

Anusol^{HC} suppositories

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

- This medicine is used for the relief of internal 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 Suppositories help to relieve the pain, swelling, itch and irritation of internal 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.

X Do not use this medicine...

- If you have ever had a **bad reaction** to Anusol or any of its ingredients.
- If you have **fungal, viral or bacterial skin sores**.

If any of these 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 if you are in doubt whether any bleeding you have experienced is caused by piles.
- Use with other medicines containing corticosteroids may increase the risk of systemic side effects.
- If symptoms worsen or do not improve after you have used the medicine for 7 days.

If any of these bullet points apply to you, **talk to a doctor or pharmacist.**

! If you are pregnant or breast-feeding

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

3 How to use this medicine

Anusol HC Suppositories should be inserted into the anus

- Wash anal area and dry gently with a soft towel before using this medicine.
- Remove plastic cover from the suppository before use.
- Wash your hands before and after using Anusol.

i Children (under 18 years):

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

i Adults and the elderly:

Age	Dose
Adults and the elderly	Insert one suppository deeply into the back passage (anus). You should use as often as prescribed by your doctor, however Anusol HC Suppositories are 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 3 suppositories a day unless prescribed otherwise by your doctor■ Do not use for more than 7 consecutive days. Prolonged use may increase the risk of systemic side effects.

! If anyone has used too much or swallowed this product.

If anyone has used too much or has accidentally swallowed Anusol HC Suppositories, contact a doctor or your nearest Accident and Emergency department, taking this leaflet and pack with you.

! If you forget to use this medicine

If you forget a dose, use the next dose when needed. **Do not** use a double dose.

4 Possible side-effects

Anusol HC Suppositories can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

If you experience the following, stop using the medicine and tell your doctor:

- Sensitivity reactions (such as a rash) which occur rarely.

Other effects which may occur include:

- Mild irritation or burning on application. This does not usually last a long time, so if this becomes troublesome or lasts longer than a few days, tell your doctor.

The above are mild side effects, which will usually stop when you stop using the suppositories.

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 reach and sight 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 strip.

6 Further information

What's in this medicine?

The active substances per suppositories are: Hydrocortisone acetate 10 mg, Zinc oxide 296 mg, Bismuth subgallate 59 mg, Balsam Peru 49 mg,

Bismuth oxide 24 mg and Benzyl benzoate 33 mg.

Other ingredients are: Kaolin light, suppicire BS2 pastilles (hard fat).

What the medicine looks like

Anusol HC Suppositories are off-white suppositories available in plastic strips with two strips (12 suppositories) in a box.

Product Authorisation holder: McNeil Healthcare (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

Manufacturer: Farmae, 10, rue Bouché Thomas, ZAC Sud d'Orgemont, 49000 ANGERS Cedex, France.

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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:

McNeil Healthcare (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

