#### PATIENT INFORMATION LEAFLET

## ANUGESIC HC CREAM

Pramocaine hydrochloride, Hydrocortisone acetate, Zinc oxide, Balsam peru, Benzyl benzoate, Bismuth oxide

## In this leaflet:

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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.

## 2. Before you use Anugesic HC Cream

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

- tubercular, fungal or viral lesions e.g genital warts
- had a reaction to Anugesic HC Cream or any of the individual ingredients
- had a reaction to other similar medicines containing balsam peru

# Important information about some of the ingredients of Anugesic HC Cream

Contains propylene glycol which may cause skin irritation Contains E216 and E218 which may cause allergic reactions (possibly delayed) Contains Balsam of Peru which may cause skin reactions

# **\*** Take special care with 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.

## **\*** Taking other medicines:

There are no known interactions with other medicines but it is wise to inform your doctor or pharmacist if you are taking, or have recently taken any other medicine –including those bought without a prescription.

# **Pregnancy and Breast-feeding:**

If you are pregnant, trying to become pregnant or breastfeeding, ask your doctor or pharmacist for advice before using Anugesic HC cream as there may be better alternative treatments for you.

# 3. How to use Anugesic HC Cream

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

## 4. Possible side effects

Like all medicines Anugesic HC Cream can sometimes 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.

If you experience any of the above side effects or notice any side effects not mentioned in this leaflet, tell your doctor or pharmacist at once.

# 5. How to store Anugesic HC Cream

- Keep out of the reach and sight of children.
- Anugesic HC Cream should not be used after the expiry date printed on the tube and on the carton.

- Store in the original container.
- Do not store above 25°C.

#### 6. Further information

## What Anugesic HC Cream contains and the contents of the pack

Anugesic HC Cream is available in tubes containing 30g of cream. Each tube of cream contains the active ingredients: Pramocaine hydrochloride, Hydrocortisone acetate, Zinc oxide, Balsam peru, Benzyl benzoate, Bismuth oxide.

Anugesic HC Cream also contains the inactive ingredients: liquid paraffin, propylene glycol,(E1520), polysorbate 60, sorbitan stearate, glyceryl monostearate, titanium dioxide (E171), the preservatives methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) and purified water.

Anugesic HC Cream is a buff coloured cream with an antiseptic odour.

# **Marketing Authorisation Holder:**

The Marketing Authorisation Holder in the United Kingdom is Pfizer Limited, Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

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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