



# **Public Assessment Report**

## **Decentralised Procedure**

**PINEWOOD MAX STRENGTH HEARTBURN RELIEF  
ORAL SUSPENSION**

**PINEWOOD MAX STRENGTH HEARTBURN RELIEF  
ORAL SUSPENSION SACHETS**

**Sodium alginate  
Sodium bicarbonate  
Calcium carbonate**

**UK/H/2675/001-4/DC**

**UK Licence No: PL 04917/0086, 0089, 0098 & 0103**

**PINEWOOD LABORATORIES LIMITED**

## **LAY SUMMARY**

On 17<sup>th</sup> February, the MHRA granted Pinewood Laboratories Limited Marketing Authorisations (licences) for Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets.

Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets belong to a group of products called reflux suppressants.

Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion.

Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets contain the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets outweigh the risks; hence these Marketing Authorisations have been granted.

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## Module 1

<b>Product Names</b>	Pinewood Max Strength Heartburn Relief Oral Suspension Pinewood Max Strength Heartburn Relief Oral Suspension Sachets
<b>Type of Application</b>	Hybrid application, Article 10.3
<b>Active Substances</b>	Sodium alginate Sodium bicarbonate Calcium carbonate
<b>Pharmaceutical Form</b>	Oral Suspension
<b>Strength</b>	Sodium alginate: 1000 mg Sodium bicarbonate: 200 mg Calcium carbonate: 200 mg
<b>MA Holder</b>	Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
<b>Reference Member State (RMS)</b>	United Kingdom (UK)
<b>Concerned Member State (CMS)</b>	Italy (IT)
<b>Procedure Number</b>	UK/H/2675/001-4/DC
<b>End of Procedure</b>	Day 210: 18 <sup>th</sup> January 2012

## Module 2

# Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Pinewood Max Strength Heartburn Relief Oral Suspension

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains:

Sodium Alginate	1000 mg
Sodium Bicarbonate	200 mg
Calcium Carbonate	200 mg

Excipients include:

Ethyl parahydroxybenzoate (E214)	15.0 mg/10 ml
Propyl parahydroxybenzoate (E216)	5.50 mg/10 ml
Butyl parahydroxybenzoate	2.50 mg/10 ml

For a full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Oral Suspension,  
Aniseed flavoured white or cream coloured suspension

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

#### 4.2 Posology and method of administration

For oral use

Adults and children over 12 years and the Elderly:	5 – 10 ml
Children under 12 years:	only under medical supervision

Doses should be taken after meals and at bedtime.

#### 4.3 Contraindications

Hypersensitivity to any of the ingredients of this medicinal product, including the esters of hydroxybenzoates (Parabens) (see section 6.1).

#### 4.4 Special warnings and precautions for use

- 1) Treatment of children younger than 12 years of age is not generally recommended, except on medical advice
- 2) This medicinal product contains about 7.5 mmol of sodium per 10ml dose. To be taken into consideration by patients on a controlled sodium diet e.g. in cases of cardiac failure and renal impairment.
- 3) Each 10 ml contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
- 4) Compound Alginate Oral suspensions should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.
- 5) Parahydroxybenzoates (E214, E216) may cause allergic reactions (possibly delayed)
- 6) If symptoms do not improve after seven days, medical advice should be sought.
- 7) There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

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

- 1) Antacids may interact with other drugs as they alter the gastric pH which may affect dissolution, solubility or ionization of the other drug. Antacids reduce the absorption of certain drugs from the following groups: ACE Inhibitors, Analgesics, Antibacterials, Antiepileptics, Antifungals, Antimalarials, Antipsychotics, Bisphosphonates, Lithium and Penicillamine.
- 2) Antacids may increase the pH of the urine and affect the rate of drug elimination. Excretion of basic drugs is decreased whereas acidic drugs are eliminated more rapidly.
- 3) Due to effects at the renal level sodium bicarbonate may reduce plasma lithium levels and increase plasma quinidine levels.

**4.6 Fertility, pregnancy and lactation**

An open, uncontrolled study in 146 pregnant women did not demonstrate any significant adverse effects of this product on the course of pregnancy or on the health of the fetus/new-born child. No effects during pregnancy are anticipated, since systemic exposure to this product is negligible. This product can be used during pregnancy. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to this product is negligible. Based on this and previous experience this product may be used during pregnancy and lactation, however it is recommended to limit the treatment duration as much as possible.

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

There are no known effects on ability to drive or operate machinery.

**4.8 Undesirable effects**

Constipation, flatulence, stomach cramps or belching may occasionally occur. Very rarely, in less than one in ten-thousand cases, patients sensitive to the ingredients develop allergic manifestations such as bronchospasm, urticaria, and anaphylaxis.

**4.9 Overdose**

As Compound Alginate Oral suspensions mode of action is physical, overdosage in terms of the alginate content is virtually no hazard. The only consequence is abdominal distension which is best treated conservatively. The relatively low concentrations of sodium and calcium carbonate in this product would also make serious consequences from overdosage very unlikely.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

ATC Code: A02BX13

Pharmaceutical group: Other drugs for peptic ulcer and gastro-oesophageal reflux

When taken after a meal Sodium Alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft.

**5.2 Pharmacokinetic properties**

The mode of action of the product is physical and does not depend on absorption into the systemic circulation.

**5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Carbomer  
Sodium Hydroxide  
Saccharin Sodium  
Ethyl Parahydroxybenzoate (E214)  
Propyl Parahydroxybenzoate (E216)  
Butyl Parahydroxybenzoate  
Isopropyl Alcohol

Aniseed Oil  
Purified Water

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

24 months  
Use within 3 months of opening

**6.4 Special precautions for storage**

Do not store above 25°C. Do not refrigerate or freeze.

**6.5 Nature and contents of container**

Pharmaceutical Grade Type III amber glass bottles with white polypropylene caps that have a Low density Polyethylene (LDPE) liner  
Pack sizes: 150ml, 200ml, 250ml and 500ml.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

Shake bottle well before use

**7 MARKETING AUTHORISATION HOLDER**

Pinewood Laboratories Limited,  
Ballymacarbry,  
Clonmel,  
Co. Tipperary,  
Ireland.

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 04917/0086

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

17/02/2012

**10 DATE OF REVISION OF THE TEXT**

17/02/2012

**1 NAME OF THE MEDICINAL PRODUCT**  
Pinewood Max Strength Heartburn Relief Oral Suspension

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 10 ml contains:

Sodium Alginate	1000 mg
Sodium Bicarbonate	200 mg
Calcium Carbonate	200 mg

Excipients include:

Ethyl parahydroxybenzoate (E214)	15.0 mg/10 ml
Propyl parahydroxybenzoate (E216)	5.50 mg/10 ml
Butyl parahydroxybenzoate	2.50 mg/10 ml

For a full list of excipients, see section 6.1

**3 PHARMACEUTICAL FORM**

Oral Suspension,  
Peppermint flavoured white or cream coloured suspension

**4 CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

**4.2 Posology and method of administration**

For oral use

Adults and children over 12 years and the Elderly:	5 – 10 ml
Children under 12 years:	only under medical supervision

Doses should be taken after meals and at bedtime.

**4.3 Contraindications**

Hypersensitivity to any of the ingredients of this medicinal product, including the esters of hydroxybenzoates (Parabens) (see section 6.1).

**4.4 Special warnings and precautions for use**

- 1) Treatment of children younger than 12 years of age is not generally recommended, except on medical advice
- 2) This medicinal product contains about 7.5 mmol of sodium per 10ml dose. To be taken into consideration by patients on a controlled sodium diet e.g. in cases of cardiac failure and renal impairment.
- 3) Each 10 ml contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
- 4) Compound Alginate Oral suspensions should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.
- 5) Parahydroxybenzoates (E214, E216) may cause allergic reactions (possibly delayed)
- 6) If symptoms do not improve after seven days, medical advice should be sought.
- 7) There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

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

- 1) Antacids may interact with other drugs as they alter the gastric pH which may affect dissolution, solubility or ionization of the other drug. Antacids reduce the absorption of certain drugs from the following groups: ACE Inhibitors, Analgesics, Antibacterials, Antiepileptics, Antifungals, Antimalarials, Antipsychotics, Bisphosphonates, Lithium and Penicillamine.

- 2) Antacids may increase the pH of the urine and affect the rate of drug elimination. Excretion of basic drugs is decreased whereas acidic drugs are eliminated more rapidly.
- 3) Due to effects at the renal level sodium bicarbonate may reduce plasma lithium levels and increase plasma quinidine levels.

#### **4.6 Fertility, pregnancy and lactation**

An open, uncontrolled study in 146 pregnant women did not demonstrate any significant adverse effects of this product on the course of pregnancy or on the health of the fetus/new-born child. No effects during pregnancy are anticipated, since systemic exposure to this product is negligible. This product can be used during pregnancy. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to this product is negligible. Based on this and previous experience this product may be used during pregnancy and lactation, however it is recommended to limit the treatment duration as much as possible.

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

There are no known effects on ability to drive or operate machinery.

#### **4.8 Undesirable effects**

Constipation, flatulence, stomach cramps or belching may occasionally occur. Very rarely, in less than one in ten-thousand cases, patients sensitive to the ingredients develop allergic manifestations such as bronchospasm, urticaria, and anaphylaxis.

#### **4.9 Overdose**

As Compound Alginate Oral suspensions mode of action is physical, overdosage in terms of the alginate content is virtually no hazard. The only consequence is abdominal distension which is best treated conservatively. The relatively low concentrations of sodium and calcium carbonate in this product would also make serious consequences from overdosage very unlikely.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

ATC Code: A02BX13

Pharmaceutical group: Other drugs for peptic ulcer and gastro-oesophageal reflux

When taken after a meal Sodium Alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft.

#### **5.2 Pharmacokinetic properties**

The mode of action of the product is physical and does not depend on absorption into the systemic circulation.

#### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Carbomer  
Sodium Hydroxide  
Saccharin Sodium  
Ethyl Parahydroxybenzoate (E214)  
Propyl Parahydroxybenzoate (E216)  
Butyl Parahydroxybenzoate  
Isopropyl Alcohol  
Peppermint Oil  
Purified Water

#### **6.2 Incompatibilities**

None known.

- 6.3 Shelf life**  
24 months  
Use within 3 months of opening
- 6.4 Special precautions for storage**  
Do not store above 25°C. Do not refrigerate or freeze.
- 6.5 Nature and contents of container**  
Pharmaceutical Grade Type III amber glass bottles with white polypropylene caps that have a Low density Polyethylene (LDPE) liner  
Pack sizes: 150ml, 200ml, 250ml and 500ml.  
  
Not all pack sizes may be marketed.
- 6.6 Special precautions for disposal**  
Shake bottle well before use
- 7 MARKETING AUTHORISATION HOLDER**  
Pinewood Laboratories Limited,  
Ballymacarbry,  
Clonmel,  
Co. Tipperary,  
Ireland.
- 8 MARKETING AUTHORISATION NUMBER(S)**  
PL 04917/0089
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
17/02/2012
- 10 DATE OF REVISION OF THE TEXT**  
17/02/2012

**1 NAME OF THE MEDICINAL PRODUCT**

Pinewood Max Strength Heartburn Relief Oral Suspension Sachets

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 10 ml contains:

Sodium Alginate	1000 mg
Sodium Bicarbonate	200 mg
Calcium Carbonate	200 mg

Excipients include:

Ethyl parahydroxybenzoate (E214)	15.0 mg/10 ml
Propyl parahydroxybenzoate (E216)	5.50 mg/10 ml
Butyl parahydroxybenzoate	2.50 mg/10 ml

For a full list of excipients, see section 6.1

**3 PHARMACEUTICAL FORM**

Oral Suspension,  
Aniseed flavoured white or cream coloured suspension

**4 CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

**4.2 Posology and method of administration**

For oral use

Adults and children over 12 years and the Elderly:	5 – 10 ml
Children under 12 years:	only under medical supervision

Doses should be taken after meals and at bedtime.

**4.3 Contraindications**

Hypersensitivity to any of the ingredients of this medicinal product, including the esters of hydroxybenzoates (Parabens) (see section 6.1).

**4.4 Special warnings and precautions for use**

- 1) Treatment of children younger than 12 years of age is not generally recommended, except on medical advice
- 2) This medicinal product contains about 7.5 mmol of sodium per 10ml dose. To be taken into consideration by patients on a controlled sodium diet e.g. in cases of cardiac failure and renal impairment.
- 3) Each 10 ml contains 200 mg (2.0 mmol) of calcium carbonate. Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis and recurrent calcium containing renal calculi.
- 4) Compound Alginate Oral suspensions should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.
- 5) Parahydroxybenzoates (E214, E216) may cause allergic reactions (possibly delayed)
- 6) If symptoms do not improve after seven days, medical advice should be sought.
- 7) There is a possibility of reduced efficacy in patients with very low levels of gastric acid.

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

- 1) Antacids may interact with other drugs as they alter the gastric pH which may affect dissolution, solubility or ionization of the other drug. Antacids reduce the absorption of certain drugs from the following groups: ACE Inhibitors, Analgesics, Antibacterials, Antiepileptics, Antifungals, Antimalarials, Antipsychotics, Bisphosphonates, Lithium and Penicillamine.

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- 3) Due to effects at the renal level sodium bicarbonate may reduce plasma lithium levels and increase plasma quinidine levels.

#### **4.6 Fertility, pregnancy and lactation**

An open, uncontrolled study in 146 pregnant women did not demonstrate any significant adverse effects of this product on the course of pregnancy or on the health of the fetus/new-born child. No effects during pregnancy are anticipated, since systemic exposure to this product is negligible. This product can be used during pregnancy. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to this product is negligible. Based on this and previous experience this product may be used during pregnancy and lactation, however it is recommended to limit the treatment duration as much as possible.

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

There are no known effects on ability to drive or operate machinery.

#### **4.8 Undesirable effects**

Constipation, flatulence, stomach cramps or belching may occasionally occur. Very rarely, in less than one in ten-thousand cases, patients sensitive to the ingredients develop allergic manifestations such as bronchospasm, urticaria, and anaphylaxis.

#### **4.9 Overdose**

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### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

ATC Code: A02BX13

Pharmaceutical group: Other drugs for peptic ulcer and gastro-oesophageal reflux

When taken after a meal Sodium Alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft.

#### **5.2 Pharmacokinetic properties**

The mode of action of the product is physical and does not depend on absorption into the systemic circulation.

#### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Carbomer  
Sodium Hydroxide  
Saccharin Sodium  
Ethyl Parahydroxybenzoate (E214)  
Propyl Parahydroxybenzoate (E216)  
Butyl Parahydroxybenzoate  
Isopropyl Alcohol  
Aniseed Oil  
Purified Water

#### **6.2 Incompatibilities**

None known.

- 6.3 Shelf life**  
24 months  
Use within 3 months of opening
- 6.4 Special precautions for storage**  
Do not store above 25°C. Do not refrigerate or freeze.
- 6.5 Nature and contents of container**  
Sachets which are composed of paper, polyethylene, aluminium and ethylene/methacrylic acid  
co-polymer partial zinc salt  
Pack sizes: 5ml  
  
Not all pack sizes may be marketed.
- 6.6 Special precautions for disposal**  
Massage sachet well before use
- 7 MARKETING AUTHORISATION HOLDER**  
Pinewood Laboratories Limited,  
Ballymacarbry,  
Clonmel,  
Co. Tipperary,  
Ireland.
- 8 MARKETING AUTHORISATION NUMBER(S)**  
PL 04917/0098
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
17/02/2012
- 10 DATE OF REVISION OF THE TEXT**  
17/02/2012

**1 NAME OF THE MEDICINAL PRODUCT**  
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**3 PHARMACEUTICAL FORM**

Oral Suspension,  
Peppermint flavoured white or cream coloured suspension

**4 CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

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### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

ATC Code: A02BX13

Pharmaceutical group: Other drugs for peptic ulcer and gastro-oesophageal reflux

When taken after a meal Sodium Alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft.

#### **5.2 Pharmacokinetic properties**

The mode of action of the product is physical and does not depend on absorption into the systemic circulation.

#### **5.3 Preclinical safety data**

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of the SmPC.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Carbomer  
Sodium Hydroxide  
Saccharin Sodium  
Ethyl Parahydroxybenzoate (E214)  
Propyl Parahydroxybenzoate (E216)  
Butyl Parahydroxybenzoate  
Isopropyl Alcohol  
Peppermint Oil  
Purified Water

#### **6.2 Incompatibilities**

None known.

- 6.3 Shelf life**  
24 months  
Use within 3 months of opening
- 6.4 Special precautions for storage**  
Do not store above 25°C. Do not refrigerate or freeze.
- 6.5 Nature and contents of container**  
Sachets which are composed of paper, polyethylene, aluminium and ethylene/methacrylic acid co-polymer partial zinc salt  
Pack sizes: 5ml  
  
Not all pack sizes may be marketed.
- 6.6 Special precautions for disposal**  
Massage sachet well before use
- 7 MARKETING AUTHORISATION HOLDER**  
Pinewood Laboratories Limited,  
Ballymacarbry,  
Clonmel,  
Co. Tipperary,  
Ireland.
- 8 MARKETING AUTHORISATION NUMBER(S)**  
PL 04917/0103
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
17/02/2012
- 10 DATE OF REVISION OF THE TEXT**  
17/02/2012

## Module 3

### Patient Information Leaflet

*Please note that there is no mock-up available. The marketing authorisation holder has stated that it does not intend to market the product; therefore no UK-specific documents have been submitted. The marketing authorisation holder has committed to submit the UK PIL to the regulatory authority for review before marketing the product.*

#### PACKAGE LEAFLET: INFORMATION FOR THE USER

#### Pinewood Max Strength Heartburn Relief Oral Suspension Pinewood Max Strength Heartburn Relief Oral Suspension Sachets

sodium alginate 1000 mg/10 ml, sodium bicarbonate 200 mg/10 ml, calcium carbonate 200 mg/10 ml

#### **Read all of this leaflet carefully before you start taking this medicine.**

This medicine is available without prescription. However, you still need to use the product carefully to get the best results from it. You must contact a doctor if your symptoms worsen or do not improve after seven days.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What this medicine is and what it is used for
2. Before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Further information

#### **1. WHAT THIS MEDICINE IS AND WHAT IT IS USED FOR**

Max Strength Heartburn Relief belongs to a group of medicines called “reflux suppressants”. Reflux is when the acid stomach contents flow back up the gullet (oesophagus) and this can cause pain and discomfort known as heartburn or acid indigestion. This medicine contains the active ingredients sodium alginate, sodium bicarbonate and calcium carbonate which together form a protective layer at the top of your stomach to stop reflux from happening. It can therefore be taken to prevent and relieve the symptoms of acid reflux, including during pregnancy.

#### **2. BEFORE YOU TAKE THIS MEDICINE**

##### **Do not take Max Strength Heartburn Relief if you:**

- are allergic (hypersensitive) to any of the ingredients in this medicine, including the esters of hydroxybenzoates (parabens) (*see Section 6 and end of Section 2*)

##### **Take special care with Max Strength Heartburn Relief**

You must tell your doctor or pharmacist and take special care if you are:

- on a sodium restricted diet or suffer from too much calcium in the blood (*see end of section 2*)
- Treatment of children younger than 12 years of age is not generally recommended, except on medical advice

Max Strength Heartburn Relief should not be taken within 1 to 2 hours of taking other medicines by mouth, or for more than 7 days if symptoms persist.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription and especially if you are taking any of the following, as interactions can occur:

- ACE inhibitors
- Analgesics
- Antibacterials
- Antiepileptics
- Antifungals
- Antimalarials
- Antipsychotics
- Bisphosphonates
- Lithium
- Penicillamine

### Taking this medicine with food and drink

This medicine should be taken after meals and at bedtime.

### Pregnancy and breast-feeding

This medicine can be used during pregnancy and breast-feeding, however it is recommended to limit the treatment duration as much as possible.

### Driving and using machines

There are no known effects of this medicine on ability to drive or operate machinery.

### Important information about some of the ingredients of Max Strength Heartburn Relief

This medicine also contains:

- **Parahydroxybenzoates:** may cause allergic reactions, possibly delayed
- **Sodium:** Each 10 ml dose of this medicine contains about 7.5 mmol of sodium and therefore care should be exercised in patients on a sodium restricted diet.

## 3. HOW TO TAKE THIS MEDICINE

To be taken by mouth, after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines. If you are unsure how to use this medicine, check with your doctor or pharmacist.

Adults and children over 12 years and the Elderly:	5 – 10 ml
Children under 12 years:	only under medical supervision

**WARNING: DO NOT EXCEED THE STATED DOSE**

### If you take more of this medicine than you should

Overdose is very unlikely but if it occurs it may cause bloating.

### **If you forget to take Max Strength Heartburn Relief**

If you forget to take your medicine, take it as soon as you remember, **Do not** take a double dose to make up for the forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this product can cause side effects, although not everybody gets them.

### Very rarely:

- Patients who are sensitive to the ingredients can develop allergic reactions such as difficulty breathing, hives and swelling of the face. If this occurs you should stop taking the medicine and seek immediate medical attention.

### Occasional:

- Constipation
- Flatulence
- Stomach cramp
- Belching

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE THIS MEDICINE**

**Keep out of the reach and sight of children.** Do not store above 25°C. Do not refrigerate or freeze.

Do not use this product after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Max Strength Heartburn Relief contains:**

- The **active ingredients** are: Sodium alginate 1000 mg/10 ml, Sodium bicarbonate 200 mg/10 ml and Calcium carbonate 200 mg/10 ml
- The **other ingredients** are: Carbomer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate, Isopropyl Alcohol, Aniseed Oil and Purified Water (*see end of Section 2 for further information*)
- The **other ingredients** are: Carbomer, Sodium Hydroxide, Saccharin Sodium, Ethyl Parahydroxybenzoate (E214), Propyl Parahydroxybenzoate (E216), Butyl Parahydroxybenzoate,

Isopropyl Alcohol, Peppermint Oil and Purified Water (*see end of Section 2 for further information*)

**What Max Strength Heartburn Relief looks like and contents of the pack**

This medicine is an aniseed flavoured white or cream coloured suspension.

This medicine is a peppermint flavoured white or cream coloured suspension.

It comes in sachets consisting of paper, polyethylene, aluminium and partial zinc salt, as well as in amber glass bottles of 150 ml, 200 ml, 250 ml, 300 ml and 500 ml with white polypropylene caps.

Not all pack sizes may be marketed.

**Manufacturer / Marketing Authorisation Holder**

Pinewood Laboratories Limited,  
Ballymacarbry,  
Clonmel,  
Co. Tipperary, Ireland.

PL Number: 04917/0086

PL Number: 04917/0089

PL Number: 04917/0098

PL Number: 04917/0103

**This leaflet was last updated in 01/2011**

## Module 4 Labelling

*Please note that there is no mock-up available. The marketing authorisation holder has stated that it does not intend to market the product; therefore, no UK-specific documents have been submitted. The marketing authorisation holder has committed to submit the UK labelling to the regulatory authority for review before marketing the product.*

### PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

**Bottle label (attached to fix-a-form)**

#### 1. NAME OF THE MEDICINAL PRODUCT

##### **Pinewood Max Strength Heartburn Relief Oral Suspension**

*Listed near product name as part of the labeling, will be written:*

sodium alginate, sodium bicarbonate, calcium carbonate

(Aniseed flavour)

(Peppermint flavour)

#### 2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate

#### 3. LIST OF EXCIPIENTS

Also contains parahydroxybenzoates (Parabens, E214 and E216) which may cause allergic reactions (possibly delayed).

This medicinal product contains about 7.5 mmol of sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet. Care should also be taken if on calcium controlled diet.

Read the attached leaflet carefully before use.

#### 4. PHARMACEUTICAL FORM AND CONTENTS

150 ml oral suspension

200 ml oral suspension

250 ml oral suspension

500 ml oral suspension

#### 5. METHOD AND ROUTE(S) OF ADMINISTRATION

To be taken by mouth after meals and at bedtime. Shake bottle well before use. Leave 1-2 hours between taking this medicine and other medicines.

#### 6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

Take special care if you are allergic to any of the ingredients of this medicine.  
Side effects are occasional. See leaflet for further information.

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store below 25°C. Do not use after the expiry date shown on the label. Do not refrigerate or freeze

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Excluded due to space restrictions and because it is outlined in section 5 of fix-a-form.

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

**Marketing Authorisation Holder:**

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

**12. MARKETING AUTHORISATION NUMBER(S)**

PL 04917/0086

PL 04917/0089

**13. BATCH NUMBER**

B/N: XXXXX

**14. GENERAL CLASSIFICATION FOR SUPPLY**

GSL

**15. INSTRUCTIONS ON USE**

Excluded due to space restrictions and because it is outlined in section 5 of fix-a-form.

**16. INFORMATION IN BRAILLE**

Pinewood Max Strength Heartburn Relief

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**  
Sachet carton

**1. NAME OF THE MEDICINAL PRODUCT**

**Pinewood Max Strength Heartburn Relief Oral Suspension Sachets**

*Listed near product name as part of the labeling, will be written:*  
sodium alginate, sodium bicarbonate, calcium carbonate

(Aniseed flavor)  
(Peppermint flavour)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

Each 10 ml of the oral suspension contains 1000 mg of sodium alginate, 200 mg of sodium bicarbonate and 200 mg of calcium carbonate

**3. LIST OF EXCIPIENTS**

Also contains parahydroxybenzoates (Parabens, E214 and E216) which may cause allergic reactions (possibly delayed).

This medicinal product contains about 7.5 mmol of Sodium per 10 ml dose. To be taken into consideration by patients on a controlled sodium diet. Care should also be taken if on calcium controlled diet.

See leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

5 ml sachet

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

Take special care if you are allergic to any of the ingredients of this medicine  
Not recommended for use in children.  
Read the enclosed leaflet before use

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store below 25°C. Do not refrigerate or freeze. Do not use after the expiry date shown on the label and carton. The expiry date refers to the last day of the month.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Excluded as this information is outlined in section 5 of the In-Pack Leaflet

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland

**12. MARKETING AUTHORISATION NUMBER(S)**

PL 04917/0098

PL 04917/0103

**13. BATCH NUMBER**

B/N: XXXXX

**14. GENERAL CLASSIFICATION FOR SUPPLY**

GSL

**15. INSTRUCTIONS ON USE**

**How to take this medicine:** To be taken by mouth, after meals and at bedtime. Massage sachet before use. Leave 1-2 hours between taking this medicine and other medicines.

Adults and children over 12 years and the Elderly:	5 – 10 ml
Children under 12 years:	only to be taken under medical supervision

Doses should be taken after meals and at bedtime.

**Take care** if you are taken other medicines, especially: ACE inhibitors, analgesics, antibiotics, antiepileptics, antifungals, antimalarials, antipsychotics, bisphosphonates, lithium and penicillamine

**Side effects** are occasional and may include: Constipation, flatulence, stomach cramps or belching

**16. INFORMATION IN BRAILLE**

Pinewood Max Strength Heartburn Relief

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS –  
Sachet labels**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

**Pinewood Max Strength Heartburn Relief Oral Suspension Sachets**

*Listed near product name as part of the labeling, will be written:*  
sodium alginate, sodium bicarbonate, calcium carbonate

(Aniseed flavour)

(Peppermint flavour)

Oral use

**2. METHOD OF ADMINISTRATION**

Read all of the package leaflet carefully before use.

**3. EXPIRY DATE**

EXP: MM/YYYY

**4. BATCH NUMBER**

B/N: XXXXX

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

5 ml sachet

**6. OTHER**

Store below 25°C.  
Do not use after the expiry date shown on the carton.  
Do not refrigerate or freeze

**Marketing Authorisation Holder:**

Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

## **Module 5**

### **Scientific discussion during initial procedure**

#### **I INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the UK as RMS and Italy as CMS considered that the applications for Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets could be approved. These products have a general sales licence (GSL) and are indicated for the alleviation of the symptoms of gastro-oesophageal reflux by suppressing the reflux itself. It is indicated for the treatment of dyspepsia and heartburn due to gastric reflux associated with hiatus hernia, pregnancy and reflux oesophagitis.

These applications for Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets is submitted as an abridged application according to Article 10.3 of Directive 2001/83/EC, as amended, claiming to be a hybrid product to Gaviscon Liquid, originally approved in the UK to Reckitt & Colman on 14<sup>th</sup> April 1977 (PL 00044/0058).

When the product is taken after a meal, sodium alginate forms a raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours. Sodium bicarbonate reacts with gastric acid to produce carbon dioxide which is retained in the gel and allows the raft to rise to the surface of the gastric contents. Calcium ions from calcium carbonate link the alginic acid molecules and strengthen the raft. This suppresses reflux.

No new non-clinical studies were conducted, which is acceptable given that the products contain widely-used, well-known active substances. No clinical studies have been performed and none are required for these applications as the pharmacology of sodium alginate, sodium bicarbonate and calcium carbonate is well-established.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

The RMS considers that the pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

A satisfactory justification was provided for the absence of a Risk Management Plan.

## II. ABOUT THE PRODUCT

Name of the products in the Reference Member State	Pinewood Max Strength Heartburn Relief Oral Suspension  Pinewood Max Strength Heartburn Relief Oral Suspension Sachets
Name(s) of the active substances (INN)	Sodium alginate Sodium bicarbonate Calcium carbonate
Pharmacotherapeutic classification (ATC code)	Other drugs for peptic ulcer and gastro-oesophageal reflux A02BX13
Pharmaceutical form and strength(s)	<b>Form:</b> Oral Suspension <b>Strength:</b> Sodium alginate: 1000 mg Sodium bicarbonate: 200 mg Calcium carbonate: 200 mg
Reference numbers for the Decentralised Procedure	UK/H/2675/001-4/DC
Reference Member State	United Kingdom (UK)
Member States concerned	Italy (IT)
Marketing Authorisation Number(s)	PL 04917/0086, 0089, 0098 & 0103
Name and address of the authorisation holder	Pinewood Laboratories Limited, Ballymacarbry, Clonmel, Co. Tipperary, Ireland

### III SCIENTIFIC OVERVIEW AND DISCUSSION

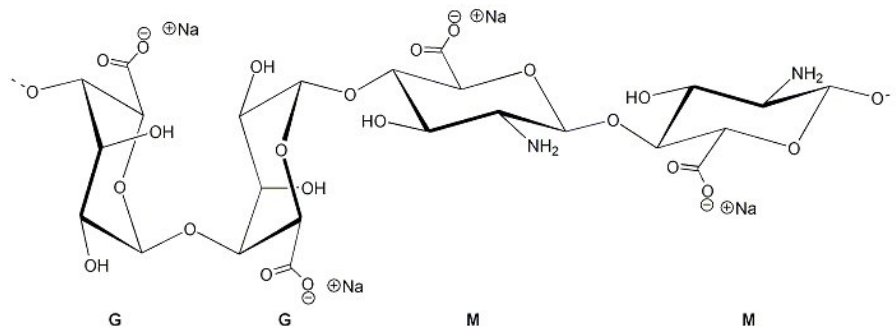
#### III.1 QUALITY ASPECTS

##### S. Active substance

###### Sodium Alginate

INN: Sodium alginate

Structure:



Physical form: A white to pale yellowish-brown powder.

Solubility: Soluble in water, practically insoluble in alcohol.

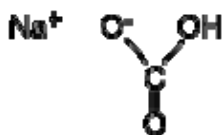
Molecular formula: (NaC<sub>6</sub>H<sub>7</sub>O<sub>6</sub>)<sub>n</sub>

Molecular weight: (216)

###### Sodium Bicarbonate (sodium hydrogen carbonate)

INN: Sodium hydrogen carbonate

Structure:



Physical form: White crystalline powder

Solubility: Soluble in water and very slightly soluble in alcohol

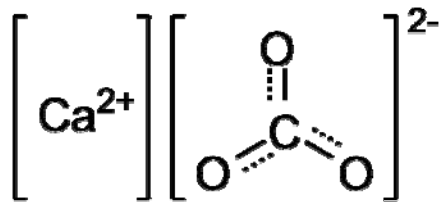
Molecular formula: NaHCO<sub>3</sub>

Molecular weight: 84.0

###### Calcium Carbonate

INN: Calcium carbonate

Structure:



Physical form: White or almost white powder

Solubility: Largely insoluble in water

Molecular formula:  $\text{CaCO}_3$   
Molecular weight: 100.09

The sources of sodium alginate, sodium bicarbonate and calcium carbonate comply with the relevant European Pharmacopoeia monographs for sodium alginate, sodium bicarbonate and calcium carbonate.

Synthesis of the active substances from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant Certificates of Analysis.

Appropriate specifications have been provided for the active substances. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Appropriate proof-of-structure data have been supplied for the active substances. Satisfactory Certificates of Analysis have been provided for all working standards. Batch analysis data are provided and comply with the proposed specification.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines.

Confirmation was provided that the active substances will be tested before each production campaign. A suitable re-test period has been provided and is approved.

## **P. Medicinal Product**

### **Other Ingredients**

Other ingredients consist of pharmaceutical excipients carbomer, sodium hydroxide, saccharin sodium, ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate, isopropyl alcohol and purified water.

PL 04917/0086 & 0098 have the additional excipient, aniseed oil.

PL 04917/0089 & 0103 have the additional excipient, peppermint oil.

All excipients comply with their relevant European Pharmacopoeia monographs.

None of the excipients used contain material of animal or human origin.

No genetically modified organisms (GMO) have been used in the preparation of these products.

### **Pharmaceutical Development**

The objective of the development programme was to produce oral suspensions containing sodium alginate, sodium bicarbonate and calcium carbonate that could be considered hybrid products of Gaviscon Liquid. The difference between the products being that the produced product would be twice as concentrated (twice as much sodium alginate) as Gaviscon Liquid therefore a smaller dosage volume dosage would be required.

The applicant has provided suitable product development information. Valid justifications for the use and amounts of each excipient have been provided.

### **Manufacturing Process**

Satisfactory batch formulae have been provided for the manufacture of the products, along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results. Satisfactory process validation data on batches have been provided.

### **Finished Product Specification**

The finished product specifications are satisfactory. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specifications. Certificates of Analysis for any working standards used have been provided.

### **Container-Closure System**

Pinewood Max Strength Heartburn Relief Oral Suspension (PL 04917/0086 & 0089): Type III amber glass bottles with white polypropylene (PP) caps that have a low-density polyethylene (LDPE) liner. Pack sizes are 150ml, 200ml, 250ml and 500ml.

Pinewood Max Strength Heartburn Relief Oral Suspension Sachets (PL 04917/0098 & 0103): Sachets which are composed of paper, polyethylene (PE), aluminium and ethylene/methacrylic acid co-polymer partial zinc salt. There is one pack size of 5ml.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary product packaging complies with EU legislation.

### **Stability of the product**

Stability studies were performed on batches of the finished products in the packaging proposed for marketing and in accordance with current guidelines. These data support a shelf-life of 24 months for an unopened product. The shelf-life after opening the product is 3 months.

The storage instructions are 'Do not store above 25°C. Do not refrigerate or freeze.' This is satisfactory.

### **Summary of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and Labelling**

The SmPCs, PIL and labelling are pharmaceutically acceptable.

User testing results have been submitted for the PIL for the previously approved product, Acidex Compound Alginate Oral Suspension Heartburn and Indigestion Liquid originally approved as Acidex liquid to Pinewood Laboratories Limited on 25<sup>th</sup> March 1998 (PL 04917/0021). The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that they contain. As the already approved PIL is similar to the PIL for the proposed product, this is satisfactory.

### **MAA Forms**

The MAA forms are pharmaceutically satisfactory.

### **Quality Overall Summary**

The quality overall summary has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical dossier.

**Conclusion**

It is recommended that Marketing Authorisations are granted for these applications from a quality point of view.

### **III.2 NON-CLINICAL ASPECTS**

The pharmacodynamics, pharmacokinetics and toxicological properties of sodium alginate, sodium bicarbonate and calcium carbonate are well-known. As sodium alginate, sodium bicarbonate and calcium carbonate are widely used, well-known active substances, the applicant has not provided any additional studies and none are required. An overview based on literature review is therefore appropriate.

The non-clinical expert report has been written by an appropriately qualified person and is a suitable summary of the non-clinical aspects of the dossier.

A satisfactory justification was provided for the absence of an Environmental Risk Assessment.

It is recommended that Marketing Authorisations are granted for this application from a non-clinical point of view.

### **III.3 CLINICAL ASPECTS**

This assessment report represents an evaluation of the key elements of the information provided by the company in the dossier.

#### **Clinical Pharmacology**

The applicant's products are hybrid products of the reference product; oral suspensions with a mainly local (mechanical effect within the gastro-intestinal tract, intended to act without systemic absorption). Therefore, as per the Guidance on the Investigation of Bioavailability and Bioequivalence CPMP/EWP/QWP/1401/98 Rev 1, a bioequivalence study based on systemic measurements is not required for these applications.

The product has twice as much sodium alginate as the reference product; therefore a smaller dosage volume dosage is required. The active ingredients and excipients remain well within safety margins.

#### **Efficacy**

No new efficacy data were submitted with these applications and none were required.

#### **Safety**

No new safety data were submitted with these applications and none were required.

#### **Summary of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and Labelling**

The SmPCs, PIL and labelling are clinically satisfactory and consistent with those for the reference product, where appropriate.

#### **Clinical Overview**

The clinical overview has been written by an appropriately qualified physician and is a suitable summary of the clinical aspects of the dossier.

#### **MAA Forms**

The MAA forms are clinically satisfactory.

#### **Conclusions**

It is recommended that Marketing Authorisations are granted for these applications from a clinical point of view.

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

##### **QUALITY**

The important quality characteristics of Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

##### **NON-CLINICAL**

No new non-clinical data were submitted and none are required for applications of this type.

##### **CLINICAL**

The applicant's products, Pinewood Max Strength Heartburn Relief Oral Suspension/Pinewood Max Strength Heartburn Relief Oral Suspension Sachets are hybrid products of Gaviscon Liquid.

No new or unexpected safety concerns arise from these applications.

The SmPCs, PIL and labelling are satisfactory and consistent with that for the reference product.

##### **RISK-BENEFIT ASSESSMENT**

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with sodium alginate, sodium bicarbonate and calcium carbonate is considered to have demonstrated the therapeutic value of the compounds. The risk benefit assessment is therefore considered to be positive.

## Module 6

### STEPS TAKEN AFTER INITIAL PROCEDURE - SUMMARY

Date submitted	Application type	Scope	Outcome