

Package leaflet: Information for the patient

Anusol[®] HC ointment
Hydrocortisone acetate, zinc oxide, bismuth oxide, bismuth subgallate, balsam peru, benzyl benzoate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

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

1 What Anusol HC Ointment is and what it is used for

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

Anusol HC Ointment is used to relieve the swelling, itch and irritation of internal and external piles (haemorrhoids) and anal itching in adults over the age of 18 years.

How Anusol HC Ointment works

This product provides antiseptic, astringent, emollient and anti-inflammatory actions.

Hydrocortisone acetate is a mild steroid which helps reduce inflammation.

Zinc oxide and **Bismuth salts** are mildly astringent and antiseptic. They soothe and protect raw areas.

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

Benzyl benzoate has mild antiseptic properties.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days using the product, if you have **rectal bleeding or blood in the stool** which has not been diagnosed as piles.

2 What you need to know before you use Anusol HC 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 Anusol HC Ointment

- If you are allergic to hydrocortisone acetate, zinc oxide, bismuth oxide, bismuth subgallate, balsam Peru, benzyl benzoate or any of the other ingredients of this medicine (listed in section 6).
- If you have **fungal, viral or bacterial skin sores**.
- If you are pregnant or breastfeeding.

⚠ Warnings and precautions

Talk to your doctor or pharmacist before using Anusol HC Ointment

- If you have **rectal bleeding or blood in the stool** or if you are in doubt whether any bleeding you have experienced is caused by piles.
- If symptoms worsen or do not improve stop using Anusol HC Ointment and talk to your doctor.
- Do not use for more than 7 days unless under the direction of a doctor.
- If you experience blurred vision or other visual disturbances contact your doctor.

⚠ Children

- Not recommended.

⚠ Other medicines and Anusol HC Ointment

- Tell your doctor or pharmacist if you are taking or using, or have recently taken or used any other medicines.
- Concurrent use with other corticosteroid preparations, either topically or orally may increase the likelihood of systemic effects.
- Co-treatment with some medicines (including some medicines for HIV, ritonavir, cobicistat), may increase the effects of Anusol HC Ointment and your doctor may wish to monitor you carefully if you are taking these 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, do not use this medicine.

⚠ Driving and using machines

- Not applicable.

Anusol HC Ointment contains Castor Oil and Lanolin anhydrous

- Castor oil may cause skin reactions.
- Lanolin anhydrous may cause local skin reactions e.g. contact dermatitis which is a local irritation at the site of use.

3 How to use Anusol HC Ointment

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is:

Age	Dose
Adults and the elderly	Apply sparingly to the affected area. You should use as often as prescribed by your doctor, however Anusol HC Ointment is usually used at night, in the morning and after each bowel movement.
■ Do NOT take orally ■ Do not use more than 4 times a day unless prescribed otherwise by your doctor	

Method of administration:

Anusol HC 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 this 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.

Duration of treatment:

Do not use for more than 7 consecutive days.

⚠ If you use more Anusol HC Ointment than you should

- If you use more Anusol HC Ointment than you should, or if you accidentally swallow Anusol HC Ointment, contact a doctor or your nearest Accident and Emergency department (Casualty) taking this leaflet and pack with you.

⚠ If you forget to use Anusol HC Ointment

- Anusol HC 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.

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

4 Possible side effects

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

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

- Hypersensitivity reactions (such as rash).

If you experience this, stop using the medicine and talk to your doctor.

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.
- Blurred vision.

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 effect you can help provide more information on the safety of this medicine.

5 How to store Anusol HC Ointment

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

Do not use your medicine after the date shown as an expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 HC Ointment contains

The active substances are per 100 g: Hydrocortisone acetate (0.25 g), Zinc oxide (10.75 g), Bismuth subgallate (2.25 g),

Balsam Peru (1.875 g), Bismuth oxide (0.875g) and Benzyl benzoate (1.25 g).

The other ingredient(s) are: Magnesium stearate, cocoa butter, lanolin anhydrous, castor oil, kaolin light, calcium hydrogen phosphate and petroleum jelly white.

Anusol HC Ointment contains Castor Oil and Lanolin Anhydrous'.

What Anusol HC Ointment looks like and contents of the pack

Anusol HC Ointment is a buff coloured ointment available in 30 g tubes.

Marketing Authorisation Holder:
Church & Dwight UK Ltd.,
Premier House, Shearway Business Park,
Pent Road, Folkestone, Kent
CT19 4RJ, United Kingdom.

Manufacturer:
Laboratoires M. Richard
Rue du Progres
ZI des Reys de Saulce
Saluce Sur Rhône
26270 France
Or
Delpharm Orléans
5 avenue de Concyr
45071 Orléans
Cedex 2
France

This leaflet was revised August 2020.

Anusol is a registered trade mark.

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 information about this medicine, please contact the Marketing Authorisation Holder:
Church & Dwight UK Ltd.,
Premier House, Shearway Business Park,
Pent Road, Folkestone, Kent
CT19 4RJ, United Kingdom.
Medical information direct line:
+44 (0) 800 028 1454
Via email: aesip@sipdrugsafety.com
PL 00203 / 0238



09078AC