# PACKAGE LEAFLET: INFORMATION FOR THE USER

#### **Anugesic HC Suppositories**

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

In this leaflet:

- 1. What Anugesic HC Suppositories are and what they are used for
- 2. Before you use Anugesic HC Suppositories
- 3. How to use Anugesic HC Suppositories
- 4. Possible side effects
- 5. How to store Anugesic HC Suppositories
- 6. Further information

Important things that you SHOULD know about your medicine:

- Anugesic HC Suppositories are used to treat the severe pain and discomfort associated with internal haemorrhoids (piles), and pruritus ani (itching around the anus) in adults. Haemorrhoids can cause varying degrees of discomfort, itching and irritation, particularly after a bowel movement.
- Anugesic HC Suppositories are for insertion into the rectum (back passage) only. Do not swallow them or insert into the vagina. If you accidentally swallow a suppository, tell your doctor at once.
- Anugesic HC Suppositories can sometimes cause burning, itching or stinging around the anus (See section 4).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 Suppositories are and what they are used for

- Anugesic HC Suppositories contain several active ingredients. One of these is
  Pramocaine hydrochloride, a local anaesthetic which acts on the skin and mucous
  membranes to relieve pain and itching. Another of the active ingredients is
  Hydrocortisone acetate, one of the group of medicines called corticosteroids which
  help to relieve inflammation. The other active ingredients have astringent, protective,
  soothing and mild antiseptic properties. (For other ingredients see Section 6)
- Anugesic HC Suppositories are used to treat the severe pain and discomfort associated with internal haemorrhoids, and pruritus ani (itching around the anus (bottom)). Haemorrhoids (piles) are enlarged or swollen blood vessels around the anus which may either be internal (inside the anus) or external (outside the anus).
- Anugesic HC Suppositories are for use by adults only and are not recommended for children.

## 2. Before you use Anugesic HC Suppositories

# **\*** Do not use Anugesic HC suppositories if you have:

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

# \* Take special care with Anugesic HC Suppositories

Tell your doctor if any of these apply to you, to help him or her decide if Anugesic HC Suppositories are 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 Suppositories 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 chickenpox or shingles or have recently had a smallpox vaccination.

## \* Taking other medicines

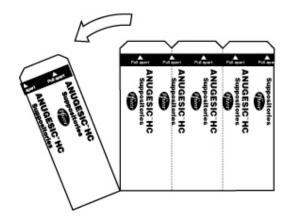
There are no known interactions with other medicines but it is wise to inform your doctor or pharmacist if you are taking, or have recently taken any other medicine, including those bought without a prescription.

## Pregnancy and Breast-feeding

If you are pregnant, trying to become pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking Anugesic HC Suppositories as there may be better alternative treatments for you.

## 3. How to use Anugesic HC Suppositories

• Tear along the perforation to remove one suppository from the strip as shown on the diagram below.



• Grasp the two halves of the plastic cover firmly, holding between thumb and forefinger of each hand. Gently pull the two halves apart to fully expose the suppository, as shown.



- With clean hands, remove the suppository and insert it into the anus (bottom), as deeply into the rectum (back passage) as possible. One suppository should be inserted at night and one in the morning and also after each bowel movement until the condition is controlled.
- Anugesic HC Suppositories are specially shaped for easy insertion into the anus. You may find insertion of the suppositories easier if you place one foot on a chair or lie on your side with one leg drawn up as high as possible under the chin.
- Do not use the suppositories for longer than seven days unless your doctor tells you to. If the condition gets worse, or if rectal bleeding starts, consult a doctor or pharmacist immediately.
- Anugesic HC Suppositories are **for rectal use only** and should only be used as directed. Do not swallow them or insert into the vagina. If you accidentally swallow a suppository or use more than your prescribed dose, tell your doctor or pharmacist immediately.

### 4. Possible side effects

Like all medicines Anugesic HC suppositories can sometimes cause side effects, although not everybody gets them. The following side effects 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 Suppositories 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 Suppositories

- Keep out of the reach and sight of children.
- Anugesic HC Suppositories should not be used after the expiry date printed on the plastic strip and on the carton.
- Store in the original container.
- Do not store above 25°C.

#### 6. Further information

#### What ANUGESIC HC SUPPOSITORIES contain and the contents of the pack

Each 2.8 g suppository contains the following active ingredients: Pramocaine hydrochloride, hydrocortisone acetate, bismuth oxide, zinc oxide, bismuth subgallate, balsam peru, benzyl benzoate.

Anugesic HC Suppositories also contain the inactive ingredients: hard fat A and C, calcium hydrogen phosphate and Theobroma oil (cocoa butter).

Anugesic HC Suppositories are buff coloured suppositories which are packaged in a plastic strip. There are 12 suppositories in each box.

#### **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:

Farmea, 10 rue Bouché Thomas, ZAC Sud d'Orgemont, 49000 Angers Cedex, 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

Leaflet last updated: IE June 2011 UK October 2011

Ref: AU 6\_1 clean