

Anusol[®] suppositories

zinc oxide, bismuth oxide, bismuth subgallate, balsam peru

- This medicine is used for the relief of internal piles and other related conditions.
- This medicine is for use by adults and children over the age of 12 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* ▶
- **Speak to your doctor:**
 - If you have **rectal bleeding** which has not been diagnosed as piles. *See section 2* ▶
- **Follow the instructions on how to use this product carefully.** *See section 3* ▶

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 Suppositories help to relieve the pain, swelling, itch and irritation of internal piles (haemorrhoids) and other related conditions, such as anal itching. It contains the following ingredients: **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.

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

If this applies 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 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 this medicine on the advice of your doctor.

3 How to use this medicine

Anusol 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 12 years):

This medicine is not recommended for children under 12 years old.

i Adults, children over 12 years and the elderly:

Age	Dose
Adults and the elderly	Insert one suppository into the back passage (anus) at night, in the morning and after each bowel movement.
■ Do NOT take orally	

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

If anyone has used too much or has accidentally swallowed Anusol 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

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 on application. This does not usually last a long time, so if this 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 HPRC 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 strip.

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: Zinc oxide 296 mg, Bismuth subgallate 59 mg, Balsam Peru 49 mg, Bismuth oxide 24 mg.

Other ingredients are: Kaolin light, suppicore BS2 pastilles (hard fat), titanium dioxide (E171), miglyol 812.

What the medicine looks like

Anusol Suppositories are white to off-white suppositories available in plastic strips with either two strips (12 suppositories) or four strips (24 suppositories) in a box.

Product Authorisation holder:

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

Manufacturer:

Farma, 10, rue Bouché Thomas, ZAC Sud d'Orgemont, 49000 ANGERS Cedex, France.

This leaflet was revised March 2019.

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.


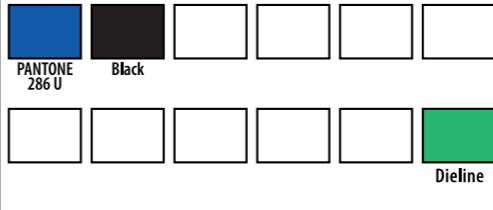
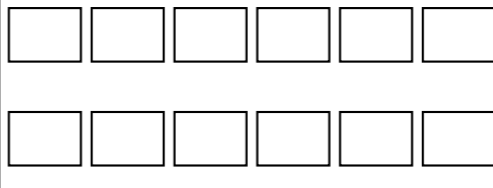

A healthy diet and lifestyle will reduce the likelihood of constipation and encourage a regular bowel habit. Go to the toilet regularly and try to avoid straining. Leaning forward from the hips may help.

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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