

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 Ointment 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 Germoloids Ointment and what is it used for?
- 2. Before vou use Germoloids Ointment
- 3. How to use Germoloids Ointment
- 4. Possible side effects
- 5. How to store Germoloids Ointment
- 6. Further information

1. WHAT IS GERMOLOIDS® OINTMENT 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 Ointment is used to relieve the symptoms of pain, swelling and irritation associated with internal and external haemorrhoids and anal itching (pruritus ani).

The ointment 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 ointment base acts as a lubricant and emollient to help the passing of stools and reduce the straining during bowel movement which is bad for haemorrhoids.

2. BEFORE YOU USE GERMOLOIDS® OINTMENT

DO NOT use Germoloids Ointment:

This medicine may 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 Ointment, see your doctor if you:

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

Pregnancy and breast-feeding:

You may use Germoloids Ointment 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 Ointment:

The ointment contains wool fat and propylene glycol which may cause local skin reactions (eg irritation, contact dermatitis).

3. HOW TO USE GERMOLOIDS® OINTMENT

Follow the directions below carefully.

Wash your hands before and after using the ointment.

Adults and children aged 12 years and over:

- 1. Before using the ointment 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 ointment directly to the affected area.
 For internal haemorrhoids, screw the applicator nozzle onto the tube and smear some of the ointment 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 ointment moves gently up the anus.

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

Apply the ointment 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 ointment more than 4 times in any 24 hour period.**

Germoloids Ointment 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 ointment is for use in and around the anus only. Do not put the ointment in your mouth or swallow it. If some of the ointment 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 Ointment can cause side effects, although not everybody gets them. Rarely, you may experience increased local irritation, burning sensations or rashes at the site of application after applying the ointment.

If you experience any of these symptoms or react badly to the ointment in any other way, stop using this product and tell your doctor or pharmacist immediately.

5. HOW TO STORE GERMOLOIDS® OINTMENT

Keep out of the reach and sight of children.

This product should be stored in its original carton.

Do not use the ointment after the expiry date which is stated on the carton and on the end of the tube of ointment. 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 Ointment contains:

The active substances are zinc oxide (6.6% w/w) and lidocaine hydrochloride (0.7% w/w). The other ingredients are yellow soft paraffin, wool fat, methyl salicylate, propylene glycol and menthol.

See end of Section 2 'Important information about some of the ingredients of Germoloids Ointment' for wool fat and propylene glycol advice.

What Germoloids Ointment looks like and contents of the pack:

Germoloids Ointment is available in tubes containing 25ml or 55ml of an off-white ointment (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: Wrafton Laboratories Ltd. Wrafton, Braunton, North Devon, EX33 2DL, UK

Remember: if you have any doubts about using Germoloids® Ointment 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.

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