IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0172/011/001
Case No: 2042372

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Whitehall Laboratories Limited

T/A Wyeth Consumer Healthcare, **Huntercombe Lane South**, **Taplow, Maidenhead**, **Berkshire SL6 0PH**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Preparation H 3% w/w + 1% w/w Rectal Ointment

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **01/04/2008** until **31/03/2013**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Preparation H 3% w/w + 1% w/w Rectal Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The ointment contains:

Live Yeast Cell Derivative	1.00	% w/w
Shark Liver Oil	3.00	% w/w

Excipients: Wool Fat 2.42 % w/w, Methyl Parahydroxybenzoate 0.1 % w/w and Propyl Parahydroxybenzoate 0.2 % w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal ointment
Collapsible aluminium tubes with detachable polythene cannula containing a soft yellow ointment with an odour of thyme oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct for the topical relief of the symptoms associated with uncomplicated external haemorrhoids.

4.2 Posology and method of administration

Perianal and Rectal.
Apply morning and evening and after defaecation.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

- If there is no improvement or the condition is aggravated, discontinue treatment and consult the doctor.
- Patients with haemorrhoids should consult the doctor to determine the cause.
- Keep out of sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Preparation H is suitable for use in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Light liquid paraffin
Wool fat
Isocreme absorption base
Thyme oil red
Glycerol
Methyl parahydroxybenzoate [E218]
Propyl parahydroxybenzoate [E216]

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Collapsible aluminium tubes with detachable polythene cannula containing 5g/25g/50g of yellow ointment with an odour of thyme oil.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Whitehall Laboratories Limited
Trading as: Wyeth consumer Healthcare
Huntercombe Lane South
Taplow
Maidenhead
Berkshire
SL6 OPH
UK

8 MARKETING AUTHORISATION NUMBER

PA 172/11/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

September 2008