

Anusol® HC ointment

hydrocortisone acetate, zinc oxide, bismuth oxide, bismuth subgallate, balsam peru, benzyl benzoate

■ This medicine is used for the relief of internal and external piles, anal itching, anal inflammation and anal fissures. It can also be used following ano-rectal surgery.

■ This medicine is for use in adults over the age of 18 years.

■ **Do not use this medicine:**

■ If you have had a **bad reaction** to Anusol or any of the ingredients in it. *See section 6*

■ If you have **fungal, viral or bacterial skin sores**. *See section 2*

■ **Speak to your doctor:**

■ If you have **rectal bleeding** which has not been diagnosed as piles. *See section 2*

■ If your symptoms have worsened or not improved within 7 days of using this product. *See section 2*

■ **Follow the instructions on how to use this product carefully.** *See section 3*

This medicine has been prescribed for you by your doctor. Do not pass it onto others. It may harm them even if their symptoms are the same as yours.

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Anusol HC Ointment helps to relieve the pain, swelling, itch and irritation of internal and external piles, it helps relieve anal inflammation, anal fissures and anal itching. It can also be used following ano-rectal surgery. It contains the following ingredients:

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.

This product is for use by adults over the age of 18 years.

2 Before using this medicine

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 Anusol or any of the other ingredients of this medicine (listed in section 6.1).

■ If you have **fungal, viral or bacterial skin sores**.

If the above bullet points apply to you, **get advice from a doctor or pharmacist without using Anusol.**

Talk to your doctor or pharmacist

- 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 after you have used the medicine for 7 days.
- Use with other medicines containing corticosteroids may increase the risk of systemic side effects.
- If you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Contact your doctor if you experience blurred vision or other visual disturbances.

If the above bullet points apply to you, **talk to a doctor or pharmacist.**

Other medicines and Anusol HC Ointment

- Some medicines may increase the effects of Anusol HC Ointment and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If you are pregnant or breast-feeding

- If you are pregnant or breast feeding only use on the advice of your doctor.

Some of the ingredients can cause problems

- 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 this medicine

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 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.

Children (under 18 years):

This medicine is not recommended for children under 18 years old.

Adults and the elderly:

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.
<ul style="list-style-type: none">■ Do NOT take orally■ Do not use more than 4 times a day unless prescribed otherwise by your doctor■ Do not use for more than 7 consecutive days	

■ Excessive use or use for long periods of time can be harmful, causing the skin to thin, develop a stripy appearance or affect the blood vessels just below the skin. It can also cause adrenal suppression (a type of hormone imbalance that causes generalised effects on the body). If affected stop treatment and speak to your doctor or pharmacist immediately.

If anyone has swallowed this product

If anyone accidentally swallows Anusol HC Ointment, contact a doctor or your nearest Accident and Emergency department, taking this leaflet and pack with you.

If you forget to use this medicine

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.

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).

Other effects which may occur but it is unknown how often:

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +35316764971; Fax: +35316762517 Website: www.hpra.ie; Email: medsafety@hpra.ie.

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

5 Storing this medicine

Keep out of the sight and reach of children.

Do not store above 25°C.

Do not use your medicine after the date shown as expiry date after "EXP" on the carton and tube.

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 Further information

What's in this medicine?

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 0.875 g and Benzyl benzoate 1.25 g.

Other ingredients are: Magnesium stearate, theobroma oil, wool fat (lanolin anhydrous), castor oil, kaolin light, calcium hydrogen phosphate and white soft paraffin.

What the medicine looks like

Anusol HC Ointment is a buff coloured ointment available in 15 g tubes.

MA Holder: SOFIBEL,

110 – 114 rue Victor Hugo

92686 Levallois Perret Cedex, France.

Manufacturer: Laboratoires M Richard, rue du Progres, ZI des Reys de Saulce, Saulce Sur Rhone, 26270, France

This leaflet was revised October 2021.

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 further information, please contact:

PA Holder: SOFIBEL, 110 – 114 rue Victor Hugo, 92686 Levallois Perret Cedex, France.

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