SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Actonorm 220mg / 200mg / 25mg in 5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Aluminium Hydroxide	220.0 mg
Magnesium Hydroxide	200.0 mg
Simeticone	25.0 mg

Excipients with known effect:

Sorbitol Solution 70% (non crystallising)	375mg/5ml
Propylene Glycol	500mg/5ml
Methyl Para Hydroxybenzoate	4.38 mg/5ml
Ethyl Para Hydroxybenzoate	0.96 mg/5ml
Propyl Para Hydroxybenzoate	0.66 mg/5ml
Butyl Para Hydroxybenzoate	1.00 mg/5ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

White suspension with the odour of peppermint.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of dyspepsia and flatulence

4.2 Posology and method of administration

Posology

Adults, Elderly and children over 12 years
One to Four 5ml spoonfuls

Children 1 to 12 years
One to Two 5ml spoonfuls.
To be taken after meals and at night as required

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Caution should be exercised when taking magnesium salts in renal failure. Patients should be advised that if symptoms persist for more than 7 days they should consult their doctor.

This medicine contains 500mg Propylene Glycol in each 5ml. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old.

While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case by case basis.

Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

This medicine contains 263mg Sorbitol in each 5ml. Sorbitol is a form of fructose. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Parahydroxybenzoates may cause allergic reactions (possible delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Reduced absorption may occur if taken simultaneously with pivampicillin, tetracyclines, ketoconazole, chlorpromazine, penicillamine and cimetidine.

4.6 Fertility, Pregnancy and lactation

There have been no specific studies using Actonorm during pregnancy. To date, no other relevant epidemiological data are available. Caution should be advised when prescribing to pregnant women, who should check with their physicians before using antacids.

4.7 Effects on ability to drive and use machines

Actonorm Gel has no or neglible influence in the ability to drive or use machines

4.8 Undesirable effects

Occasional and mild disturbance of bowel function

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ordinary salt combinations and antiflatulents
ATC code: A02AF02

Aluminium Hydroxide	Antacid
Magnesium Hydroxide	Antacid
Simeticone	Anti-flatulent

5.2 Pharmacokinetic properties

Aqueous suspension, bioavailable

5.3 Preclinical safety data

None

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol Solution
Sodium Saccharin
Methyl hydroxybenzoate
Ethyl hydroxybenzoate
Propyl hydroxybenzoate
Butyl hydroxybenzoate,
Propylene Glycol
Buttermint Toffee Flavour
Oil of Peppermint
Purified Water

6.2 Incompatibilities

Not known

6.3 Shelf life

24 months in original container

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

Amber Glass bottle of 200ml

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PL 00400/0008R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/06/1982 / 28/01/2005

10 DATE OF REVISION OF THE TEXT

02/10/2023