

PACKAGING LEAFLET: INFORMATION FOR THE USER

**Benzalkonium Chloride Reckitt Benckiser 0.20%w/w
CUTANEOUS SPRAY, SOLUTION
(Benzalkonium Chloride)
FOR EXTERNAL USE ONLY**

Important information about the ingredients of Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray

This product contains benzalkonium chloride 0.20% w/w as the active ingredient and 20.8 mg propylene glycol in each 100 ml, which may cause skin irritation.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

You must contact your Doctor if symptoms worsen or do not improve after 5 days.

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1. WHAT Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution IS AND WHAT IT IS USED FOR

Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution is used to cleanse fresh minor wounds and to get rid of common bacteria associated with infection of minor wounds. The product is not intended to improve wound healing or be used to improve wound healing.

It must not be used for large or serious wounds and it is intended for occasional, localised, short-term use only. It should be used only once in 24 hours.

It is ready to use and requires no dilution.

2. BEFORE YOU USE Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution

Do not use Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution

- On infants under 12 months of age

- If you are allergic or hypersensitive to Benzalkonium Chloride or any of the other ingredients of Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution.
- Not for continuous use or for use more than once in 24 hours.

Take special care and avoid use

- Around the eyes, ears or genitalia, or in the mouth. In the case of accidental eye contact, wash the eye out with large amounts of cold water.
- Do not inhale, for External use only.
- On large injuries covering more than 5% of body area (5% is estimated to reflect minor wounds of both knees and elbows).

Using other medicines

The use of Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution is not recommended while using any other similar product as there are no studies about the effects when used with any other medicines.

Pregnancy and Breast feeding

Use during pregnancy and breast feeding is not expected to be associated with harmful effects as skin absorption is minimal.

To avoid ingestion by a breast fed child, use on the breasts during breast feeding is not advised.

Please seek the advice of a pharmacist or healthcare professional if you want to use this product while pregnant or breast feeding.

Driving and using machines

Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution will not affect your ability to drive or operate machines.

Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution contains Mild Pine Fragrance

This medicine contains Mild Pine fragrance containing D-Limonene and Linal. D-Limonene and Linal may cause allergic reactions.

3. HOW TO USE BENZALKONIUM CHLORIDE RECKITT BENCKISER 0.20%W/W CUTANEOUS SPRAY

Always use Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution exactly as follows unless your doctor has told you something different. You should check with your doctor or pharmacist if you are not sure.

For external use only.

When first using or after a long period of not being used it may be necessary to prime the spray first by spraying into a tissue or similar first to ensure a full spray is delivered to the wound.

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 before 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.

Spray from between 4 and 15 cms. Do not inhale.

Soap can deactivate the spray so do not use as well to wash the wound.

The Spray can be re-applied if the wound is reopened but it is not for continuous use and **should be used only once in 24 hours for a maximum of 3 – 5 days.**

If you have any further questions on the use of this product, or have concerns about your symptoms please consult a healthcare professional.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution can cause side effects, although not everybody gets them.

Very rare side effects (occur in less than 1 user in 10,000) have been reported following the localised cleansing of minor wounds and have included skin itching, rashes, irritation, burning, swelling and discolouration or reddening. There may be a reaction in the place where the product was used, such as the skin splitting. In the event of such reactions please stop using the product and seek the advice of a pharmacist or healthcare professional. If you suffer from eczema, use of this product may make it worse. Hair loss has been reported.

If any of the side effects persist or gets serious, or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution

Keep out of the reach and sight of children.

Do not use Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

There are no special requirements for storage.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray Solution contains

- The active substance is Benzalkonium chloride 0.20% w/w.
- The other ingredients are propylene glycol, sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dodecahydrate, mild pine fragrance, disodium edentate dihydrate and purified water

What Benzalkonium Chloride Reckitt Benckiser 0.20% Cutaneous Spray Solution looks like and contents of the pack

Benzalkonium Chloride Reckitt Benckiser 0.20% Cutaneous Spray Solution is a clear colourless solution with the mild odour of pine. It comes ready to use in pump spray bottles of 10ml and 100ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

MA holder:
Reckitt Benckiser Ireland, Ltd.
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd,
Dansom Lane, Hull, HU8 7DS.

For product queries please call: 01-6305429

This leaflet was last approved in December 2012

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of Member state	Name of Medicine
Belgium	Dettolmedical Benzalkoniumchloride 0.2% Huidspray, oplossing
Bulgaria	Dettol Med Wound Spray 0.20 % w/w Cutaneous Spray Solution
Cyprus	Dettol Med Wound Spray 0.20 % w/w
Czech Republic	Dettol 0.20% antiseptický sprej
Estonia	Dettol Med
Finland	Dettolmed, 2 mg/ml Sumute iholle, liuos
France	Dettolpro 0.2%, solution pour pulvérisation cutanée
Greece	Dettox Wound Spray 0.20% w/v
Hungary	Dettol Med külsőleges oldatos spray
Iceland	Dettolmed, 0,20% w/w Húdúdi, lausn
Ireland	Benzalkonium Chloride Reckitt Benckiser 0.20%w/w Cutaneous Spray solution
Italy	Dettolmed 0.2% w/w Spray Cutaneo Soluzione (Benzalconio Cloruro)
Latvia	Dettol Med 0,20 % uz ādas izsmidzināms aerosols, šķīdums
Lithuania	Dettol Med 0,20 % odos purškalas, tirpalas
Luxembourg	Dettolmedical Benzalkoniumchloride 0,2% solution
Netherlands	Dettol Med Benzalkoniumchloride 2 mg/g huidspray,oplossing voor cutaan gebruik
Norway	Dettolmed, 0,2 % w/w Huidspray, oppløsning
Poland	Dettol Med do przemywania ran

Name of Member state	Name of Medicine
Portugal	Detolpro, 2 mg/g solução para pulverização cutânea
Romania	DettolMed 0,2% spray cutanat, soluție
Slovak Republic	Dettolmed 0,20%w/w Antiseptický sprej
Slovenia	DettolMed 2 mg/g dermalno pršilo, raztopina
Spain	DettolMed 2 mg/ml solución para pulverización cutánea
Sweden	Dettolmed, 2 mg/ml Kutan spray, lösning