

WITH LOCAL ANAESTHETIC

germoloids[®] Suppositories

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 Suppositories 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 ARE GERMOLOIDS[®] SUPPOSITORIES AND WHAT ARE THEY 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 Suppositories are used to relieve the symptoms of pain, swelling and irritation associated with internal haemorrhoids and anal itching (pruritus ani).

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

2. BEFORE YOU USE GERMOLOIDS[®] SUPPOSITORIES

DO NOT use Germoloids Suppositories:

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 Suppositories, see your doctor if you:

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

Pregnancy and breast-feeding:

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

3. HOW TO USE GERMOLOIDS[®] SUPPOSITORIES

Follow the directions below carefully.

Wash your hands before and after using the suppository.

Adults and children aged 12 years and over:

The suppositories are only for use inside the anus.

1. Gently clean and dry the area around the anus.
2. Tear down on the perforation to remove one suppository from the strip.
3. Peel apart the blister to remove the suppository.
4. Insert the suppository into the anus (round end first).

Insert one suppository into the anus when you go to bed at night and one in the morning, preferably after a bowel movement. If necessary the suppositories may be used at any time during the day, with a minimum of 3 to 4 hours between suppositories. **Do not use more than 4 suppositories in any 24 hour period.**

Germoloids Suppositories are not recommended for children under the age of 12 years, unless they are used under the supervision of a doctor.

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

The suppositories are for use in the anus only. Do not put the suppository in your mouth or swallow it. If the suppository 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 Suppositories can cause side effects, although not everybody gets them. Rarely, you may experience increased local irritation after inserting the suppository. If you experience these symptoms, 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[®] SUPPOSITORIES

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 the suppositories after the expiry date which is stated on the carton and on the suppository blister pack. 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 Suppositories contain:

The active substances are zinc oxide (263.5 mg) and lidocaine hydrochloride (13.2 mg). The other ingredients are fat suppository base, methyl salicylate and glyceryl tristearate.

What Germoloids Suppositories look like and contents of the pack:

Germoloids Suppositories come in strips of six white, torpedo-shaped suppositories, packed in cartons containing 12 or 24 suppositories (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: Delpharm Huingue S.A.S., 26, rue de la Chapelle, F68330 Huingue, France

Remember: if you have any doubts about using Germoloids[®] Suppositories 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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