

BAYER ARTWORK PANEL

Bayer Ref No:

BAY615012

Trident Reference No:

TR3230974

Brand:

Germolene

Range:

Antiseptic Cream

Product:

Dual Action

Pack Type:

Leaflet

Pack Size:

30G/55G/30G g

Action:

D

Date:

08/07/2024

Country:

UK

Finished Goods Code:

84149004 84149012 84149020

Synaps Request Code:

TL032487

Component Code:

8080899000-04

2nd Component Code:

N/A

CAD Ref No:

PIL 148 x 210 (P041)

Printer:

Generic Bayer

Packaging Site:

Ke n Phz [ES]

Substrate:

White Paper

Barcode 1 Type:

Pharmacode Standard

Barcode 1 Mag:

100%

Barcode 2 Type:

N/A

Barcode 2 Mag:

N/A

Barcode 3 Type:

N/A

Barcode 3 Mag:

N/A

Pharmacode No/NE:

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Height (based on lower case x):

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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.

IN THIS LEAFLET:

1. What is Germolene Antiseptic Cream and what is it used for?
2. Before you use Germolene Antiseptic Cream
3. How to use Germolene Antiseptic Cream
4. Possible side effects
5. How to store Germolene Antiseptic Cream
6. Further information

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).

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 Antiseptic 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 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.

BAYER ARTWORK PANEL

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Pack Size:	30G/55G/30G g
Action:	D
Date:	08/07/2024
Country:	UK

Finished Goods Code:	84149004 84149012 84149020
Synaps Request Code:	TL032487
Component Code:	8080899000-04
2nd Component Code:	N/A

CAD Ref No:	PIL 148 x 210 (P041)
Printer:	Generic Bayer
Packaging Site:	K€ n ES]
Substrate:	White Paper

Barcode 1 Type:	Pharmacode Standard
Barcode 1 Mag:	100%
Barcode 2 Type:	N/A
Barcode 2 Mag:	N/A
Barcode 3 Type:	N/A
Barcode 3 Mag:	N/A
Pharmacode No/NE:	110100111 (934)

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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 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.

Other possible side effects include 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 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 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.

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,
400 South Oak Way,
Reading
RG2 6AD, UK

Manufacturer:

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

This leaflet was last revised in June 2024.

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

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Germolene®
antiseptic cream

Bayer 8080899000-04

