

Germolene®

wound care cream

Chlorhexidine Dihydrochloride 0.5% w/w

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 Germolene Wound Care Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again. serious symptoms, severe rash, or shock),
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

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I. WHAT IS GERMOLENE® WOUND CARE CREAM AND WHAT IS IT USED FOR?

Germolene Wound Care Cream is a gentle but effective treatment for minor abrasions, cuts, scratches, burns, bites and stings.

The cream contains chlorhexidine dihydrochloride which has a gentle antiseptic action to help prevent infection.

The cream base helps to soften the skin and soothe irritation.

2. BEFORE YOU USE GERMOLENE® WOUND CARE CREAM

DO NOT use Germolene Wound Care Cream:

- If you are allergic (hypersensitive) to chlorhexidine dihydrochloride or any of the other ingredients of Germolene Wound Care Cream (See section 6, Further information).
- On the inside of your ears if you have a hole or tear in your eardrum.

Warnings and precautions

Rare but serious allergic reactions including anaphylaxis have been reported with use of chlorhexidine containing antiseptic products. If symptoms of a serious allergic reaction appear (e.g. wheezing or difficulty breathing, swelling of the face, hives that can quickly progress to more serious symptoms, severe rash, or shock), immediately stop using this product and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

Germolene Wound Care Cream must not come into contact with the eye due to risk of visual damage. If it comes into contact with the eyes, wash out immediately and thoroughly with water. In case of any irritation, redness or pain in the eye, or visual disturbance, ask for medical advice promptly.

Serious cases of persistent corneal injury (injury to the surface of the eye) potentially requiring corneal transplant have been reported when similar products have accidentally come in contact with the eye during surgical procedures, in patients under general anaesthesia (deep painless sleep).

Pregnancy and breast-feeding:

You may use the cream if you are pregnant or breast-feeding but as with all medicines at this time, you should discuss it with your doctor first.

Important information about some of the ingredients of Germolene Wound Care Cream:

This cream contains cetyl alcohol, stearyl alcohol and wool fat (lanolin) which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE GERMOLENE® WOUND CARE CREAM

Follow the directions below carefully.

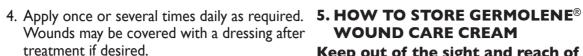
Wash your hands before and after using the cream.

- 1. Before using the product for the first time, check that the tube seal is not broken.
- other ingredients of Germolene Wound Care 2. Pierce the tube seal by inverting the cap over Cream (See section 6, Further information). the end of the tube and press.
 - 3. Thoroughly clean the affected area of skin with warm water (do not use soap).









5. Replace the cap firmly after use.

If your condition does not improve, tell your

Avoid applying other antiseptics at the same time as Germolene Wound Care Cream as this may reduce its effectiveness.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

This cream is for external use only.

Do not put in your ears or mouth. If some of the cream is swallowed accidentally, tell your doctor straight away or contact your nearest Accident and Emergency Department.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Germolene Wound Care Cream can cause side effects, although not everybody gets them.

You may experience the following:

- A serious allergic reaction which causes difficulty in breathing and dizziness. If this happens stop using this product, tell your doctor straight away or go to the Accident and Emergency Department of your nearest hospital.
- An allergic skin reaction (local irritation, rash, itching) and/or a burning sensation. Applying the product over large areas of skin may increase the risk of these reactions.
- Corneal injury (injury to the surface of the eye), and permanent eye damage including permanent visual impairment (following accidental ocular exposure during head, face and neck surgical procedures) in patients under general anaesthesia (deep painless sleep).

If you are concerned about this, or if the cream affects you in any other way, stop using Germolene Wound Care Cream and tell your doctor or pharmacist immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

WOUND CARE CREAM

Keep out of the sight and reach of children.

Store below 25°C.

This product should be stored in its original carton. Do not use Germolene Wound Care Cream after the expiry date which is stated on the carton and on the end of the tube. The expiry date refers to the last day of that month. 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 Germolene Wound Care Cream** contains:

The **active substance** is chlorhexidine dihydrochloride 0.5% w/w.

The **other ingredients** are dexpanthenol, DL-lactone, cetyl alcohol, stearyl alcohol, white soft paraffin, liquid paraffin, wool fat (lanolin), macrogol stearate and purified water.

See the end of section 2 'Important information about some of the ingredients of Germolene Wound Care Cream' for cetyl alcohol, stearyl alcohol and wool fat (lanolin) advice.

What Germolene Wound Care Cream looks like and contents of the pack:

Germolene Would Care Cream is available in tubes containing 30g or 90g of white cream (not all pack sizes may be marketed).

Marketing Authorisation Holder:

Bayer plc 400 South Oak Way, Reading, RG2 6ÅD United Kingdom

Manufacturer:

GP Grenzach Produktions GmbH Emil-Barell-Straße 7 D-79639 Grenzach-Wyhlen Germany

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Remember: if you have any doubts about using Germolene® Wound Care Cream correctly, seek the advice of your doctor or pharmacist.

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