NEW ZEALAND DATA SHEET

1 GASTRO-SOOTHE® (Hyoscine-N-butylbromide 10mg film coated tablet)

(Gastro-Soothe) 10 mg Hyoscine-N-butylbromide film coated tablet

GASTRO-SOOTHE FORTE® (Hyoscine-N-butylbromide 20mg film coated tablet)

(Gastro-Soothe Forte) 20 mg Hyoscine-N-butylbromide film coated tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Gastro-Soothe
Each tablet contains 10 mg Hyoscine-N-butylbromide.

Gastro-Soothe Forte
Each tablet contains 20 mg Hyoscine-N-butylbromide.

For the list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

White, circular biconvex film coated tablet plain on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Muscle spasm of the gastrointestinal tract.

4.2 Dose and method of administration

Gastro-Soothe and Gastro-Soothe Forte are for oral administration only.

Gastro-Soothe and Gastro-Soothe Forte should be swallowed whole with adequate water.

Gastro-Soothe 10 mg/tablet
Adults and children over 6 years: 2 tablets (two 10 mg tablets = 20 mg) four times a day.

Gastro-Soothe Forte 20 mg/tablet
Adults and children over 6 years: 1 tablet (20 mg) four times a day.

4.3 Contraindications

Gastro-Soothe & Gastro-Soothe Forte are contraindicated in myasthenia gravis, megacolon, and narrow glaucoma. In addition, they should not be given to patients who have demonstrated prior sensitivity to the product.

4.4 Special warnings and precautions for use

Gastro-Soothe and Gastro-Soothe Forte should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure and in cardiac surgery where it may further accelerate the heart rate. Due to the risk of anticholinergic complications, caution should be used in patients susceptible to intestinal or urinary outlet obstructions.

Because of the possibility that anticholinergics may reduce sweating, Gastro-Soothe and Gastro-Soothe Forte should be administered with caution to patients with pyrexia

Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as Gastro-Soothe and Gastro-Soothe Forte in patients with undiagnosed and therefore untreated narrow angle glaucoma. Therefore, patients should seek urgent ophthalmological advice in case they should develop a painful, red eye with loss of vision whilst or after taking Gastro-Soothe and Gastro-Soothe Forte.

4.5 Interaction with other medicines and other forms of interaction

The anticholinergic effect of tricyclic antidepressants, antihistamines, quinidine, amantadine and disopyramide may be intensified by Gastro-Soothe & Gastro-Soothe Forte.

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both medicines on the gastrointestinal tract.

The tachycardic effects of beta-adrenergic agents may be enhanced by Gastro-Soothe & Gastro-Soothe Forte.

4.6 Fertility, pregnancy and lactation

Pregnancy
Long experience has shown no evidence of ill effects during human pregnancy. Preclinical studies in rats and rabbits did not show either embryotoxic or teratogenic effects. Hyoscine-N-butylbromide is classified with medications that have been taken by only a limited number of pregnant women but without an increase to the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. However, the usual precautions regarding the use of medicines at this time, especially during the first trimester, should be observed

Lactation
Safety during lactation has not yet been established, however, adverse effects on the new born have not been reported.

4.7 Effects on ability to drive and use machines

In rare cases Gastro-Soothe & Gastro-Soothe Forte may cause drowsiness, if affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Many of the listed undesirable effects can be assigned to the anticholinergic properties of Gastro-Soothe and Gastro-Soothe Forte.

Adverse events have been ranked under headings of frequency using the following convention: Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100); rare (≥ 1/10000, <1/1000); very rare (<1/10000); not known – cannot be estimated from the available data.

Immune system disorders
Uncommon: skin reactions (e.g. urticaria, pruritus)
Not known*: anaphylactic shock , anaphylactic reactions, dyspnoea, rash, erythema, other hypersensitivity

Cardiac disorders
Uncommon: tachycardia

Gastrointestinal disorders:
Uncommon: dry mouth

Skin and subcutaneous tissue disorders
Uncommon: dyshidrosis

Renal and urinary disorders
Rare: urinary retention

* This adverse reaction has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than uncommon (3/1,368), but might be lower. A precise frequency estimation is not possible as the adverse drug reaction did not occur in a clinical trial database of 1,368 patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Symptoms
Serious signs of poisoning following acute overdosage have not been observed in man. In case of overdosage, anticholinergic symptoms such as urinary retention, dry mouth, reddening of skin, tachycardia, inhibition of gastrointestinal motility, and transient visual disturbances may occur.

Therapy
In the case of oral poisoning, gastric lavage with activated charcoal should be followed by magnesium sulphate (15%). Symptoms of Gastro-Soothe & Gastro-Soothe Forte overdosage respond to parasympathomimetics. For patients with glaucoma, urgent ophthalmological advice should be sought and pilocarpine should be given locally. If necessary, parasympathomimetics should be administered, e.g. neostigmine 0.5-2.5 mg i.m. or i.v. cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis: intubation, artificial respiration should be considered. Catheterisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Gastro-Soothe & Gastro-Soothe Forte exert a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and urinary tracts. As a quaternary ammonium derivative, hyoscine-N-butylbromide does not enter the central nervous system. Therefore, anticholinergic side effects at the central nervous system do not occur. Peripheral anticholinergic effects result from a ganglion-blocking action within the visceral wall as well as from anti-muscarinic activity.

5.2 Pharmacokinetic properties

As a quaternary ammonium compound, hyoscine-N-butylbromide is highly polar and hence only partially absorbed following oral (8%) administration and the systemic availability was found to be less than 1%. Nevertheless, despite the briefly measurable low blood levels, hyoscine-N-butylbromide and/or its metabolites have been observed at the sites of action.
The half-life of the terminal elimination phase $t1/2\gamma$ is approximately 5 hours. The total clearance is 1.2 l/min, approximately half the clearance is renal. The main metabolites found in urine bind poorly to the muscarinic receptor. Hyoscine-N-butylbromide does not pass the blood-brain barrier and plasma protein binding is low.

5.3 Preclinical safety data

In limited reproductive toxicity studies hyoscine butylbromide showed no evidence of teratogenicity in rats at 200 mg/kg in the diet or in rabbits at 200 mg/kg by oral gavage or 50 mg/kg by subcutaneous injection. Fertility in the rat was not impaired at doses of up to 200 mg/kg in the diet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose, maize starch, microcrystalline cellulose, methocel A4C, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate, hydroxyl propyl methyl cellulose, polyethylene glycol, talc, titanium dioxide

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30 °C
Store in a safe place out of the reach of children.

6.5 Nature and contents of container

Gastro-Soothe is available in
Tender blister pack of 20 tablets
OTC blister pack of 20 tablets.

Gastro-Soothe Forte is available in
OTC blister pack of 10 tablets

6.6 Special precautions for disposal

None stated.

7 MEDICINE SCHEDULE

Pharmacist only medicine

8 SPONSOR

AFT Pharmaceuticals Ltd
129 Hurstmere Road (Level 1)
Takapuna
AUCKLAND

Telephone: 09 488 0232

9 DATE OF FIRST APPROVAL

Gastro-Soothe: 5 November 2012

Gastro-Soothe Forte: 21 August 2014

10 DATE OF REVISION OF THE TEXT

6 September 2017

SUMMARY TABLE OF CHANGES

Section changed	Summary Table of Changes
4.4	Information that anticholinergics may reduce sweating, medicine should be administered with caution to patients with pyrexia added.
4.8	Updated undesirable effect to the most up-to-date information. Information on reporting of suspected adverse reactions added.
5.3	Information on preclinical safety data added.
6.3	Information on shelf life added.