

**BOOTS HAEMORRHOID SPRAY/ANUSOL SPRAY**

**PL 00014/0616**

**UKPAR**

**TABLE OF CONTENTS**

Lay summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 17
Summary of product characteristics	Page 19
Product information leaflet	Page 23
Labelling	Page 26

## **BOOTS HAEMORRHOID SPRAY/ANUSOL SPRAY**

**PL 00014/0616**

### **LAY SUMMARY**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted The Boots Company plc a Marketing Authorisation (licence) for the medicinal product Boots Haemorrhoid Spray or Anusol Spray (Product Licence number: 00014/0616). This product is available from pharmacies without prescription.

Boots Haemorrhoid Spray or Anusol Spray contains a local anaesthetic that can relieve the pain and irritation of external haemorrhoids.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Boots Haemorrhoid Spray or Anusol Spray outweigh the risks, hence a Marketing Authorisation has been granted.

# **BOOTS HAEMORRHOID SPRAY/ANUSOL SPRAY**

**PL 00014/0616**

## **SCIENTIFIC DISCUSSION**

### **TABLE OF CONTENTS**

Introduction	Page 4
Pharmaceutical assessment	Page 5
Preclinical assessment	Page 10
Clinical assessment	Page 12
Overall conclusions and risk benefit assessment	Page 16

## **INTRODUCTION**

The UK granted marketing authorisations for the medicinal products Boots Haemorrhoid Spray or Anusol Spray (PL 00014/0616) to The Boots Company plc on 6 October 2006.

This applications was submitted as a standard abridged application, according to Article 10a of Directive 2001/83/EC.

Boots Haemorrhoid Spray or Anusol Spray contains the active ingredient lidocaine hydrochloride, which works by blocking the nerve impulses that are sent to the brain in response to pain. When this product is applied to the affected area haemorrhoid sufferers can experience pain relief.

## **PHARMACEUTICAL ASSESSMENT**

### **INTRODUCTION**

This is a standard abridged application submitted under Article 10a of Directive 2001/83/EC, as amended. The application is for a topical spray containing lidocaine hydrochloride 1.0% w/w. The product is indicated for the symptomatic relief of pain and itching and to soothe the discomfort associated with external haemorrhoids.

The marketing authorisation will be held by The Boots Company plc.

### **PROPOSED INDICATIONS AND POSOLOGY**

#### Adults and Children over 14 years

Two to three sprays to be applied to the anal area, three or four times a day, as needed.

To assist application to the anal area, the spray can be turned upside down.

#### Children under 14 years

Not recommended.

Before each use the product should be primed by spraying three times away from the face into a sink.

Do not use for prolonged periods of time.

#### Indications

For the treatment of pain and itching and to soothe the discomfort associated with external haemorrhoids.

### **BACKGROUND**

Lidocaine is currently licensed in 93 products for use as a local anaesthetic. A number of these products are intended for topical application as ointments, creams and gels for haemorrhoids.

#### Legal Status

Lidocaine hydrochloride is a P medicine at the proposed concentration when intended for non-ophthalmic use.

## **PHARMACEUTICAL ASSESSMENT**

### **1. Composition**

The product consists of a solution containing lidocaine hydrochloride with the following excipients:

<b>Ingredient</b>		<b>Ref Standard</b>
Lidocaine HCl		Ph Eur
Polysorbate		Ph Eur
Sodium citrate		Ph Eur
Citric acid monohydrate		Ph Eur
Disodium edetate		Ph Eur
Methyl hydroxybenzoate		Ph Eur
Purified Water		Ph Eur

### **2. Development Pharmaceutics**

The objective was to develop an aqueous spray for relief of the pain and itching of haemorrhoids. Lidocaine was selected in preference to benzocaine due to its lower potential for hypersensitivity reactions. The hydrochloride was used to provide adequate water solubility. Lidocaine is widely used in rectal preparations at levels from 1-4% w/w.

Methyl hydroxybenzoate was selected as a preservative having sufficient aqueous solubility and activity in the pH range. Levels of preservative were tested and a suitable level of methyl hydroxybenzoate was selected to adequately preserve the formulation.

Polysorbate 80 was selected as a surfactant to aid application by wetting the skin; a suitable level was determined. The buffer system of sodium citrate and citric acid monohydrate was selected to control the pH at a level suitable for the skin.

A pump spray was selected to provide a convenient method for application to the affected area. The pump mechanism operates in an inverted position to aid application. Details of the packaging are provided in the dossier together with details of the tests for spray weight reproducibility. The applicant has confirmed that the pump is designed to deliver an average of 0.12ml±10% per stroke. Product is taken up into the pump through a dip tube and an orifice so that it works in any attitude. Data on the average of 10 strokes (weight and volume) on five samples in both upright and inverted positions are presented. The applicant has also confirmed that a spray weight reproducibility test is carried out on receipt of components and details have been provided.

### **3. Method of Manufacture**

Manufacture is a simple process. Purified water is placed in a vessel fitted with a stirrer. Polysorbate is added and dissolved followed by the other ingredients. The batch is stirred for 30 minutes to ensure complete mixing. Product is filled into bottles and the pumps applied. There are no critical steps that require in-process controls.

#### **Process validation**

Three samples were taken from the top, middle and bottom of each of the stability batches after manufacture. The samples were analysed for lidocaine HCl and methyl hydroxybenzoate content. All results were satisfactory.

### **4. Control of Starting Materials**

#### **Lidocaine Hydrochloride**

A European Certificate of Suitability for the manufacturer of lidocaine hydrochloride has been provided, together a raw material specification and certificates of analysis. This source of active is currently in use by Boots for their existing lidocaine products. The lidocaine HCl complies with the current Ph Eur monograph and there are no issues arising from this source of active ingredient.

#### **Excipients**

All of the excipients comply with their current Ph Eur monographs that are considered to be acceptable specifications. Microbiological control of the water is carried out routinely and the applicant has provided details of the normal, alert and action limits.

#### **Container**

The product is presented in a white pigmented cylindrical 25ml HDPE bottle, fitted with a plastic 360 degree metered dose spray pump, dip tube and overcap. All contact materials are stated to be suitable for contact with food. The bottles are tested for closure, leakage and identification of the material.

#### **Spray Weight Reproducibility**

This is determined using five spray pumps and determining the average spray weight of 10 sprays from each, after priming shots. The average spray weight must be within  $\pm 10\%$  of the nominal spray weight. The individual spray weight must be within  $\pm 15\%$  of the nominal spray weight.

### **5. Control of the Finished Product**

The finished product specification has been provided and applies to both release and shelf-life. All tests and limits proposed by the applicant are satisfactory.

#### **Analytical Methods:**

An HPLC method is used to determine the levels of lidocaine HCl, the preservative methyl hydroxybenzoate and the degradation product 2,6-dimethylaniline. Propyl hydroxybenzoate is used as the internal standard and good separation is achieved for all compounds involved, as shown by sample chromatograms. Full details of the method are provided as well as satisfactory validation data showing selectivity, linearity, accuracy, precision and ruggedness.

## **Batch Analyses**

Results are presented on three batches (batch numbers 406L, 407L and XF 28105L).

All parameters are well within specification. The levels of 2,6-dimethylaniline are stated as below the LOD,. The batch results also include results of preservative efficacy testing for the three batches. All are shown to comply with the Ph Eur test.

## **6. Stability**

### **Stability of the active ingredient**

This is covered in the Certificate of Suitability. The data presented supports a retest date of 5 years. A stress storage study has been performed on lidocaine hydrochloride. A report of the study is provided together with an expert statement. The results show that the extra degradation products listed on the Certificate of Suitability have not been detected and that the degradation product of lidocaine hydrochloride is 2, 6 dimethylaniline.

### **Stability of the finished product**

The proposed shelf-life is 3 years; no storage restrictions are proposed.

Stability studies have been carried out on three batches of the finished product (406L, 407L, XF 28105L) in the packaging proposed for marketing. These are the batches quoted in the validation studies and the batch analyses above. Two batches are pilot-scale and one is a small production scale batch.

The batches were stored in line with CPMP guidelines at 25°C/60% RH, 30°C/60% RH and 40°C/75% RH. Results are presented up to 3 years at 25°C/60% RH and 30°C/60% RH and 6 months at 40°C/75% RH. Samples were tested in accordance with the FPS test parameters and methods.

Results on all three batches are within the proposed specification limits at 25 and 30°C. Notably, the degradation product, 2,6-dimethylaniline, remained below the LOD limit. There are no significant detrimental changes even at 40°C.

The applicant has confirmed that the production mould had been completed and that the pump complied with the specification for dose reproducibility.

Preservative efficacy testing was carried out on the stored batches (25°C/60% RH, 30°C/60%) at 3, 6, 12 and 36 months and shown to be compliant with Ph Eur. The Applicant has given assurance that preservative efficacy testing will be carried out on batches at the end of the proposed shelf-life.

The stability data provided support the proposed 3 year shelf-life.

### **Product particulars:**



### **Summary of Product Characteristics (SPC)**

This is satisfactory.

### **Patient Information Leaflet (PIL)**

This is satisfactory.

### **Labelling**

All labelling is satisfactory.

### **Clinical Studies**

This application has been submitted under Article 10a and is supported by bibliographic evidence of efficacy. No clinical studies have been conducted on the applicant's product proposed for marketing.

### **Discussion**

This is a standard abridged application for a cutaneous spray consisting of a simple aqueous solution of lidocaine hydrochloride with methyl hydroxybenzoate as preservative. The solution is buffered with sodium citrate and citric acid, polysorbate is added as a non ionic surfactant and disodium edetate as a stabilising agent. The active ingredient and all of the excipients are pharmacopoeial and are sourced from known suppliers. Manufacture is straightforward. The FPS is acceptable. The stability data is comprehensive and there are no concerns. The product particulars are satisfactory.

### **Conclusion**

A marketing authorisation may be granted for this product.

## **PRECLINICAL ASSESSMENT**

### **I INTRODUCTION**

This is a bibliographical abridged application for Haemorrhoid Spray or Anusol Spray submitted in 2000 by The Boots Company plc under Article 10a of Directive 2001/83/EC, as amended.

The product is a topical spray containing lidocaine hydrochloride 1.0% w/w and is indicated for the symptomatic relief of pain and itching and to soothe the discomfort associated with external haemorrhoids. The dose for adults and children over 14 years is two or three sprays to be applied to the affected area three or four times a day as required. The maximum recommended daily dose of lidocaine is approximately 15 mg.

No Part III data have been received from the applicant. Following an initial assessment, a revised Preclinical Expert Report (PCER) was provided on 5 April 2001, citing four compendial references.

#### **I.1 Good Laboratory Practice (GLP) aspects**

No preclinical data or references on animal studies have been submitted.

### **II PHARMACODYNAMICS / PHARMACO / TOXICOKINETICS / TOXICOLOGY**

Lidocaine hydrochloride is a local anaesthetic of the amine type used topically for the symptomatic relief of pain and is contained in a number of proprietary over-the-counter (OTC) topical products currently available in the UK. It is an established ingredient and the concentration in the finished product is based on that recommended in the literature and is consistent with other similar products. The active ingredient and all the excipients comply with the European Pharmacopoeial monographs.

The Preclinical Expert has justified the absence of any preclinical studies in animals.

The Preclinical Expert has also argued against reiterating all the toxicological details on the active ingredient on the basis that most of the toxicity data was generated ten to twenty years ago. Instead, the revised report notes that lidocaine hydrochloride can be categorised as a substance with “well-established use.” The case is made that all components fall within safe limits defined by expert groups and the limits for each are stated. The supporting references show that this is true of the lidocaine hydrochloride, polysorbate 80 and methyl hydroxybenzoate. However, for sodium citrate, citric acid monohydrate and disodium edetate, the report states that the United Kingdom General Sales List places no limits on their external use and the supporting information has not been presented.

*Assessor's comment*

Given that the application is for a topical formulation of a well-established active ingredient, and the indicated rate of delivery of the lidocaine is considerably lower than that permitted in other topical preparations, there is no need for additional preclinical studies.

### **III PRECLINICAL EXPERT REPORT**

The PCER was written by a suitably qualified toxicologist. While the report does not strictly meet the requirements of a bibliographic application in that a narrative summary of all the relevant preclinical data has not been provided, the argument of well-established use is accepted.

### **IV SUMMARY OF PRODUCT CHARACTERISTICS**

The SPC is satisfactory.

### **V CONCLUSION**

There is no objection to the grant of a licence for Boots Haemorrhoid Spray or Anusol on preclinical grounds.

## CLINICAL ASSESSMENT

### 1. INTRODUCTION

This is a standard abridged application submitted under Article 10a of Directive 2001/83/EC, as amended. The application is for a topical spray containing lidocaine hydrochloride 1.0% w/w. The product is indicated for the symptomatic relief of pain and itching and to soothe the discomfort associated with external haemorrhoids.

The marketing authorisation will be held by The Boots Company PLC.

### 2. BACKGROUND

Lidocaine is currently licensed in 93 products for use as a local anaesthetic. A number of these products are intended for topical application as ointments, creams and gels for haemorrhoids. One spray product is currently licensed viz: Perinal Spray (also Germoloids HC Spray), PL 00173/0049, which contains lidocaine HCl 1% and hydrocortisone 0.2%.

#### Legal Status

Lidocaine hydrochloride is a P medicine at the proposed concentration of 1.0% w/w when intended for non-ophthalmic use.

### 3. INDICATIONS

The Applicant requested the following:

‘For the treatment of pain and itching and to soothe the discomfort associated with external haemorrhoids.’

This is satisfactory and in-line with current guidelines

### 4. POSOLOGY AND METHOD OF ADMINISTRATION

The Applicant presented the following:

#### Adults and Children over 14 years

Two to three sprays to be applied to the anal area, three or four times a day, as needed.

To assist application to the anal area, the spray can be turned upside down.

#### Children under 14 years

Not recommended.

Before each use the product should be primed by spraying three times away from the face into a sink

Do not use for prolonged periods of time.’

This guidance is suitable for this product.

**5. TOXICOLOGY**

The toxicology data submitted is satisfactory and sufficiently detailed for an application of this kind.

**6. CLINICAL PHARMACOLOGY**

Suitable clinical pharmacological literature was submitted to support this application.

**7. EFFICACY**

As required with literature applications, the applicant has shown that the route, dose and administration of the medicinal product are widely accepted in the indications requested.

Supporting efficacy data have been provided along with detailed references that support the clinical pharmacology and efficacy of the active in the indications claimed.

**8. SAFETY**

A tolerance study is described below.

Aim

To assess local irritancy potential.

Design & Methods

Twenty human volunteers were given two forearm patches to wear for 6h on 5 consecutive days. Each patch consisted of occlusive tape-backed lint squares of 1cm square containing either 0.05ml of Boots Haemorrhoid Spray and the other the same volume of Pertinal Haemorrhoid Spray (containing hydrocortisone 0.2%w/w and lignocaine hydrochloride BP 1.0%w/w, manufacturer not given). The same forearm and patch of skin was used for each application. After 6h on each day the area was washed with soap and water and assessed visually according to an in-house six point erythema grading (cross-referenced in the submission to the Dermatology Clinic Scoring Grades as follows:

BCM Erythema Grades	Visual Description	Dermatology Clinic Scoring Grades
0, 1, 2	Negative reaction	--
3, 4, 5	Doubtful reaction	?
6	Weak reaction (non vesicular)	+
No grade	Strong reaction (oedematous or vesicular)	++
No grade	Extreme reaction (ulcerative or bullous)	+++

Results:

Erythema							
Sample	BCM Reaction Grades						No. of Subjects Affected
	1	2	3	4	5	6	
Boots Haemorrhoid Spray		2	1				3
Pertinal Haemorrhoid Spray		5					4

Assessor's comment

The skin study shows evidence of minor forearm skin irritation only. No details of the scoring system used were given. The comparator product showed no reaction. The comparator product was inappropriate as it contains a potent topical steroid which could suppress any local inflammation produced. However, in this context Boots Haemorrhoid spray results appear to indicate only minor skin irritation from the active.

At the request of the MHRA a local tolerability study on 30 patients suffering from haemorrhoids was also conducted. The trial used an appropriate design and methods and the results submitted are satisfactory.

Assessor's comment

The applicant has provided sufficient safety data to support the application.

## 9. EXPERT REPORTS

The expert reports on the pharmaco-toxicological aspects of the product proposed for marketing were satisfactory and signed by persons with appropriate qualifications.

The expert reports on the clinical aspects of the product proposed for marketing were satisfactory and signed by persons with appropriate qualifications.

## 10. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC for this product is satisfactory.

## 11. PATIENT INFORMATION LEAFLET

The PIL for this product is satisfactory.

## 12. LABELLING

All labelling is satisfactory.

## 13. APPLICATION FORM

The Marketing Authorisation Application form submitted with this application is satisfactory.

**14. DISCUSSION**

This application is medically acceptable.

**15. CONCLUSION**

A product licence should be granted.

## **OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT**

### **QUALITY**

The important quality characteristics of Boots Haemorrhoid Spray or Anusol Spray (PL 00014/0616) are well defined and controlled. The specifications and batch analysis results confirm consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

### **PRECLINICAL**

No new preclinical data were submitted and none are required for an application of this type.

### **EFFICACY**

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory.

### **RISK BENEFIT ASSESSMENT**

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The risk benefit ratio is considered to be positive.



## **BOOTS HAEMORRHOID SPRAY/ANUSOL SPRAY**

**PL 00014/0616**

### **STEPS TAKEN FOR ASSESSMENT**

- 1** The MHRA received the marketing authorisation application on 2 March 2000
- 2** Following assessment of the application the MHRA requested further information relating to the quality dossier on 21 August 2000 and the clinical dossier on 28 September 2000
- 3** The applicant responded to the MHRA's requests, providing further information on the quality dossier on 9 April 2001 (providing additional information on 12 May 2003) and the clinical dossier on 12 May 2003
- 4** Following assessment of the response the MHRA requested further information relating to the quality dossier on 30 April 2001 and 5 June 2001 and the clinical dossier on 17 May 2001
- 5** The applicant responded to the MHRA's requests, providing further information on the quality dossier on 12 February 2002
- 7** Following assessment of the response the MHRA requested further information relating to the clinical dossier on 21 February 2002
- 8** The applicant responded to the MHRA's requests, providing further information on the 5 August 2002
- 9** The applicant responded to the MHRA's requests, providing further information on the quality dossier on 13 May 2003
- 10** Following assessment of the response the MHRA requested further information relating to the clinical dossier on 16 June 2003
- 11** The applicant responded to the MHRA's requests, providing further information on the clinical dossier on 31 July 2003
- 12** Due to issues raised during the clinical assessment this application was reviewed by the Committee for Safety of Medicines (CSM) during a meeting on 7 July 2004 and a decision was sent to the applicant on 14 July 2004
- 13** The applicant responded to the CSM points, providing further information on the clinical dossier on 12 January 2005
- 14** Following assessment of the response the MHRA requested further information relating to the clinical dossier on 24 May 2005
- 15** The applicant responded to the MHRA's requests, providing further information on the clinical quality dossier on 26 October 2005 and 19 January 2006
- 16** Following assessment of the response the MHRA requested further information relating to the quality dossier on 25 July 2006
- 17** The applicant responded to the MHRA's requests, providing further information

on the quality dossier on 2 August 2006

**18**

The application was determined on 6 October 2006

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Boots Haemorrhoid Spray or Anusol Spray

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active ingredient**

Lidocaine hydrochloride 1% w/w

(Each actuation of the spray delivers 0.12ml which is equivalent to 1.2mg of lidocaine hydrochloride)

### **3 PHARMACEUTICAL FORM**

Cutaneous Spray

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For the treatment of pain and itching and to soothe the discomfort associated with external haemorrhoids.

#### **4.2 Posology and method of administration**

##### **Adults and Children over 14 years**

Two to three sprays to be applied to the anal area, three or four times a day, as needed.

To assist application to the anal area, the spray can be turned upside down.

##### **Children under 14 years**

Not recommended.

Before each use the product should be primed by spraying three times away from the face into a sink

Do not use for prolonged periods of time.

#### **4.3 Contraindications**

Hypersensitivity to any of the ingredients. Not to be applied to broken or infected skin. Not to be used internally (inside the anus) or anywhere other than the anal region.

#### **4.4 Special warnings and precautions for use**

For external use only.

Keep all medicines out of the reach and sight of children.

If patients experience persistent pain or bleeding from the anus, particularly when associated with a change in bowel habit, distended stomach or weight loss, medical advice should be sought. Prompt medical treatment may be very important under

such circumstances.

If skin irritation occurs, stop using the product immediately and seek medical advice.

For use on the anal area only.

Avoid the eyes, nose and mouth.

Continuous treatment should not be for more than 7 days, unless advised by a doctor.

The label will state:-

This spray should not be used during pregnancy, while breastfeeding or by children under the age of 14 without medical advice. Keep spray away from the eyes, nose and mouth, and do not apply to broken or infected skin, or to any part of the body except the anal area. Prime pump before each use by depressing its top three times. Wash hands, and replace cap after use. Consult your doctor if the condition does not improve, or if rectal bleeding occurs. Do not use continuously for more than 7 days, unless recommended by your doctor. Do not use if sensitive to any of the ingredients. For external use only.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

There are no clinically significant drug interactions known to be associated with the use of topical lidocaine.

#### **4.6 Pregnancy and lactation**

Haemorrhoids are common during pregnancy and topical lidocaine is not considered to be contraindicated during this time. However, medical advice should be sought before using this product.

#### **4.7 Effects on ability to drive and use machines**

No adverse effects known.

#### **4.8 Undesirable effects**

A temporary tingling sensation may be experienced after applying the product. Hypersensitivity reactions due to lidocaine have been reported rarely.

#### **4.9 Overdose**

Topical overdosage with Haemorrhoid Spray is unlikely to constitute a hazard and therefore symptomatic treatment only is necessary.

Ingestion of significant quantities is also in practice unlikely. However, in cases where significant amounts of the product have been ingested, this may lead to high plasma levels and adverse central nervous and cardiovascular effects including medullary depression, tonic and clonic convulsions and cardiovascular collapse. For severe convulsions, small increments of diazepam or an ultra-short acting barbiturate (thiopentone) may be given intravenously. Patency of the airway and adequacy of ventilation must be assured. Should circulatory depression occur vasopressors such as metaraminol may be used.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Lidocaine is a local anaesthetic of the amide type. As a local anaesthetic, lidocaine acts by preventing the generation and transmission of impulses along nerve fibres and

at nerve endings by decreasing the permeability of the neuronal membrane to sodium ions. The product is specifically indicated for the treatment of external piles and not internal piles, because in the case of the latter, symptoms are not relieved because of the lack of rectal sensory nerve fibres.

## **5.2 Pharmacokinetic properties**

Absorption of lidocaine through intact skin is poor. The plasma elimination half life is about 2 hours. Lidocaine is bound to plasma proteins, particularly  $\alpha$  - 1 acid glycoprotein. The extent of protein binding is about 65%.

Lidocaine undergoes significant first pass metabolism (65%-70%) in the liver and is rapidly de-ethylated to the active metabolite monoethylglycinexylidide and then hydrolysed to various metabolites particularly glycinexylidide. Less than 10% is excreted unchanged by the kidneys. The metabolites are also excreted in the urine.

## **5.3 Preclinical safety data**

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Polysorbate 80, E433  
Sodium citrate, E331  
Citric acid monohydrate, E330  
Disodium edetate  
Methyl hydroxybenzoate, E218  
Purified water

## **6.2 Incompatibilities**

None

## **6.3 Shelf life**

36 months

## **6.4 Special precautions for storage**

None

## **6.5 Nature and contents of container**

25ml white pigmented HDPE bottle, fitted with a plastic 360 degree metered dose pump, dip tube and over cap.

## **6.6 Special precautions for disposal**

None

# **7 MARKETING AUTHORISATION HOLDER**

The Boots Company PLC  
1 Thane Road West

Nottingham NG2 3AA  
Trading as: BCM

- 8     MARKETING AUTHORISATION NUMBER(S)**  
PL00014/0616
- 9     DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**  
06/10/2006
- 10    DATE OF REVISION OF THE TEXT**  
06/10/2006

## **PATIENT INFORMATION LEAFLET**

# Anusol<sup>®</sup> spray

**This leaflet provides a summary of the information you should know before using this medicine. Please read it carefully. If you want to know more about your illness or this medicine, your pharmacist can help. The name of your medicine is Anusol Spray.**

## What is in this medicine?

This pack contains 25 ml of Anusol Spray. A cutaneous spray containing Lidocaine hydrochloride 1% w/w. Each spray delivers 0.12 ml equivalent to 1.2 mg Lidocaine hydrochloride. As well as an active ingredient, this spray also contains purified water, polysorbate 80 (E433), methyl hydroxybenzoate (E218), sodium citrate (E331), disodium edetate, citric acid monohydrate (E330).

## What type of medicine is this?

Anusol Spray belongs to a group of medicines called local anaesthetics which help to relieve the symptoms of pain.

## Who makes this medicine?

The Product Licence holder is BCM, Nottingham, NG2 3AA and the manufacturer is BCM Ltd, Nottingham, NG2 3AA.

## What is this medicine for?

Anusol Spray is used to relieve pain and itching, thus soothing the discomfort which is associated with external haemorrhoids.

## Before using this medicine

This product can be used by adults and children from the age of 14 years. However, some people should not use this medicine or should talk to their doctor first.

**These include:** Anyone with a known allergy to any of the ingredients listed above. Anyone who has persistent pain or bleeding from the anus, particularly if it is associated with a change of bowel habit, stomach discomfort and swelling or unintended weight loss. Pregnant and breast-feeding women should talk to their doctor before using this product.

## Anusol Spray and other medicines

As this product is used externally it is not expected to interact with any other medicines.

## How to use this Spray

Check that the carton seal is not broken before first use. (This spray is only for use on the external anal area). To assist in spraying the anal area this spray can be turned upside down. Before each use, spray 3 times away from the face into a sink. Avoid contact with the eyes. Replace overcap after use.

Age	Dosage
Adults (including the elderly) and Children over 14 years.	Two or three sprays to be applied to the anal area three or four times a day as required.

Do not use more than the dose recommended above. Do not use for children under 14 years. Do not use on broken or infected skin. Do not use this product on large areas of skin or use for prolonged periods of time. Do not use continuously for more than 7 days, unless advised by your doctor. If symptoms do not go away or if irritation occurs stop using this medicine and talk to your doctor.

## What if you use too much?

If too much has been used, talk to a doctor. Take your spray with you.

## Does this medicine have any side-effects?

Anusol Spray can sometimes cause side-effects such as a temporary tingling sensation after applying the product, or allergic reactions such as rash. If concerned, or anything unusual happens, talk to a pharmacist or doctor.

## How do you store this medicine?

Keep all medicines out of the reach and sight of children. Keep in a safe place, preferably in a locked cupboard. Do not use any medicines after the "use by" date on the carton and keep them in their original pack.

Leaflet prepared 09/05

If you would like any further information on this product, please contact **Pfizer Consumer Healthcare**, Walton-on-the-Hill, Surrey, KT20 7NS.

*Anusol is a registered trade mark of Pfizer Consumer Healthcare.*

 Pfizer Consumer Healthcare

QPZA5





## Haemorrhoid Spray

This leaflet provides a summary of the information you should know before using this medicine. Please read it carefully. If you want to know more about your illness or this medicine, your pharmacist can help.

The name of your medicine is Haemorrhoid Spray.

### What is in this medicine?

This pack contains 25 ml of Haemorrhoid Spray. A cutaneous spray containing Lidocaine Hydrochloride 1% w/w. Each spray delivers 0.12ml equivalent to 1.2mg Lidocaine Hydrochloride. As well as an active ingredient, this spray also contains Purified Water, Polysorbate 80 (E433), Methyl Hydroxybenzoate (E218), Sodium Citrate (E331), Disodium Edetate, Citric Acid Monohydrate (E330).

### What type of medicine is this?

Haemorrhoid Spray belongs to a group of medicines called local anaesthetics which help to relieve the symptoms of pain.

### Who makes this medicine?

The manufacturer and the Product Licence holder is The Boots Company PLC Nottingham NG2 3AA.

### What is this medicine for?

Haemorrhoid Spray is used to relieve pain and itching, thus soothing the discomfort which is associated with external haemorrhoids.

### Before using this medicine

This product can be used by adults and children from the age of 14 years. However, some people should not use this medicine or should talk to their doctor first.

These include: Anyone with a known allergy to any of the ingredients listed above.

Anyone who has persistent pain or bleeding from the anus, particularly if it is associated with a change in bowel habit, stomach discomfort and swelling or unintended weight loss.

Pregnant and breastfeeding women should talk to their doctor before using this product.

### Haemorrhoid Spray and other medicines

As this product is used externally it is not expected to interact with any other medicines.

### How to use this Spray

Check that the carton seal is not broken before first use. For use on the anal area only. This spray is for external use only. To assist in spraying the anal area this spray can be turned upside down. Before each use, spray 3 times away from the face into a sink.

Avoid contact with the eyes.

Replace overcap after use.

Age	Dosage
Adults (including the elderly) and Children over 14 years	Two or three sprays to be applied to the anal area three or four times a day as required

Do not use more than the dose recommended above.

Do not use for children under 14 years.

Do not use this product on large areas of skin or use for prolonged periods of time. Do not use continuously for more than 7 days, unless advised by your doctor.

If symptoms do not go away or if irritation occurs stop using this medicine and talk to your doctor.

### What if you use too much?

If too much has been used, talk to a doctor.

Take your spray with you.

### Does this medicine have any side effects?

Haemorrhoid Spray can sometimes cause side effects such as a temporary tingling sensation after applying the product, or allergic reactions such as rash.

If concerned, or anything unusual happens, talk to a pharmacist or doctor.

### How do you store this medicine?

Keep all medicines out of the reach and sight of children. Keep all medicines in a safe place, preferably in a locked cupboard.

Do not use any medicines after the "use by" date on the carton and keep them in their original pack. Leaflet prepared 8/05

If you would like any further information on this product, please contact The Boots Company PLC Nottingham NG2 3AA.

XXXXX

## PACKAGING

80mm

40mm



### Haemorrhoid Spray

(Lidocaine Hydrochloride)

Soothing relief from  
the pain and itching  
associated with  
external  
haemorrhoids.

e25ml

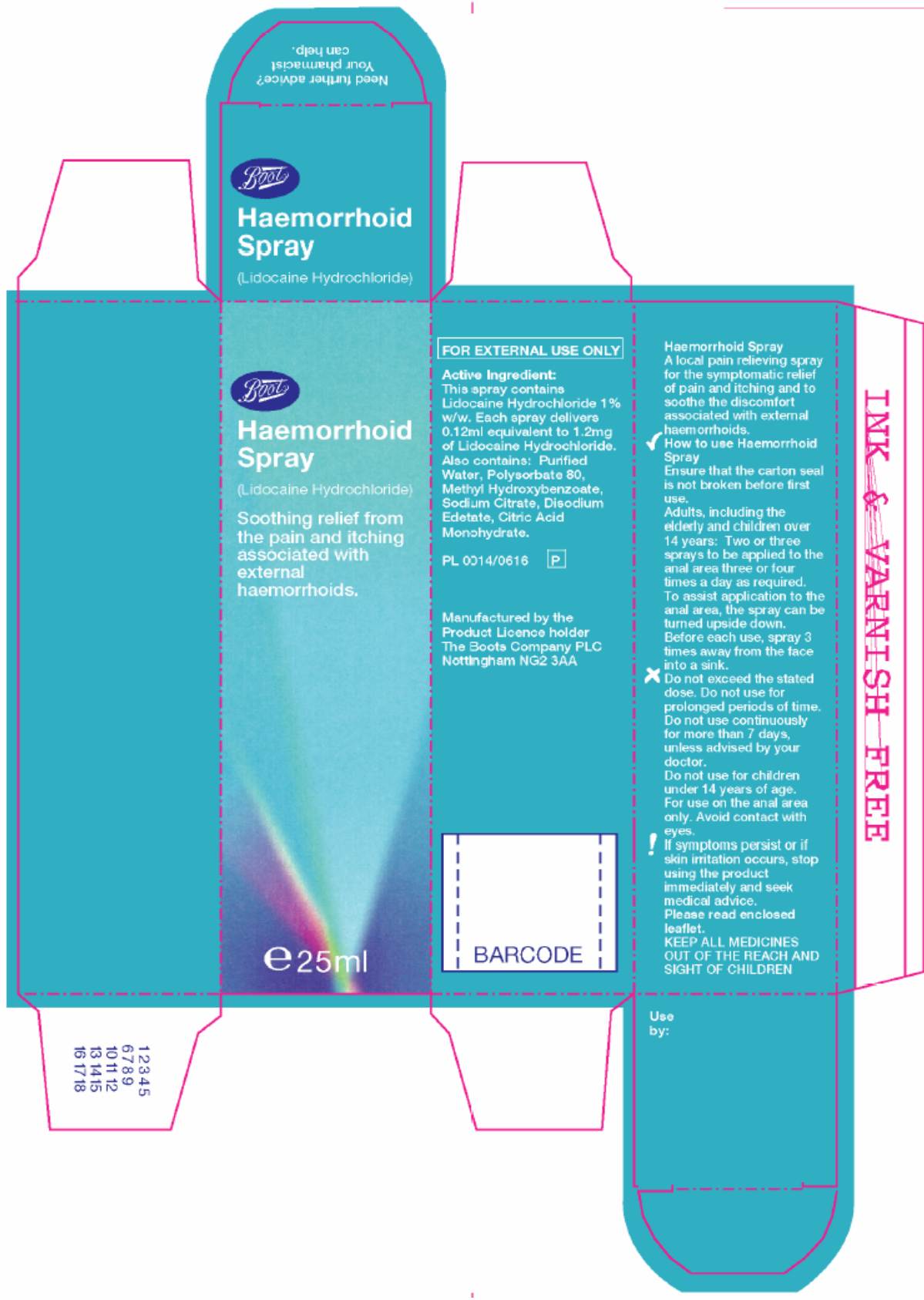
**Before you use this medicine:**  
Read leaflet for full instructions.  
This spray should not be used during pregnancy, while  
breast feeding or by children under the age of 14 without  
medical advice. Keep spray away from the eyes, nose  
and mouth, and do not apply to broken or infected skin,  
or to any part of the body except the anal area. Prime  
pump before each use by depressing its top three times.  
Wash hands, and replace cap after use. Consult your  
doctor if the condition does not improve, or if rectal  
bleeding occurs. Do not use continuously for more than  
7 days, unless recommended by your doctor. Do not use  
if sensitive to any of the ingredients.

**KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT  
OF CHILDREN.**

FOR EXTERNAL USE ONLY

Active Ingredients: in a cutaneous spray Lidocaine  
Hydrochloride 1% w/w. Also contains: Purified Water,  
Polysorbate 80, Methyl Hydroxybenzoate, Sodium  
Citrate, Disodium Edetate, Citric Acid Monohydrate.

PL 0014/0616 P  
The Boots Company PLC Nottingham NG2 3AA.



Need further advice?  
Your pharmacist  
can help.



## Haemorrhoid Spray

(Lidocaine Hydrochloride)



## Haemorrhoid Spray

(Lidocaine Hydrochloride)

Soothing relief from the pain and itching associated with external haemorrhoids.

e 25ml

**FOR EXTERNAL USE ONLY**

**Active Ingredient:**  
This spray contains Lidocaine Hydrochloride 1% w/w. Each spray delivers 0.12ml equivalent to 1.2mg of Lidocaine Hydrochloride. Also contains: Purified Water, Polysorbate 80, Methyl Hydroxybenzoate, Sodium Citrate, Disodium Edetate, Citric Acid Monohydrate.

PL 0014/0616 **P**

Manufactured by the Product Licence holder The Boots Company PLC Nottingham NG2 3AA

BARCODE

**Haemorrhoid Spray**  
A local pain relieving spray for the symptomatic relief of pain and itching and to soothe the discomfort associated with external haemorrhoids.

**How to use Haemorrhoid Spray**

Ensure that the carton seal is not broken before first use.

Adults, including the elderly and children over 14 years: Two or three sprays to be applied to the anal area three or four times a day as required. To assist application to the anal area, the spray can be turned upside down. Before each use, spray 3 times away from the face into a sink.

**X** Do not exceed the stated dose. Do not use for prolonged periods of time. Do not use continuously for more than 7 days, unless advised by your doctor.

Do not use for children under 14 years of age. For use on the anal area only. Avoid contact with eyes.

**!** If symptoms persist or if skin irritation occurs, stop using the product immediately and seek medical advice. Please read enclosed leaflet.

**KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN**

INK & VARNISH FREE

Use by:

12345  
6789  
101112  
131415  
161718