

**Anusol®** cream

**zinc oxide, bismuth oxide, balsam peru**

■ This medicine is used for the relief of internal and external piles and other minor ano-rectal conditions such as anal itching.

■ 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 Cream or any of the ingredients in it. See *section 6*

■ **Speak to your doctor:**

■ If you have **rectal bleeding** or blood in your stool 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 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 as diagnosed by a doctor. It can be used post-operatively following ano-rectal surgery as advised by a doctor.

Anusol Cream has a vanishing base which means it is rapidly absorbed. The cream can also provide lubrication when used with suppositories. It contains the following ingredients:

**Zinc oxide** which is an astringent which soothes and protects raw areas and helps reduce swelling. It also acts as an antiseptic.

**Balsam Peru** 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.

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

## **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 Cream or any of the other ingredients of this medicine (listed in section 6.1).

If the above applies to you, **get advice from a doctor or pharmacist without using Anusol Cream.**

**Talk to your doctor or pharmacist.**

■ If you have **rectal bleeding** or **blood in your 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.

### **Some of the ingredients can cause problems**

- Glycerol monostearate may have a mild laxative effect.
- Propylene glycol may cause skin irritation.
- Methyl (E218) and Propyl (E216) Parahydroxybenzoate may cause an allergic reaction, which may be delayed.

### **3 How to use this medicine**

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 (under 18 years):**

This medicine should not be used in children under the age of 18 years except on the advice of a doctor.

#### **Adults and the elderly:**

- If symptoms persist or worsen, consult your doctor.

#### **If anyone has swallowed this product**

If anyone accidentally swallows Anusol Cream, contact a doctor or your nearest Accident &

<b>Age</b>	<b>Dose</b>
<b>Adults and the elderly</b>	Anusol Cream should be applied sparingly to the affected area at night, in the morning and after each bowel movement.
■ Do <b>NOT</b> take orally	

Emergency Department, taking this leaflet and pack with you.

#### **If you forget to use this medicine**

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.

### **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 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](http://www.hpra.ie); Email: [medsafety@hpra.ie](mailto: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. Store in the original packaging.

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:** Zinc oxide 10.75 g, Bismuth oxide 2.14 g, Balsam peru 1.8 g.

**Other ingredients are:** Glycerol monostearate, liquid paraffin, propylene glycol, polysorbate 60, sorbitan stearate, titanium dioxide (E171), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and purified water.

### **What the medicine looks like**

Anusol Cream is a light 'buff' coloured cream available in 23 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

Or

Delpharm Orléans, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France.

### **This leaflet was revised September 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, Cream 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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