SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Actonorm Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Gram of powder contains:
Atropine Sulfate 0.1mg
Magnesium Trisilicate 50.0mg
Magnesium Carbonate 381.4mg
Calcium Carbonate 145.0mg
Aluminium Hydroxide Gel Dried 50.0mg
Sodium Bicarbonate 373.0mg
Oil of Peppermint 0.5mg

3 PHARMACEUTICAL FORM

Oral Powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an adjunct in the symptomatic relief of dyspepsia and gastrointestinal disorders characterised by smooth muscle spasm.

4.2 Posology and method of administration

Adults: One level 5ml spoonful to be taken in milk or water three or four times a day.

Elderly: The elderly are more at risk of anticholinergic effects and therefore are advised to start with one 5ml level spoonful twice a day

Children: Not recommended for use in children

4.3 Contraindications

Hypersensitivity to atropine, pregnancy, breast feeding, unstable angina pectoris, fixed gastrointestinal obstruction (e.g. pyloric stenosis), paralytic ileus, toxic megacolon, severe ulcerative colitis, obstructive uropathy, glaucoma, myasthenia gravis

4.4 Special warnings and precautions for use

To be used with caution in patients with renal or hepatic dysfunctions, asthma, hypertension, cardiac arrhythmias or tachycardia, severe coronary artery

disease, hyperthyroidism, and the elderly. Anticholinergic drugs aggravate gastro-oesophageal reflux in hiatus hernia. Patients should consult a doctor if symptoms deteriorate or persist after 5 days.

4.5 Interaction with other medicinal products and other forms of interaction

The gastrointestinal effects of atropine can alter the bioavailability of a number of drugs. Metoclopramide antagonises the gastrointestinal effects of atropine. Actonorm can potentiate anticholinergic effects of other drugs such as tricyclic antidepressants, antihistamines, antipsychotics, anti-parkinsonian and antiarrhythmic drugs. There is a risk of interaction with other drugs acting on the autonomic nervous system. The efficacy of sublingual preparations, e.g. of Glyceryl trinitrate may be adversely affected due to failure of rapid and adequate dissolution. The absorption of a number of drugs e.g. chlorpromazine and tetracycline may be affected by the antacids. Administration of antacids may alkalinise urine sufficiently to alter renal clearance of a number of drugs, e.g. quinidine and mexiletine.

4.6 Pregnancy and lactation

Contraindicated in pregnancy and lactation

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Dry mouth, constipation, dysphagia, nausea, vomiting, feeling of abdominal fullness, impotence, urinary retention or hesitancy, impairment of visual accommodation, tachycardia, palpitation, dizziness, weakness, insomnia, excitement, agitation, nervousness, suppression of lactation, heat prostration, allergic reactions.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

The symptoms and signs of overdosage include dilated pupils, blurred vision, dry skin, urinary retention, dry mouth, dysphagia, vomiting, muscular weakness, drowsiness, stupor, agitation, tremor, confusion, excitation, hallucinations, tachycardia, tachypnoea and possibly circulatory collapse. Treatment is symptomatic and supportive and should include gastric lavage and aspiration. Activated charcoal

has been recommended. Central stimulant effects may respond to intravenous sedatives while beta-blockers control tachycardia. Other anticholinergic effects respond to IV injections of 0.5 - 2mg neostygmine methylsulfate at suitable intervals. Assisted respiration andurinary catherisation may be necessary. Haemodialysis is not effective in atropine poisoning.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Atropine Sulfate is an Antispasmodic.
Oil of Peppermint is a Carminative.
Magnesium Trisilicate, Magnesium Carbonate, Calcium Carbonate, Aluminium Hydroxide and Sodium Bicarbonate are Antacids.

5.2 Pharmacokinetic properties

The antacids have a direct action on excess acidity in the gastro-intestinal tract. Atropine Sulfate is soluble and bioavailable. Peppermint Oil is released following the solution of its carrier and exerts a direct action.

5.3 Preclinical safety data

None Stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

There are no excipients in this product

6.2 Incompatibilities

See 4.5 (Interactions with other Medicaments and other forms of Interaction)

6.3 Shelf life

60 months

6.4 Special precautions for storage

Store in a cool dry place

6.5 Nature and contents of container

Jar containing 85g

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Wallace Manufacturing Chemists Ltd.
Wallace House
51-53 Stert Street
Abingdon
Oxfordshire OX14 3JF
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00400/5002R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/01/1989 / 25/05/2005

10 DATE OF REVISION OF THE TEXT

04/12/2015