

Package leaflet: Information for the patient

AnuSol cream

Zinc oxide, bismuth oxide, 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, if you feel worse or if you have **rectal bleeding** which has not been diagnosed as piles.

What is in this leaflet

1. What AnuSol cream is and what it is used for
2. What you need to know before you use AnuSol cream
3. How to use AnuSol cream
4. Possible side effects
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1. What AnuSol cream is and what it is used for

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

AnuSol cream is a medicine which 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. It can be used post-operatively following ano-rectal surgery as advised by a doctor. This product is for use by adults over the age of 18 years.

AnuSol cream has a vanishing base formulation which means it is rapidly absorbed. The cream can also provide lubrication when used with suppositories.

How AnuSol cream works

This product provides antiseptic, astringent and emollient properties which help to relieve discomfort associated with minor ano-rectal conditions.

Zinc oxide 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 oxide 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, if you feel worse or if you have **rectal bleeding** which has not been diagnosed as piles.

2. What you need to know before you use AnuSol cream

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 cream

- If you are allergic to zinc oxide, bismuth oxide, Peru balsam or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using AnuSol cream 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.

Children and adolescents under 18 years of age

Not recommended unless under medical supervision.

Other medicines and AnuSol cream

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, only use this medicine on the advice of your doctor.

Driving and using machines

AnuSol cream has no or negligible influence on the ability to drive and use machines.

AnuSol cream contains propylene glycol and Peru balsam

- This medicine contains 8.0 g propylene glycol in each 100 g which is equivalent to 80 mg/g.
- Peru balsam contains benzyl alcohol, benzyl benzoate and benzyl cinnamate. It may cause allergic reactions, mild local irritation and/or skin reactions.

3. How to use AnuSol cream

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 cream should be applied sparingly to the affected area at night, in the morning and after each bowel movement.
■ Do NOT take orally	

Method of administration:

AnuSol cream 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 cream into the back passage (anus).
- **For external piles** - after washing and drying the affected area, the cream should be gently applied to the affected area.
- **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 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.

If you use more AnuSol cream than you should

If you use more AnuSol cream than you should, or if you accidentally swallow AnuSol cream, contact a doctor or your nearest Accident & Emergency Department (Casualty), taking this leaflet and pack with you.

If you forget to use AnuSol cream

AnuSol cream 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.

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 cream. 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 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 this medicine.

5. How to store AnuSol cream

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

Do not use this medicine after the 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. Store in the original packaging.

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 cream contains

The active substances are per 100 g: zinc oxide 10.75 g, bismuth oxide 2.14 g, Peru balsam 1.8 g.

The other ingredients are glycerol monostearate, liquid paraffin, propylene glycol, polysorbate 60, sorbitan stearate, titanium dioxide (E171), phenoxyethanol, chlorphenesin, glycerol and water. See section 2 'AnuSol cream contains propylene glycol and Peru balsam'.

What AnuSol cream looks like and contents of the pack

AnuSol cream is a buff coloured cream available in 23 g and 43 g tubes.

Marketing Authorisation Holder

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

Manufacturer

Laboratoires M Richard
Rue du Progrès
ZI des Reys de Saulce
Saulce-Sur-Rhône 26270
France.

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AnuSol is a trademark of Church & Dwight Co., Inc.

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, cream 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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