Reclassification of Hyoscine butylbromide for oral use in medicines containing not more than 20 milligrams per dose (Addition of oral liquids in the current classification)

Present classification:	Restricted
Proposed classification:	Restricted

AFT Pharmaceuticals Limited

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Takapuna, Auckland, 0622
PO Box 33-203, Takapuna, Auckland

Objective:

This application seeks reclassification of hyoscine butylbromide for oral use in medicines containing not more than 20 milligrams per dose.

PART A

1. International Non-Proprietary Name of the Medicine

Hyoscine butylbromide

2. Proprietary name(s)

Gastrosoothe (Proposed)
(hyoscine butylbromide 1 mg/mL)

3. Name of the company/organisation/individual requesting a reclassification

AFT Pharmaceuticals Ltd
129 Hurstmere Road
Takapuna 0622
Auckland
New Zealand

4. Dose form(s) and strength(s) for which a change is sought

Dose form: Oral liquid
Strength: 1 mg/mL Pack size: 200 mL.

5. Proposed pack size, storage conditions and any other qualifications

Proposed pack size: Bottle containing 200 mL (1 mg/mL) of hyoscine butylbromide oral liquid
Storage conditions: Store below 30 °C.

6. Indications for which change is sought

Indication: for the relief of muscle spasm of the gastrointestinal tract

7. Present classification of the medicine

Ingredient	**Conditions (if any)**	**Classification**
Hyoscine butylbromide	**except** when specified elsewhere in this schedule	Prescription
Hyoscine butylbromide	for oral use in medicines containing not more than 10 milligrams per dose form and in packs containing not more than 20 tablets or capsules; for oral use in medicines containing not more than 20 milligrams per dose form and in packs containing not more than 10 tablets or capsules for the relief of muscle spasm of the gastrointestinal tract	Restricted

8. Classification sought

Restricted:
for oral use in medicines containing not more than 10 milligrams per dose and in packs containing not more than 20 doses;
for oral use in medicines containing not more than 20 milligrams per dose and in packs containing not more than 10 doses for the relief of muscle spasm of the gastrointestinal tract

9. Classification status in other countries (especially Australia, UK, USA and Canada)

AUSTRALIA:	Pharmacist only: HYOSCINE BUTYLBROMIDE in undivided preparations for oral use with a recommended single dose not exceeding 20 mg of hyoscine butylbromide in a pack containing 100 mg or less of hyoscine butylbromide when labelled for adults and children 6 years and over (A copy of the recent decision to amend the Poisons Standard is available at https://www.tga.gov.au/scheduling-decision-final/notice-final-decisions-amend-or-not-amend-current-poisons-standard-may-2020).
UNITED KINGDOM:	Tablets are classified as GSL, P and POM
UNITED STATES:	Butylbromide salt is not available
CANADA:	Tablets are ethical (unscheduled)

10. Extent of usage in New Zealand and elsewhere (eg, sales volumes) and dates of original consent to distribute

Sales data in New Zealand (IMS accessed on 14 April 2020)

Product	Units sales to Dec 16	Units sales to Dec 17	Units sales to Dec 18	USD sales to Dec 16	USD sales to Dec 17	USD sales to Dec 18
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Sales data in Australia (IMS accessed on 14 April 2020)

Product	Units sales to Dec 16	Units sales to Dec 17	Units sales to Dec 18	USD sales to Dec 16	USD sales to Dec 17	USD sales to Dec 18
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Product approval dates in New Zealand

Product	Approval date
Buscopan Tablet, 10 mg (Prescription)	31/12/1969
Buscopan Forte Film coated tablet, 20 mg (Restricted)	28/04/2016
Gastro-Soothe Tablet, 10 mg (Restricted)	28/09/2006
Gastro-Soothe Forte Film coated tablet, 20 mg (Restricted)	21/08/2014
Stomach Soothe Film coated tablet, 10 mg (Restricted)	29/05/2014
Stomach Soothe Film coated tablet, 10 mg (Prescription)	7/12/2017

11. Local data or special considerations relating to New Zealand (if applicable)

Not applicable.

12. Labelling or draft labelling for the proposed presentation(s)

Please refer to Appendix A.

13. Proposed warning statements (if applicable)

- Not recommended for children under 6 years. Phenylketonurics are warned that this product contains aspartame.
- Products containing sorbitol may have a laxative effect or cause diarrhoea. Also contains saccharin and hydroxybenzoates.
- If pregnant or likely to become pregnant, consult a pharmacist or a doctor before use.

14. Other products containing the same active ingredient(s) and which would be affected by the proposed change

Nil

PART B

1) Indications and dose

- **What is the medicine indicated for, and for which indication(s) is the reclassification application for?**

  The medicine is used for the relief from pain and discomfort of stomach cramps and spasm.

  The reclassification application is intended for the following indication:

  “relief from pain and discomfort of stomach cramps and spasm.”

- **What is the evidence that the proposed indication is an OTC indication (ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised)?**

  Hyoscine butylbromide (for oral use) is already classified as a non-prescription (OTC) medicine in Medsafe Classification database. It is available as a restricted medicine in packs containing no more than 200 mg of hyoscine butylbromide. AFT also markets Hyoscine butylbromide tablets 10 mg and 20 mg (under the same trade-name “Gastro-Soothe”) as Restricted medicines. There are also other medicines containing Hyoscine butylbromide in tablet form on the market in New Zealand such as Buscopan. Hence, patients are already taking this medicine in consultation with the pharmacist. Thus, the possibility of diagnosis or treatment to be misunderstood by the consumer or the risk of inappropriate treatment is minimal. The proposed medicine, Hyoscine butylbromide oral liquid will just provide flexibility of administration to patients who are unable to take the tablets.

- **What is the treatment population for the indication (ie, age, gender, etc.)?**

  The treatment population for the indication is:
  Adults and Children (6 years and over)

- **What is the dose and dose frequency of the medicine for this indication?**

  The dose and dose frequency of the medicine for this indication is:
  Adults and Children (6 years and over): 10-20 mL four times a day

2) Presentation

- **What is the proposed dose from and strength of the medicine to be reclassified? Is this the same for all indications?**

  The proposed dose form is oral liquid. The strength of the medicine is 1 mg/mL. This is same for all indications.

- **What disposal considerations need to be made for the medicine?**

  No special disposal considerations are required for this medicine.

- **How practical and easy to use is the proposed presentation?**

  The proposed presentation is patient-friendly and convenient to use. The oral liquid is packed in a plastic bottle. A graduated (with markings of 10 and 20 mL) measuring cup is provided along with the product. The patient can easily measure the required dose using the measuring cup and take the right amount of medicine.

3) Consumer benefit

- **What is the history of this medicine's use for the proposed indication(s) (ie, number of users, number of countries used in)?**

  Hyoscine salts are widely available as medicines all over the globe and are indicated for the treatment/ management of motion sickness and other forms of nausea and vomiting, and visceral spasms. They are also used as premedicant in anaesthesia. Single ingredient preparations are available in Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, Denmark, Finland, France, Germany, Hong Kong, Hungary, India, Indonesia, Ireland, Italy, Japan, Malaysia, Mexico, Netherland, Norway, New Zealand, Philippines, Poland, Portugal, Russia, South Africa, Singapore, Spain, Sweden, Switzerland, Thailand, Turkey, UAE, UK, Ukraine, USA and Venezuela. Multi-ingredient preparations are available in Argentina, Australia, Austria, Belgium, Brazil, Chile, Germany, Greece, Hong Kong, Indonesia, Ireland, Italy, Mexico, Philippines, Poland, Portugal, South Africa, Spain, Sweden, Thailand, Turkey, UK, USA and Venezuela. [1]

- **To what extent is this medicine used for the proposed indication(s) (ie, duration of use, frequency of use)?**

  The recommended dose of hyoscine butylbromide oral liquid is 10-20 mL four times a day. The time of administration can be varied to suit individual patient needs.

- **What is the evidence that improved access is beneficial for the individual?**

  Since the current application is not intended to change the scheduling of the medicine, the access to the medicine (i.e. through consultation with the pharmacist) remains unchanged. However, the availability of the medicine as an oral liquid will greatly benefit the patients who are unable to swallow tablets.

- **What is the evidence of improved consumer involvement in their health?**

  With the availability of the medicine as an oral liquid, consumers will be able to take care of their stomach ache and muscular spasm in a more efficient way. Especially elderly patients and children who tended to ignore the symptoms of spasm due to their inability to swallow tablets will be largely benefitted.

- **What are the benefits from a consumer viewpoint?**

  Stomach ache and cramps or spasm SAR can have a detrimental effect on patients' quality of life. Particularly, children experience this situation quite often and it leads to substantial loss of studies. For adults too, the cost of treating this condition and indirect costs related to loss of workplace productivity resulting from the disease are substantial. It is a significant cause of lost work and school days for patients. Hence, the availability of this medicine as an oral liquid will enable the patients (or their parents) to efficiently manage the condition as soon as the symptoms get noticed.

4) Contraindication and precautions

- **What are the contraindications for the medicine and how easy are they to identify and prevent?**

  Hyoscine butylbromide oral liquid is 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. [2]

- **What are the precautions for this medicine and how easy are these to understand?**

  There are a few precautions to be undertaken and all of these are very easy to understand. The precautions are same as advised for Hyoscine butylbromide tablets. The precautions are listed below: [2]

  Hyoscine butylbromide oral liquid 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, Hyoscine butylbromide oral liquid should be administered with caution to patients with pyrexia. Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as Hyoscine butylbromide oral liquid 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 Hyoscine butylbromide oral liquid.

- **Does the medicine have a low therapeutic index?**

  Specific data about the therapeutic index of hyoscine butylbromide is not available.

- **What class effects need to be considered and what are the risks?**

  Hyoscine butylbromide oral liquid exerts 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.

Hyoscine-N-butylbromide does not pass the blood-brain barrier and plasma protein binding is low. [2]

- **What are the risks of the medicine being used in OTC environment?**

  The medicine is already available as an OTC medicine in New Zealand, hence there is no risk.

- **What other drug interactions need to be considered?**

  The anticholinergic effect of tricyclic antidepressants, antihistamines, quinidine, amantadine and disopyramide may be intensified by Hyoscine butylbromide oral liquid.

  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 Hyoscine butylbromide oral liquid. [2]

- **What food and/or drink interactions need to be considered?**

  Hyoscine butylbromide oral liquid can be taken before or after meals. [3]

- **Are there any other restrictions when taking the medicine (ie, driving restrictions or operating machinery)?**

  In rare cases hyoscine butylbromide may cause drowsiness, if affected, patients should not drive or operate machinery. This statement, however, is not present on the label under “warnings”.

- **Are there any special populations where exposure to the medicine needs to be restricted?**

  Hyoscine butylbromide oral liquid should not be administered to children 6 years of age. Phenylketourics should also take the product with caution. The warnings are also included in the label under “warnings”.

5) Undesirable effects

- **What are the known undesirable effects and the frequencies of these? Do these vary for special populations? Are these reversible or treatable?**

  Many of the listed undesirable effects can be assigned to the anticholinergic properties of hyoscine butylbromide. [2] 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.

- **What are risks and consequences of known undesirable effects?**

  As described above, majority of the adverse effects are uncommon do not pose any serious risk. These again are same as experienced with Hyoscine butylbromide tablets which are already available as Restricted medicine.

- **Are there any significant safety concerns for the medicine under review?**

  No, there are no significant safety concerns for the medicine under review.

- **Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?**

  To the best of our knowledge, there were no withdrawals or regulatory actions of the medicine for safety reasons.

- **Are there any withdrawal effects following cessation of use of the medicine?**

  There are no withdrawal effects following cessation of the use of the medicine.

6) Overdose

- **Is there a potential for overdose of the medicine?**

  The dosing instructions are clearly mentioned on the pack. The product is supplied with a measuring cup which has a clear marking of 10 and 20 mL. The patient (or their parents) can very easily measure the exact dose. Moreover, the maximum dosing of the medicine is 20 mL four times a day (i.e. 80 mL). Hence, in worst case, an

accidental measuring error (with the measuring cup) will not cause any harm. Hence the potential of overdose of the medicine is extremely low.

- **What are the consequences of overdose of the medicine?**

  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. [2]

- **Are there any reports of overdose of the medicine?**

  AFT has not received any report of overdose of Gastro-soothe tablets.

7) Medication errors and abuse/ misuse potential

- **Would reclassification affect the risk of unnecessary use?**

  The medicine is already available as Restricted medicine in tablet form. Including the oral liquid pack would just allow better access of patients to the medicine without increasing the risk of unnecessary use.

- **Will the medicine be provided with necessary tools to allow correct dosing (eg, liquids supplied with a measuring device)?**

  Yes, the medicine will be provided with a measuring cup with a marking corresponding to one dose.

- **What are reported medication errors post-market?**

  As mentioned above, since the medicine will be provided with a measuring cup with a marking corresponding to one dose, the chances of medication error are negligible.

- **What are the reported cases of abuse/ misuse/ accidental overdose?**

  There have been some cases of abuse/ misuse of hyoscine butylbromide. [4, 5] However, since the proposed medicine will only be available upon consultation with a qualified healthcare professional, the chances of the medicine being misused are negligible.

- **How would reclassification affect import considerations?**

  Reclassification would not affect import considerations.

- **What is the addiction potential of this medicine?**

  As mentioned above, the active substance of the medicine does have an abuse/ addiction potential. However, since the proposed medicine will only be available upon

consultation with a qualified healthcare professional, the chances of the medicine being misused are negligible.

8) Communal harm and/ or benefit

- **What are the possibilities of community harm resulting from wider use of the medicine in question (eg, the development of antibiotic resistance in bacteria)?**

  There is no possibility of community harm from wider use of the medicine.

- **What are the possibilities of community benefit resulting from wider use of the medicine in question (eg, greater herd immunity as a result of improved access to a communicable disease vaccine or increased rates of immunisation)?**

  Wider access to this medicine will lead to better management of stomach ache and pain due to cramps or spasm in those patients who are unable to swallow tablets.

9) Integrated benefit-risk statement

- **A summary of reclassification benefits**

  The present application does not seek to reclassify a medicine but to include another dosage form in the same classification. Hence, the benefits of including oral liquid dosage form of hyoscine butylbromide in the same class as tablets, i.e. Restricted medicine are described in the section “A summary of the need for the medicine at the classification proposed”.

- **A summary of reclassification harm.**

  No harm to the consumer/ patient is expected as a result of this reclassification.

- **A summary of the need for the medicine at the classification proposed.**

  Abdominal muscle spasm, also known as abdominal rigidity, is a powerful, involuntary contraction of the muscles of the abdomen. During a spasm, the muscle will feel stiff and tender if pressure is applied. The major abdominal muscles include the transversus abdominus, the deepest layer of muscle, which stabilizes the trunk; the rectus abdominus, sometimes called the “six pack,” which runs between the ribs and the pubic bone and supports movements between the rib cage and the pelvis; and the internal and external oblique muscles, which provide support and are used when twisting the trunk.

  Like any other muscles in the body, the abdominal muscles can have spasms that occur as a result of muscle strain during heavy use or overuse, fatigue, dehydration, and alcohol. Abdominal muscle spasms, especially when related to a known cause such as strenuous exercise, are usually not serious and require symptomatic treatment. [6] Patients usually do not prefer to visit a general physician and tend to self-medicate or consult a pharmacist. This medical need is addressed by the availability hyoscine butylbromide tablets as Restricted medicine. However, since it is not always feasible to swallow tablets especially for paediatric and geriatric patients, we propose to include the oral liquid also under the same classification, i.e. Restricted medicine.

- **Precedent – how are other medicines in the same class classified?**

  Cetirizine is a second-generation antihistamine. The classification of other second-generation antihistamines in New Zealand is described below:

Ingredient	Conditions (if any)	Classification
Atropine	**except** when specified elsewhere in this schedule; **except** when used as an antidote in a device designed for self-injection; **except** in medicines containing 300 micrograms or less per litre or per kilogram	Prescription
Atropine	for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose or in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose; in medicines containing atropine sulphate for the treatment of organophosphorus poisoning either in packs of not more than 20 dose units containing 0.6 milligrams or less per dose unit or in injections in packs of not more than 5 vials containing 0.6 milligrams per millilitre; **except** when sold as an antidote in a device designed for self-injection from outlets licensed to sell organophosphorus poisons; **except** in medicines containing 300 micrograms or less per litre or per kilogram	Pharmacy Only
Atropine methonitrate		Prescription
Clidinium		Prescription
Cyclopentolate	**except** when used in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board	Prescription
Darifenacin		Prescription
Flavoxate		Restricted
Homatropine		Prescription
Hyoscine	**except** when specified elsewhere in this schedule; **except** in medicines containing 300 micrograms or less per litre or per kilogram	Prescription
Hyoscine	for transdermal use in medicines containing 2 milligrams or less of total solanaceous alkaloids per dose unit; for oral use in liquid form in medicines containing 0.03% or less and 0.3 milligrams or less per dose and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids; in solid dose form in medicines containing 0.3 milligrams or less per dose form and not more than 1.2 milligrams per recommended daily dose of total solanaceous alkaloids	Pharmacy Only
Hyoscine butylbromide	**except** when specified elsewhere in this schedule	Prescription

Ingredient	Conditions (if any)	Classification
Hyoscine butylbromide	for oral use in medicines containing not more than 10 milligrams per dose form and in packs containing not more than 20 tablets or capsules; for oral use in medicines containing not more than 20 milligrams per dose form and in packs containing not more than 10 tablets or capsules for the relief of muscle spasm of the gastrointestinal tract	Restricted
Ipratropium	**except** for nasal use	Prescription
Ipratropium	for nasal use	Pharmacy Only
Orphenadrine		Prescription
Oxybutynin		Prescription
Propantheline		Prescription
Solifenacin		Prescription
Tiotropium		Prescription
Tolterodine		Prescription

10) Risk mitigation strategies

- **Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required (eg, healthcare professional education, integration of care, consumer information to be provided, etc.)?**

  No risk mitigation strategies are required for this reclassification since the product is already available in tablet form as Restricted medicine.

- **What is the evidence that these proposed risk mitigation strategies would be effective?**

  Not applicable.

- **What post-market surveillance activities would be carried out?**

  No specific post-marketing surveillance activities would be carried out as a result of this reclassification.

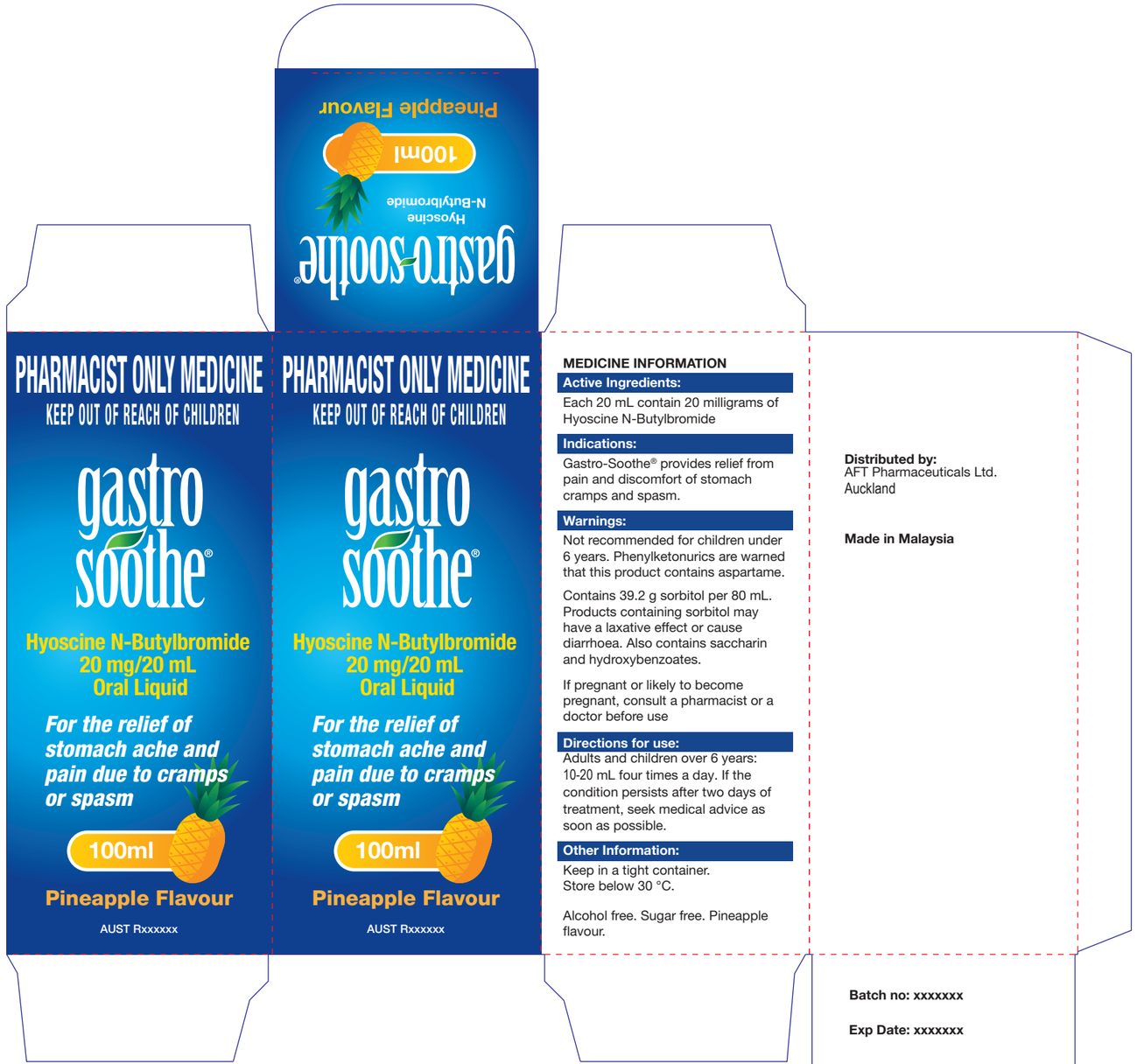
- **Is the proposed reclassification supported by professional bodies?**

  Not applicable.

References

1. Martindale The Complete Drug Reference. 39th ed., London, UK: Pharmaceutical Press.
2. Gastro-Soothe: New Zealand Data Sheet. https://www.medsafe.govt.nz/profs/Datasheet/g/GastroSoothetab.pdf. Accessed 14 April 2020.
3. Patient Information: Hyoscine butylbromide tablets Buscopan, https://patient.info/medicine/hyoscine-butylbromide-tablets-buscopan. Accessed 14 April 2020.
4. Kummer, S., Rickert, A., Daldrup, T., and Mayatepek, E., Abuse of the over-the-counter antispasmodic butylscopolamine for the home synthesis of psychoactive scopolamine. Eur J Pediatr., 2016. 175(7): p. 1019-21. doi: 10.1007/s00431-015-2683-5. Epub 2015 Dec 22.
5. Jalali, F., Afshari, R., and Babaei, A., Smoking crushed hyoscine/scopolamine tablets as drug abuse. Subst Use Misuse., 2014. 49(7): p. 793-7. doi: 10.3109/10826084.2014.880178. Epub 2014 Feb 4.
6. Abdominal Muscle Spasm. https://www.healthgrades.com/right-care/bones-joints-and-muscles/abdominal-muscle-spasm. Accessed 14 April 2020.

FUS - New Zealand
Packing - 100ml
29 Oct 18



Job Ref:	Client/Date:	Proof No.	CMYK
2504	18-03-20	1	C M Y K

UTOPIA CREATIVE
0212 050947
BRANDING | PACKAGING | DESIGN

(H) 116mm x (L) 50mm x (W) 50mm

FUS - New Zealand
Packing - 100ml
29 Oct 18

PHARMACIST ONLY MEDICINE
KEEP OUT OF REACH OF CHILDREN

gastro-soothe®

Hyoscine N-Butylbromide
20 mg/20 mL Oral Liquid

For the relief of stomach ache and pain due to cramps or spasm

Pineapple Flavour • 100ml

AUST Rxxxxxx

MEDICINE INFRMATION

Active Ingredients: Each 20 mL contain 20 milligrams of Hyoscine N-Butylbromide

Indications: Gastro-Soothe® provides relief from pain and discomfort of stomach cramps and spasm.

Warnings: Not recommended for children under 6 years. Phenylketonurics are warned that this product contains aspartame (phenylalanine). Contains 39.2 g sorbitol per 80 mL. Products containing sorbitol may have a laxative effect or cause diarrhoea. Also contains saccharin and hydroxybenzoates. If pregnant or likely to become pregnant, consult a pharmacist or a doctor before use.

Directions for use: Adults and children over 6 years: 10-20mL four times a day. If the condition persists after two days of treatment, seek medical advice as soon as possible.

Other Information: Keep in a tight container. Store below 30 °C.
Alcohol free. Sugar free. Pineapple flavour.

Distributed by: AFT Pharmaceuticals Ltd.
Auckland

(L)137mm X (W)50mm

Job Ref:	Client/Date:	Proof No.	CMYK
2504	18-03-20	1	C M Y K