

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

Galways Antidiarrhoea Mixture (Galways ADM)

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

Each 30ml contains:

Pectin 250mg

Light Kaolin 6g

For a full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Oral suspension.

A white coloured, flavoured homogenous suspension.

## **4. Clinical particulars**

### **4.1 Therapeutic indications**

For the symptomatic relief of moderate to severe diarrhea and stomach cramps in adults and children.

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

Method of administration

Oral.

Posology

**Dosage:**

Adults and children over 12 years: 30ml.

Children 7 - 12 years: 15ml

Children 3 - 6 years: 10ml

Infants under 3 years: 2.5ml

Directions for use: Shake the bottle before use.

### **Dosage schedule:**

The appropriate dose should be taken at half-hourly intervals until symptoms abate.

Normally 3 – 4 doses should be sufficient.

If symptoms persist, consult your doctor.

Treatment should be accompanied by adequate fluid intake and electrolyte replacement.

### **4.3 Contraindications**

Galways ADM is contraindicated in intestinal obstruction; and in patients with known hypersensitivity to pectin and kaolin.

It should be used in reduced dosage in all patients with severe liver disease, especially if there's evidence of jaundice, or encephalopathy. It should also be kept to a minimum in patients with renal failure, to avoid possibility of toxicity, increased sensitivity and side effects.

Concomitant use of this preparation with Analgesics, Antibacterials, Antiepileptics, Antimalerials, Antifungals and Antipsychotics should be avoided because of the reduction in absorption of these drugs when taken with Kaolin and pectin preparation.

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

Avoid prolonged use.

If symptoms persist, consult your doctor.

Treatment should be accompanied by adequate fluid intake and electrolyte replacement.

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

Since pectin and kaolin are adsorbents, the absorption of other drugs from the gastro-intestinal tract may be reduced if administered concomitantly. Therefore concurrent administration with other drugs should be avoided. Kaolin possibly reduces absorption of aspirin, tetracycline, chloroquine and hydroxychloroquine, and phenothiazines.

#### **4.6 Pregnancy and Lactation**

No teratogenic effect has been reported with the use of this medication. It is not excreted in breast-milk. Galways ADM can be used during pregnancy; however the policy of avoiding drug therapy especially in the first trimester of pregnancy should be borne in mind.

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

Galways ADM has no influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

The most common side effects associated with administration of the preparation include constipation, bloating and fullness mostly due to the large quantity taken in cases where the diarrhoeal episodes recur in rapid succession over several hours.

Formation of insoluble complexes with other drugs occurs in the gastrointestinal tract; thereby reducing their absorption when administered concurrently with light kaolin.

Constipation and dehydration may also occur.

#### **4.9 Overdose**

Prolonged use or overdosage may result in diarrhoea with excessive loss of water and electrolytes, particularly potassium. Since pectin and kaolin are little or unabsorbed, excessive dosage can be removed by emesis.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Intestinal adsorbent, ATC code: A07BC02.

Kaolin is an adsorbent; it adsorbs toxic and other substances from the alimentary tract and increases the bulk of the faeces.

Pectin is an adsorbent that binds to bacteria, toxins and other irritants in the intestinal mucosa. Pectin is able to decrease the pH in the intestinal lumen and provides a soothing effect on the irritated mucosa. Pectin increases viscosity and volume of stools which helps it to be used for constipation and diarrhea.

#### **5.2 Pharmacokinetic properties**

##### KAOLIN

Kaolin is little or unabsorbed from the stomach therefore the pharmacokinetic property is irrelevant.

##### PECTIN

Pectin is not absorbed and it is not distributed in the body and pharmacokinetic studies have not been performed as pectin is not absorbed

Pectin is depolymerized and de-esterified to a very small extent. It passes to the small intestine as a macromolecule and the majority of the pectin is eliminated unchanged. It is completely excreted in the feces, including a small amount of trigalacturonic acid that can be found in the colon.

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

No data of relevance to the prescriber, which is additional to that included in other sections of the SPC.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Methyl Hydroxybenzoate  
Apple Flavour  
Glycerol  
Dichlorobenzyl Alcohol  
Xanthan Gum  
Purified Water

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Store below 30°C. Protect from light and replace the cap securely after use.  
Keep all medicines out of the reach of children.

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

60ml bottle with aluminium ROPP screw cap.

### **6.6 Special precautions for disposal**

No special requirements.

## **7 APPLICANT/MANUFACTURER**

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