

# Anusol ointment

zinc oxide, bismuth oxide, bismuth subgallate, peru balsam

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse or if you have **rectal bleeding** or **blood in the stool** which has not been diagnosed as piles.

## What is in this leaflet

1. What Anusol Ointment is and what it is used for
2. What you need to know before you use Anusol Ointment
3. How to use Anusol Ointment
4. Possible side effects
5. How to store Anusol Ointment
6. Contents of the pack and other information

## 1. What Anusol Ointment is and what it is used for

Anusol Ointment contains the active substances zinc oxide, bismuth oxide, bismuth subgallate, Peru balsam. It belongs to a group of agents used for the treatment of haemorrhoids and anal fissures for topical use.

Anusol Ointment is used to relieve the pain, swelling, itch and irritation of internal and external piles (haemorrhoids) and other minor ano-rectal conditions such as anal itching and fissures as diagnosed by a doctor. It can be used post-operatively following ano-rectal surgery as advised by a doctor.

Anusol Ointment is for use by adults over the age of 18 years

## How Anusol Ointment works

Anusol Ointment provides antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions. Anusol Ointment also provides lubricating properties for use with suppositories.

**Zinc oxide** which is an astringent which soothes and protects raw areas and helps reduce swelling. It also acts as an antiseptic

**Peru balsam** which is mildly antiseptic and has a protective action on sore areas and may help healing.

**Bismuth salts** which is astringent and antiseptic and also protects raw, irritated areas around the anal area.

You must talk to a doctor if you do not feel better or if you feel worse or if you have **rectal bleeding** or blood in your stool or if **you are in doubt whether any bleeding you have experienced is caused by piles**.

## **2. What you need to know before you use Anusol Ointment**

This medicine is suitable for most people but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

### **Do not use this medicine....**

- If you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6)

### **Warnings and precautions**

- Not to be taken orally
- Talk to your doctor or pharmacist before using Anusol Ointment
- If you have **rectal bleeding** or blood in your stool **or if you are in doubt whether any bleeding you have experienced is caused by piles**.

If symptoms persist or worsen stop use and consult your doctor.

### **Children and adolescents under 18 years of age**

Not recommended.

### **Other medicines and Anusol Ointment**

Tell your doctor or pharmacist if you are taking or using, have recently taken or used or might take or use any other medicines.

### **Pregnancy, breast-feeding and fertility**

- If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

### **Driving and using machines**

Not relevant.

### **Some of the Ingredients can cause problems**

- Castor oil may cause skin reactions.
- Wool fat may cause local skin reactions (e.g. contact dermatitis). Wool fat may contain an antioxidant, butylated hydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis) or irritation to the mucous membranes.
- Peru balsam may cause skin reactions.
  - This medicine contains approximately 131 mg benzyl alcohol in each 100g. Benzyl alcohol may cause allergic reactions and/or mild local irritation.
  - This medicine contains approximately 1406 mg benzyl benzoate in each 100g. Benzyl benzoate may cause local irritation.
  - Benzyl cinnamate may cause allergic reactions.

### 3. How to use Anusol Ointment

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**The recommended dose is:**

**Adults and the elderly:**

Age	Dose
Adults and the elderly	Anusol Ointment should be applied sparingly to the affected area at night, in the morning after each bowel movement.
• Do NOT take orally	

**Children and adolescents (under 18 years of age):**

This medicine should not be used in children under the age of 18 years except on the advice of a doctor.

**Method of administration:**

Anusol Ointment is for topical use only, which means it is applied directly to the affected area.

- Wash the anal area and dry gently with a soft towel before using the medicine.
- There is a nozzle supplied with the product which can be used to apply the ointment into the back passage (anus).
- **For external piles** -after washing and drying the affected area, the ointment should be applied using a gauze dressing.
- **For Internal piles** -after washing and drying the affected area, screw the nozzle provided onto the tube, remove the nozzle cap; insert the nozzle into the back passage and squeeze gently. Clean the nozzle after each use.
- Wash your hands before and after using Anusol.
- Use Anusol ointment cautiously to avoid large amounts of disposal via wastewater or household waste.

**If you use more Anusol Ointment than you should**

If you use more Anusol Ointment than you should or if you accidentally swallow Anusol Ointment, contact a doctor or your nearest Accident and Emergency Department, taking this leaflet and pack with you.

**If you forget to use Anusol Ointment**

Anusol Ointment should be used on an as required basis. However, if you were unable to use this product when needed, **do not** use a double dose next time you use it.

### 4. Possible side-effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**If you experience the following, stop using the medicine and talk to your doctor:**

**Rare: may affect up to 1 in 1,000 people**

- Hypersensitivity reactions (such as rash).

**Not known: frequency cannot be estimated from the available data**

- Burning, redness, irritation, itching, or pain may occur when applying the ointment. This does not usually last a long time, so if this lasts longer than a few days, tell your doctor.

**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 HPRRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie).

By reporting side effects you can help provide more information on the safety of the medicine.

## **5. How to store Anusol Ointment**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the date shown as expiry date which is stated on the carton and tube. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Anusol Ointment contains?**

**The active substances are per 100 g:** Zinc oxide 10.75 g, Bismuth subgallate 2.25 g, Peru balsam 1.875 g (contains benzyl alcohol, benzyl benzoate and benzyl cinnamate), Bismuth oxide 0.875 g.

**Other Ingredients are:** Magnesium stearate, cocoa butter, kaolin light, paraffin, white soft, wool fat (E913) (may contain butylated hydroxytoluene (E321)) and castor oil.

### **What the medicine looks like and contents of the pack**

Anusol is a buff coloured ointment available in 25 g tubes.

### **Marketing Authorization Holder:**

SOFIBEL,  
110-114 rue Victor Hugo,  
92686 Levallois Perret Cedex, France.

### **Manufacturer:**

Laboratories M Richard, rue du Progres,

ZI des Reys de Saulce, Saulce Sur Rhone. 26270 France

Or

Delpharm Orleans, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France

**This leaflet was revised in January 2022.**

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## **A Healthy Living Plan for Piles Sufferers**

### **What are piles?**

Piles (haemorrhoids) are swollen blood vessels which occur inside or outside the back passage (anus).

### **Symptoms**

Some people have piles without experiencing any symptoms, but sufferers may notice the following:

- **Bleeding:** Although streaks of bright red blood on the toilet paper are not uncommon in people with piles, it may be a sign of a more serious condition and you should see your doctor to check this.
- **Swelling:** The swollen blood vessels may be felt as a lump or blockage in the anus.
- **Pain, itching and irritation** in the anal region. At least 40% of people suffer from piles at some time in their lives. However, many people are too embarrassed to seek advice or treatment and, as a result, suffer unnecessary discomfort.

Fortunately, there is much you can do to ease the situation and relieve the symptoms.

### **What causes piles?**

A number of factors can contribute to the development of piles:

- The most common cause is straining during bowel movement, usually as a result of constipation.
- During pregnancy, the growing baby exerts increased pressure on the anal vessels, which can lead to piles.
- Heredity: you may be more likely to develop piles if your family has a history of suffering.

## **A Healthy Living Plan for Piles Sufferers**

You can reduce the risk of piles by following a healthy diet and lifestyle that helps to keep your bowels working regularly and prevents constipation. This can also help to speed recovery from piles.

- Eat a high fibre diet including foods like brown rice, wholemeal bread, wholewheat pasta etc.
- Eat plenty of fresh fruit, vegetables and salads.
- Drink plenty of water.
- Don't eat too much salty, fatty or sugary foods such as crisps, burgers and cakes.
- Cut back on the amount of alcohol, tea and coffee you drink.
- Exercise regularly.

A healthy diet and lifestyle will reduce the likelihood of constipation and encourage a regular bowel habit. Go to the toilet regularly and try to avoid straining. Leaning forward from the hips may help.

For external and internal piles, Ointment can be used.

If internal haemorrhoids are the problem, Suppositories deliver a measured dose to the affected area.

**For any further information about this medicine, please contact the Marketing Authorisation Holder:**

SOFIBEL,

110 -114 rue Victor Hugo,

92686 Levallois Perret Cedex, France.

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