

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Lowasa Tablets 75 mg

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 75mg Aspirin (acetylsalicylic acid)

#### 3 PHARMACEUTICAL FORM

White, uncoated tablets

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Aspirin has analgesic, antipyretic and anti-inflammatory actions and an antithrombotic effect through inhibition of platelet activation. This preparation is indicated for the prophylactic management of cardiovascular disease or myocardial infarction.

##### 4.2 Posology and method of administration

The tablets should be dispersed in water before administration, and taken immediately.

Adults including elderly: The usual dose is 75-150mg daily.

Children: Do not give to children and adolescents under 16 years, except on medical advice, where the benefit outweighs the risk.

##### 4.3 Contraindications

Aspirin should not be taken by patients with a known idiosyncrasy to aspirin or other nonsteroidal anti-inflammatory drugs or those suffering from active peptic ulceration or coagulation disorders. Children particularly those under 16 years of age, unless advised by a doctor.

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

Patients treated with Aspirin long-term should undergo regular medical supervision to monitor for adverse events. Elderly patients are particularly susceptible to the adverse effects of NSAIDs.

There is possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason aspirin should not be given to children and adolescents under 16 years unless specifically indicated.

Aspirin should be used with caution in patients with a history of peptic ulceration, inflammatory bowel disease or coagulation abnormalities. It may induce gastrointestinal haemorrhage, occasionally major.

In patients with strokes, aspirin should not be given until the possibility of cerebral haemorrhage has been excluded.

Aspirin should be used with caution in patients with impaired renal function or hepatic function, since the use of NSAIDs may lead to deterioration in renal function.

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

**It is considered unsafe to take NSAIDs in combination with warfarin or heparin unless under direct medical supervision.**

Care should be taken in patients treated with any of the following drugs as interactions have been reported.

Antihypertensives: reduced anti-hypertensive effect.

Diuretics: reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

Lithium: decreased elimination of lithium.

Methotrexate: decreased elimination of methotrexate.

Cyclosporin: increased risk of nephrotoxicity with NSAIDs.

Other NSAIDs: avoid concomitant use of two or more NSAIDs.

Corticosteroids: increased risk of gastrointestinal bleeding.

Aminoglycosides: reduction in renal function in susceptible individuals, decreased elimination of aminoglycoside and increased plasma concentrations.

Probenecid: reduction in metabolism and elimination of NSAIDs and metabolites.

Oral hypoglycaemic agents: inhibition of metabolism of sulfonylurea drugs, prolonged half-life and increased risk of hypoglycaemia.

## 4.6 Pregnancy and lactation

Aspirin may prolong labour and contribute to maternal and neonatal bleeding and is best avoided at term. Routine use should be avoided during pregnancy, and when breast-feeding, since it is excreted into breast milk.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Aspirin may precipitate bronchospasm, and induce attacks of asthma in susceptible subjects; it may induce gastrointestinal haemorrhage, occasionally major.

## 4.9 Overdose

Symptoms include hyperventilation, tinnitus, deafness, vasodilatation and sweating. Coma is uncommon but indicates very severe poisoning. The associated metabolic and acid-base disturbances are complex.

Hypoglycaemia may be severe in children.

Gastric emptying should be carried out; a worthwhile recovery of salicylates may be achieved up to 24 hours after ingestion. Plasma salicylate, pH and electrolytes should be measured, fluid losses replaced and forced alkaline diuresis should be considered when the plasma salicylate concentration is greater than 500mg/L (3.6mmol) in adults or 300mg/L (2.2mmol/l) in children. Haemodialysis may sometimes be necessary.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Aspirin is an anti-inflammatory analgesic and antipyretic. It inhibits prostaglandin synthetase and platelet aggregation.

### 5.2 Pharmacokinetic properties

Absorption of non-ionised aspirin occurs in the stomach. Hydrolysis to salicylic acid occurs rapidly in the intestine and in the circulation. Aspirin is bound to plasma proteins and is rapidly distributed to all body tissues. It appears in breast milk and crosses the placenta. The rate of excretion of aspirin depends upon urinary pH, increasing as pH rises and being greatest at pH 7.5 and above. It is excreted as salicylic acid and as glucuronide conjugates and as salicyluric and gentisic acids.

### 5.3 Preclinical safety data

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Citric acid  
Lactose  
Maize starch  
Saccharin sodium  
Calcium carbonate (E170)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

3 years.

### 6.4 Special precautions for storage

Do not store above 25°C. Keep container tightly closed.

### 6.5 Nature and contents of container

The product containers are rigid injection moulded polypropylene or injection blow-moulded polyethylene containers with snap-on polyethylene lids. Amber glass containers with screw caps and polyfoam wad or cotton wool may be used as an alternative.

Lowasa tablets 75mg are available in pack sizes of 28 tablets and 100 tablets.

*Also included in each pack is a 2g silica gel capsule.*

## **6.6 Instructions for use and handling**

Disperse in water immediately before use.

## **7 MARKETING AUTHORISATION HOLDER**

Mayne Pharma Ireland Ltd.,  
Unit 31 Sandyford Industrial Estate,  
Foxrock,  
Dublin 18.

## **8 MARKETING AUTHORISATION NUMBER**

PA 422/6/1

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

Date of first authorisation: 22<sup>nd</sup> October 1996

Date of last renewal: 22<sup>nd</sup> October 2001

## **10 DATE OF REVISION OF THE TEXT**

July 2004