Approved Patient Information Leaflet

PREPARATION H® SUPPOSITORIES

SCHEDULING STATUS

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PREPARATION H® SUPPOSITORIES

(**Yeast Cell Extract** 23 mg and **Shark Liver Oil** 69 mg)

Read all of this leaflet carefully because it contains important information for you.

PREPARATION H SUPPOSITORIES is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PREPARATION H SUPPOSITORIES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PREPARATION H SUPPOSITORIES with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve

What is in this leaflet

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

1. WHAT PREPARATION H SUPPOSITORIES IS AND WHAT IT IS USED FOR

PREPARATION H SUPPOSITORIES are used for the treatment of haemorrhoids (piles).

PREPARATION H SUPPOSITORIES works by relieving pain, irritation and itching.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PREPARATION H SUPPOSITORIES

Do not use PREPARATION H SUPPOSITORIES if you are allergic to any of the above listed ingredients (see “What PREPARATION H SUPPOSITORIES contains”).

Warnings and precautions

If you are suffering from haemorrhoids (piles) you are advised to consult a healthcare professional.

If you are in doubt whether any bleeding you have experienced is caused by piles, you should see your doctor as soon as possible.

Other medicines and PREPARATION H SUPPOSITORIES

Always tell your health care provider if you are taking other medicines on a regular basis, including complementary or traditional medicines, concomitant use of PREPARATION H SUPPOSITORIES may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

PREPARATION H SUPPOSITORIES with food, drink and alcohol

No data available

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine

Driving and using machines

No data available

3. HOW TO TAKE PREPARATION H SUPPOSITORIES

Do not share medicines prescribed for you with any other person.

Always take PREPARATION H SUPPOSITORIES exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

For rectal use.

PREPARATION H SUPPOSITORIES is not to be swallowed.

Adults: Insert one suppository into the rectum, round end first, in the morning and at night and after every bowel movement.

Do not stop treatment as soon as you get signs of improvement – carry on with the treatment for a little longer to obtain the full benefit.

Children: Not to be used in children

To remove the suppository from the packaging:

1. To remove one suppository from the strip:

   Tear down the perforation, between two suppositories, from the “V” notch.
2. To remove the packaging from the single-suppository torn-off: gently peel down wrapping to reveal the suppository.
3. Remove the suppository from the wrapping and insert it as far as possible into the rectum, rounded end first. This is best done in a stooping position.

If you use more PREPARATION H SUPPOSITORIES than you should

In case of accidental overdose, immediately consult your doctor or pharmacist. If neither is available, immediately contact the nearest hospital or poison control centre

PREPARATION H SUPPOSITORIES are not to be swallowed. If you accidentally swallow any, contact your doctor or pharmacist immediately.

If you forget to take PREPARATION H SUPPOSITORIES

Do not take double dose to make up for forgotten individual doses

4. POSSIBLE SIDE EFFECTS

PREPARATION H SUPPOSITORIES can have side effects.

Not all side effects reported for PREPARATION H SUPPOSITORIES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PREPARATION H SUPPOSITORIES, please consult your doctor, pharmacist or other health care provider for advice.

PREPARATION H SUPPOSITORIES may not suit everybody. Some patients may have side effects, although these should be temporary. If an unwanted effect is severe or lasts for more than a few days, you should tell your doctor or pharmacist.

Preventing Piles: The discomfort of piles can be avoided by following these simple preventative measures:

Regular Bowel Habits: Try not to overstrain your bowels, especially if you come from a family that is prone to piles. Get into the habit of opening your bowels naturally and easily every day – if possible, at the same time each morning. Avoid laxatives and purgatives.

A Good Diet: Try to eat food high in fibre content and drink plenty of water. Piles are more common now than they were 50 years ago because of the tendency to eat too many refined foods. Suitable foods to eat on a regular basis include bran, wholemeal breads, fruit and fresh vegetables. Try to avoid foods which you know will disrupt your regular bowel movements.

Hygiene: Careful cleansing and removal of irritating matter that causes pain, swelling and itching can help to relieve symptoms of piles. Keep the affected area as dry as possible as this will encourage the healing processes. Wear cotton underwear in preference to nylon as this will keep the area drier.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the '6.04 Adverse Drug Reaction Reporting Form', found on-line under SAHPRA'S publications: htpp://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of PREPARATION H SUPPOSITORIES.

5. HOW TO STORE PREPARATION H SUPPOSITORIES

Store at or below 25 °C.

Do not use this medicine after the expiry date stated on the pack.

Speak to your pharmacist on the correct disposal of any unused medicine.

Store all medicines out of reach of children

Store in the original container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

WHAT PREPARATION H SUPPOSITORIES contains

The active substances in PREPARATION H SUPPOSITORIES is yeast cell extract and shark liver oil.

Each suppository contains 23 mg yeast cell extract and 69 mg shark liver oil

The other ingredients are: Hard Fat, Hydrocarbon Wax, Polyethylene Glycol 600 Dilaurate, Cocoa Butter, Glycerol.

What PREPARATION H SUPPOSITORIES looks like and contents of the pack

A pale yellow, solid, bomb-shaped suppository.

The PREPARATION H SUPPOSITORIES are packed in pack sizes of 12 or 24 suppositories per carton.

Holder of Certificate of Registration

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