

Germolene[®]

antiseptic cream

Phenol and Chlorhexidine Digluconate

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 Antiseptic Cream 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.
- 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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1. WHAT IS GERMOLENE[®] ANTISEPTIC CREAM AND WHAT IS IT USED FOR?

Germolene Antiseptic Cream is used to ease pain and help prevent infections of minor cuts and grazes, minor burns, scalds, blisters, stings and insect bites, spots and chapped or rough skin.

The cream contains two active substances, phenol and chlorhexidine digluconate. Phenol and chlorhexidine digluconate have antiseptic properties for the disinfection of skin, wounds and burns. Phenol also has a local anaesthetic action for the relief of pain. The cream base helps to soften the skin and soothe irritation.

2. BEFORE YOU USE GERMOLENE[®] ANTISEPTIC CREAM

DO NOT use Germolene Antiseptic Cream:

- If you are allergic (hypersensitive) to phenol or chlorhexidine digluconate or any of the other ingredients of Germolene Antiseptic Cream (See section 6, Further information).

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 Antiseptic Cream:

This cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE GERMOLENE[®] ANTISEPTIC 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.
2. Break the tube seal by peeling from the tag.
3. Thoroughly clean the affected area of skin with warm water (do not use soap).
4. **Minor cuts, grazes etc** - apply the cream directly or on a dressing.
Minor burns, scalds and blisters - apply the cream generously and massage in gently.
5. Replace the cap firmly after use.

If your condition does not improve, tell your doctor.

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

This cream is for external use only.
Avoid contact with your eyes and 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 Antiseptic Cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream. Seek medical advice straight away if you experience any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body). These are signs of an allergic reaction which may be serious and require medical treatment.

Rarely, you may experience local irritation, rash, or other skin reactions at the site of application after applying the cream.

Frequent application of the cream to the same area for long periods of time or over large areas of skin may lead to skin irritation.

If you are concerned about this, or if the cream affects you in any other way, stop using Germolene Antiseptic 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE GERMOLENE® ANTISEPTIC CREAM

Keep out of the sight and reach of children.

Do not store above 25°C.

This product should be stored in its original carton.

Do not use Germolene Antiseptic 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 Antiseptic Cream contains:

The **active substances** are phenol 1.2% w/w and chlorhexidine digluconate 0.25% w/w.

The **other ingredients** are cetostearyl alcohol, light liquid paraffin, polyoxyethylene stearyl ethers, colours (ponceau 4R (E124), sunset yellow (E110)), dimeticone, methyl salicylate and water.

See the end of section 2 'Important information about some of the ingredients of Germolene Antiseptic Cream' for cetostearyl alcohol advice.

What Germolene Antiseptic Cream looks like and contents of the pack:
Germolene Antiseptic Cream is available in tubes containing 20g, 30g, 35g, 40g or 55g of a pale pink cream (not all pack sizes may be marketed).

Marketing Authorisation Holder:

Bayer plc, Consumer Care Division
Bayer House, Strawberry Hill
Newbury, Berkshire RG14 1JA
United Kingdom

Manufacturer:

Kern Pharma, S.L.
Polígono Industrial Colon II
C/ Venus, 72
E-08228-Terrassa (Barcelona)
SPAIN

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

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