikely that any significant systemic toxic effects would arise from its use. There is evidence that it can have an irritant effect on mucous membranes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Propylene glycol
- Sodium dihydrogen phosphate dihydrate
- Disodium hydrogen phosphate dodecahydrate
- Mild Pine fragrance
- Disodium edetate, dihydrate
- Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

10ml polypropylene bottle has a shelf life of 2 years.

100ml HDPE bottle has a shelf life of 3 years.

6.4 Special precautions for storage

No special storage conditions

6.5 Nature and contents of container

Polypropylene container, spray pump, with a polypropylene co-polymer overcap packed into polyethylene terephthalate (PET) blister and carton envelope.

The pack size is 10 ml.

HDPE container, spray pump, with a polypropylene co-polymer overcap.

The pack size is 100ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Benzalkonium Chloride Reckitt Benckiser 0.20% w/w Cutaneous Spray solution should not be disposed of via wastewater or household waste. Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 979/49/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 November 2009

10 DATE OF REVISION OF THE TEXT

January 2013