

## **Package leaflet: Information for the patient**

### **Anugesic HC Cream**

pramocaine hydrochloride, hydrocortisone acetate, zinc oxide, balsam peru, benzyl benzoate, bismuth oxide

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Anugesic HC Cream is and what it is used for
2. What you need to know before you use Anugesic HC Cream
3. How to use Anugesic HC Cream
4. Possible side effects
5. How to store Anugesic HC Cream
6. Contents of the pack and other information

Important things that you SHOULD know about your medicine:

- Anugesic HC Cream is used to treat severe pain and discomfort associated with haemorrhoids (piles), and pruritus ani (itching around the anus) in adults. Anugesic HC Cream may be used for either of these conditions.
- Anugesic HC Cream is for topical use and should only be used as directed. Do not swallow the cream or use on other areas of the skin. If you accidentally swallow Anugesic HC Cream, tell your doctor immediately.
- Anugesic HC Cream can sometimes cause burning, itching or stinging around the anus (See Section 4 for more details). See your doctor immediately if these symptoms do not go away

Please read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important to you.

#### **1. What Anugesic HC Cream is and what it is used for**

- Anugesic HC Cream contains several active ingredients. One of these is pramocaine hydrochloride which is an anaesthetic which acts on the skin and mucous membranes to relieve pain and itching. Another of the active ingredients is hydrocortisone acetate which is one of the group of medicines called corticosteroids which help to relieve inflammation. The other active ingredients of Anugesic HC Cream have astringent, protective, soothing and mild antiseptic properties. The cream may also provide lubrication for the insertion of suppositories. (For other ingredients see section 6).
- Anugesic HC Cream is used to treat the severe pain and discomfort associated with haemorrhoids (piles), and pruritus ani (itching around the anus). Haemorrhoids (piles) are enlarged or swollen blood vessels around the anus, which can cause varying degrees of discomfort, itching and irritation, particularly after a bowel movement. They may either be internal (inside the anus) or external (outside the anus).

- Anugesic HC Cream is used in adults only and not recommended for children.

You must talk to a doctor if you do not feel better or if you feel worse.

## **2. What you need to know before you use Anugesic HC Cream**

### **Do not use Anugesic HC Cream if you:**

- have tubercular, fungal or viral lesions e.g. genital warts
- are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6)
- had a reaction to other similar medicines containing balsam peru

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Anugesic HC Cream

Tell your doctor if any of these apply to you, to help him or her decide if Anugesic HC Cream is suitable for you:

- If you suffer from any rectal bleeding (bleeding from the back passage). Although bleeding, (shown as streaks of blood on toilet paper), is 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.
- If you have any cuts or infection around the anus. Ask your pharmacist or doctor if you are in any doubt about this as it is important not to use Anugesic HC Cream if the area around the anus is infected.
- If you are pregnant, trying to become pregnant now, or likely to want to try to become pregnant in the future.
- If you have chicken pox or shingles.
- If you have recently had a smallpox vaccination.

### **Other medicines and Anugesic HC Cream:**

There are no known interactions with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Pregnancy and breast-feeding:**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using Anugesic HC cream as there may be better alternative treatments for you.

### **Anugesic HC Cream contains propylene glycol, propyl and methyl parahydroxybenzoate and balsam peru**

Propylene glycol which may cause skin irritation.

Propyl parahydroxybenzoate (E216) and Methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

Balsam peru which may cause skin reactions.

### **3. How to use Anugesic HC Cream**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Wash the anal area thoroughly and then dry carefully with a soft towel. Apply a small amount of Anugesic HC cream to the affected area at night, again in the morning and after each bowel movement.
- For internal application, use the plastic applicator nozzle provided. After use the nozzle should be washed each time in hot soapy water and then thoroughly rinsed in cold water.
- Do not use the cream for longer than seven days unless your doctor tells you to. If the condition gets worse, or if rectal bleeding starts, consult a doctor immediately.
- Anugesic HC Cream is for topical use only. Do not swallow the cream or apply it to any part of the body except for the area around the anus (bottom) or into the rectum (back passage) using the applicator.

#### **If you use more than you should or accidentally swallow Anugesic HC Cream**

If you accidentally swallow any cream or use more than your prescribed dose, tell your doctor or pharmacist immediately.

The following side effects may occur as a result of swallowing the Anugesic HC Cream.

- fever
- nausea
- vomiting
- stomach pain
- diarrhoea

#### **If you forget to use Anugesic HC Cream**

If you forget to use Anugesic HC Cream, use it as soon as you remember unless it is time for your next application. Do not use double the amount to make up for a forgotten application.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects that have been seen with Anugesic HC Cream mostly affect the skin and tissues around the anus. These side effects are usually mild and go away after a short time:

- A burning, itching or stinging is occasionally felt around the anus, especially if the skin is broken.
- Very rarely there are sensitivity reactions, such as a rash.

- Continuous use for long periods of time (longer than seven days) can be harmful, causing the skin to thin, develop a stripy appearance or affect the blood vessels just below the skin. If you use Anugesic HC Cream regularly and are at all worried, speak to your doctor or pharmacist immediately.

### **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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

### **Ireland**

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 676 4971; Fax: +353 1 676 2517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

## **5. How to store Anugesic HC 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 tube and on the carton after EXP. The expiry date refers to the last day of that month.
- Store in the original container.
- Do not store above 25°C.
- 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 Anugesic HC Cream contains**

The active substances are: pramocaine hydrochloride, hydrocortisone acetate, zinc oxide, balsam peru, benzyl benzoate, bismuth oxide. Each 100g of Anugesic HC cream contains pramocaine hydrochloride 1.0g, hydrocortisone acetate 0.5g, zinc oxide 12.35g, balsam peru 1.85g, benzyl benzoate 1.2g, bismuth oxide 0.875g.

The other ingredients are: liquid paraffin, propylene glycol (E1520), polysorbate 60, sorbitan stearate, glyceryl monostearate, titanium dioxide (E171), the preservatives methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)(see section 2 Anugesic HC Cream contains propylene glycol, propyl and methyl parahydroxybenzoate and balsam peru) and purified water.

### **What Anugesic HC Cream looks like and contents of the pack**

Anugesic HC Cream is a buff coloured cream with a characteristic odour of balsam peru. Anugesic HC Cream is available in tubes containing 15g, 25g or 30g of cream. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder:**

The Marketing Authorisation holder in Ireland is Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24.

### **Manufacturer:**

Famar Orléans, 5 avenue de Concyr, 45071 Orléans Cedex 2, France.

**Company contact address:**

For further information on your medicine, please contact Medical Information at the address below  
Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS  
Telephone 01304 616161

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