

WITH LOCAL ANAESTHETIC

germoloids[®]

Zinc Oxide and Lidocaine

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 Germoloids 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 GERMOLOIDS[®] CREAM AND WHAT IS IT USED FOR?

Haemorrhoids (also known as piles) are swollen or enlarged blood vessels, which can cause discomfort, itching and irritation, particularly after a bowel movement. They may be either internal (inside the anus) or external (outside the anus).

Germoloids Cream is used to relieve the symptoms of pain, swelling and irritation associated with internal and external haemorrhoids and anal itching (pruritus ani).

The cream contains two active substances, zinc oxide and lidocaine. Zinc oxide has astringent properties (causes contraction when applied to the skin), which help to shrink swelling. It also helps to soothe and protect the area around the anus from damage and has mild antiseptic properties. Lidocaine is a local anaesthetic, which helps to soothe swelling, pain and irritation and relieve itching. The cream base acts as an emollient to help the passing of stools and reduce straining during bowel movement which is bad for haemorrhoids.

2. BEFORE YOU USE GERMOLOIDS[®] CREAM

DO NOT use Germoloids Cream:

This medicine must not be used if you are allergic (hypersensitive) to zinc oxide or lidocaine, or any of the other ingredients in the product (see section 6, Further information).

Before using Germoloids Cream, see your doctor if you:

- Continually suffer from haemorrhoids or have severe haemorrhoids.
- Experience excessive bleeding.

Pregnancy and breast-feeding:

You may use Germoloids 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 Germoloids Cream:

The cream contains methyl hydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

3. HOW TO USE GERMOLOIDS[®] CREAM

Follow the directions below carefully.

Wash your hands before and after using the cream.

Adults and children aged 12 years and over:

1. Before using the cream for the first time, check that the tube seal is not broken.
2. Remove the seal by peeling from the tag.
3. For **external haemorrhoids**, apply the cream directly to the affected area.

For **internal haemorrhoids**, screw the applicator nozzle onto the tube and smear some of the cream on the outside of the nozzle to ease application. Carefully insert the applicator into the opening of the anus. Gently squeeze the tube whilst slowly withdrawing the nozzle so that the cream moves gently up the anus.

4. Replace the cap firmly after use. Always keep the tube of cream, cap and nozzle clean.

Apply the cream to the affected area at least twice a day with a minimum of 3 to 4 hours between applications. Further applications can be made at any time of the day, and are particularly recommended after a bowel movement. **Do not use the cream more than 4 times in any 24 hour period.**

Germoloids Cream is not recommended for children under the age of 12 years, unless it is used under the supervision of a doctor.

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

The cream is for use in and around the anus only. Do not put the cream in your mouth or swallow it. If some of the cream is swallowed accidentally, tell your doctor straight away or contact your nearest Accident and Emergency Department.

How to help reduce the occurrence and/or severity of the condition:

Constipation and straining during bowel movement can make haemorrhoids worse. To help avoid this, the following steps can be taken: eat a high fibre diet of fruits, vegetables and whole grain food; drink plenty of fluids, at least eight glasses a day (preferably water); go to the toilet immediately when you need to pass stools and try to avoid straining during bowel movement; exercise regularly as it can help to stimulate regular bowel movement.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Germoloids Cream can cause side effects, although not everybody gets them. Rarely, you may experience increased local irritation at the site of application after applying the cream. If you experience any of these symptoms or react badly to the cream in any other way, stop using this product 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 GERMOLOIDS® CREAM

Keep out of the reach and sight of children.

Do not store above 25°C. This product should be stored in its original carton.

Do not use the cream after the expiry date which is stated on the pack and on the end of the tube of cream. 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 Germoloids Cream contains:

The active substances are zinc oxide (6.6% w/w) and lidocaine hydrochloride (0.7% w/w).

The other ingredients are emulsifying wax, white soft paraffin, methyl salicylate, methyl hydroxybenzoate (E218), butyl hydroxybenzoate and water.

See end of Section 2 'Important information about some of the ingredients of Germoloids Cream' for methyl hydroxybenzoate (E218) advice.

What Germoloids Cream looks like and contents of the pack:

Germoloids Cream is available in tubes containing 25g or 55g of a white cream (not all pack sizes may be marketed).

Marketing Authorisation Holder: Bayer plc, Consumer Care Division, Bayer House, Strawberry Hill, Newbury, Berkshire RG14 1JA, UK

Manufacturer: Famar A.V.E. Avlon Plant, 49th km National Road Athens-Lamia, Avlona Attiki, 19011, Greece

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

UK residents only: if you have any questions or would like more information on haemorrhoids, call the Germoloids Advice line on 0845 60 10 901*

*calls charged at local rate.