MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Classification of Oral Sedating Antihistamines

Submission to the Medicines Classification Committee

Medsafe
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MANATŪ HAUORA
MINISTRY OF HEALTH

Te Kāwanatanga o Aotearoa
New Zealand Government

Contents

Background

At the 182nd meeting held on 11 June 2020, the Medicines Adverse Reactions Committee (MARC) advised on the use of oral sedating antihistamines in children for sedation. The MARC recommended that the indication for sedation of children be removed from all over-the-counter (OTC) medicines containing sedating antihistamines (Medsafe 2020).

On the 3 December 2020, Medsafe published a Prescriber Update (41(4): 68) article to inform healthcare professionals that oral sedating antihistamines are no longer indicated for sedation of children. This article included a table listing uses of oral sedating antihistamines, by indication and age (Medsafe 2020). This table is shown below:

Indication	Age
Allergy	From 2 years of age
Nausea and vomiting (including travel sickness)	From 2 years of age
In cough and cold medicines	From 6 years of age
Insomnia	From 12 years of age
Sedation	Adults only

The classification entries for sedating antihistamines in Schedule 1 of the Medicines Regulations 1984 include restrictions based on patient age and indications that are out of step with the MARC recommendation (as seen in above table).

Currently, the OTC classification statements for insomnia have no age limit and those for sedation have a lower limit of over 2 years old. OTC sedating antihistamines that are for insomnia and/or sedation (and meet classification conditions) are restricted medicines, those that do not meet the classification conditions are prescription medicines.

The initial submission to the MARC was for the following sedating antihistamines in oral dose forms: brompheniramine, chlorpheniramine, cyclizine, dexchlorpheniramine, diphenhydramine, doxylamine, meclozine and promethazine. This submission for reclassification includes all sedating antihistamines from the MARC submission, along with mepyramine and pheniramine. While there are currently no approved products in oral dose forms containing either mepyramine or pheniramine, their classification currently refers to 'oral use' and corresponding revisions are proposed for consistency.

Oral sedating antihistamines are used for a range of conditions in both adults and children. Diphenhydramine, doxylamine and promethazine are the only sedating antihistamines with approved products indicated for sedation or insomnia.

The MARC recommended that the indication for sedation of children be removed from all OTC sedating antihistamines because the sedation of children should occur under the guidance of a medical practitioner. The labelling and Data Sheets for all affected products have been amended to reflect the MARC recommendation.

This submission proposes that the classification conditions for sedating antihistamines are updated to align with the MARC recommendation.

PART A – Regulatory Context and Proposed Classifications

1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine

- Brompheniramine
- Chlorpheniramine
- Cyclizine
- Dexchlorpheniramine
- Diphenhydramine
- Doxylamine
- Meclozine
- Mepyramine
- Pheniramine
- Promethazine

2. Proprietary Names

Examples of products approved for use in insomnia are listed below:

Unisom Sleep Gels- capsules containing diphenhydramine hydrochloride (50 mg).

The New Zealand Data Sheet indications are for "a night-time sleep aid for the short-term management of insomnia". The Data Sheet dosing instructions are for "Adults and children over 12 years of age. The dose is one softgel (50 mg) at bedtime if needed. Should sleeplessness persist for more than 7 to 10 nights further medical advice should be sought. Do not give to children under 12 years of age. Do not exceed the recommended dosage". (Pharmaco (NZ) Ltd 2018).

New Zealand Datasheet:
https://www.medsafe.govt.nz/profs/datasheet/u/unisomsleepgels.pdf

Dozile – capsules containing doxylamine succinate (25 mg).

The New Zealand Data Sheet indications are for "temporary use in the relief of insomnia". The Data Sheet dosing instructions include the statement, 'Dozile is not recommended for children under 12 years of age' (Wilson Consumer Products 2019).

New Zealand Datasheet: https://www.medsafe.govt.nz/profs/datasheet/d/dozilecap.pdf

Examples of products approved for use in sedation are listed below:

Phenergan Tablets and Phenergan Elixir- tablets containing promethazine hydrochloride (10 mg or 25 mg) and elixir containing promethazine hydrochloride (1mg/mL).

The Data Sheet indications includes sedation for short term use in adults under the advice of a doctor or pharmacist. Do not use for more than 7 to 10 consecutive days. The Data Sheet only lists dosing instructions for adults. The Data Sheet also notes that "this product should not be used in children under 2 years of age" (Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics 2022).

New Zealand Data Sheet:
https://www.medsafe.govt.nz/profs/datasheet/p/Phenergantabelixir.pdf

The product labelling does not include directions for use for sedation.

Allersoothe- tablets containing promethazine hydrochloride (10 and 25 mg) and elixir containing promethazine hydrochloride (5mg/5mL).

The Data Sheet for Allersoothe Tablets includes indications for sedation. The Data Sheet only includes dosing instructions for adults when for sedation. The Data Sheet also notes that Allersoothe is contraindicated in those under 2 years old (AFT Pharmaceuticals Ltd 2022).

New Zealand Data Sheet: https://www.medsafe.govt.nz/profs/datasheet/a/Allersoothetab.pdf

The product labelling does not include directions for use for sedation.

Note: Allersoothe 10 mg and 25 mg tablets and Allersoothe oral liquid 1 mg/ mL are included on the PHARMAC Community Schedule.

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

Medsafe, Ministry of Health New Zealand.

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

Oral dose forms only, all strengths.

5. Pack size, storage conditions and other qualifications

Not applicable.

6. Indications for which change is sought

This submission proposes changes to the classification conditions of oral sedating antihistamines to restrict OTC products for sedation to adults and those for insomnia to adults and children over 12 years old. Please note that insomnia is not the same as sedation, although sedative medicines may be used to treat insomnia.

7. Present classification of the medicine

The current New Zealand classifications of sedating antihistamines included in this submission are detailed below (as according to the Medsafe Classification Database accessed on 16 February 2024).

Statements in the classification conditions which are relevant to this submission are highlighted in yellow (i.e. encompass indications of insomnia and sedation).

Brompheniramine

Ingredient	Conditions (if any)	Classification
Brompheniramine	**except** when specified elsewhere in this schedule	Prescription
Brompheniramine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Brompheniramine	for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing brompheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant	Pharmacy Only

Chlorpheniramine

Ingredient	Conditions (if any)	Classification
Chlorpheniramine	**except** when specified elsewhere in this schedule	Prescription
Chlorpheniramine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Chlorpheniramine	for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing chlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant	Pharmacy Only

Cyclizine

Ingredient	Conditions (if any)	Classification
Cyclizine	**except** when specified elsewhere in this schedule	Prescription
Cyclizine	for oral use other than in medicines used for the treatment of insomnia when sold in the manufacturer's original pack containing not	Restricted

	more than 6 dosage units; for oral use in medicines used for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	

Dexchlorpheniramine

Ingredient	Conditions (if any)	Classification
Dexchlorpheniramine	**except** when specified elsewhere in this schedule	Prescription
Dexchlorpheniramine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Dexchlorpheniramine	for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing dexchlorpheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant	Pharmacy Only

Diphenhydramine

Ingredient	Conditions (if any)	Classification
Diphenhydramine	**except** when specified elsewhere in this schedule	Prescription
Diphenhydramine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Diphenhydramine	for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing diphenhydramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age **except** when sold at a transport terminal or aboard a ship or aircraft	Pharmacy Only

Doxylamine

Ingredient	Conditions (if any)	Classification
Doxylamine	**except** when specified elsewhere in this schedule	Prescription

Doxylamine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Doxylamine	for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing doxylamine or when at least 1 of the other active ingredients is a sympathomimetic decongestant	Pharmacy Only

Meclozine

Ingredient	Conditions (if any)	Classification
Meclozine	**except** when specified elsewhere in this schedule	Prescription
Meclozine	in a pack size of up to 10 dosage units for the treatment of insomnia	Restricted
Meclozine	in a sealed container of not more than 12 tablets or capsules for the prevention or treatment of travel sickness **except** when sold at a transport terminal or aboard a ship or aircraft	Pharmacy Only

Mepyramine

Ingredient	Conditions (if any)	Classification
Mepyramine	**except** when specified elsewhere in this schedule	Prescription
Mepyramine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Mepyramine	for dermal use	Pharmacy Only
Mepyramine	for external use in medicines containing 2% or less in packs not exceeding 25 grams.	General Sale

Pheniramine

Ingredient	Conditions (if any)	Classification
Pheniramine	**except** when specified elsewhere in this schedule	Prescription
Pheniramine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Pheniramine	for ophthalmic use **except** when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a	Pharmacy Only

	day/night pack containing pheniramine or when at least 1 of the other active ingredients is a sympathomimetic decongestant	

Promethazine

Ingredient	Conditions (if any)	Classification
Promethazine	**except** when specified elsewhere in this schedule	Prescription
Promethazine	for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units	Restricted
Promethazine	for oral use in medicines for adults and children over 6 years of age when combined in the same container with 1 or more other therapeutically active ingredients either when in the bedtime dose of a day/night pack containing promethazine or when at least 1 of the other active ingredients is a sympathomimetic decongestant; for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age **except** when sold at a transport terminal or aboard a ship or aircraft	Pharmacy Only

For brompheniramine, chlorpheniramine, cyclizine, dexchlorpheniramine, diphenhydramine, doxylamine, mepyramine, pheniramine and promethazine the restricted classification conditions include: *"for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia; for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units"*.

For meclozine the restricted classification conditions include: *"in a pack size of up to 10 dosage units for the treatment of insomnia"*.

Overview of classification of sedating antihistamines for use in insomnia or sedation:
Oral sedating antihistamines when indicated for insomnia are classified as restricted (pharmacist-only) in New Zealand. The classification conditions for insomnia for sedating antihistamines include a maximum pack size (up to 10 dosage units) but does not include an age limit.
Oral sedating antihistamines (except meclozine) when indicated for sedation are classified as restricted in New Zealand, for those over two years old.

8. Classification sought

The restricted classification statement for brompheniramine, chlorpheniramine, cyclizine, dexchlorpheniramine, diphenhydramine, doxylamine, mepyramine, pheniramine, promethazine is proposed to be updated to the following:

> Restricted*; for oral use in medicines for adults or children over 2 years of age other than in medicines used for* ***sedation*** *or the treatment of insomnia; for oral use for the*

treatment of insomnia ***in adults and children 12 years of age and older*** *when sold in the manufacturer's original pack containing not more than 10 dosage units;* ***For oral use for sedation in adults only when sold in the manufacturer's original pack***

The restricted classification statement for meclozine is proposed to be updated to the following:

Restricted; ***for oral use*** *for the treatment of insomnia* ***in adults and children over 12 years of age when sold in the manufacturer's original pack containing not more than 10 dosage units***

This submission also proposes that any mention to a 'sealed container' in the classification conditions of sedating antihistamines is updated to 'manufacturer's original pack'. This is proposed as 'sealed container' holds no legislative meaning. It should be noted that regulation 37 of the Medicines Regulations 1984 requires that when for sale in oral dose forms, promethazine must be enclosed in a safety container.

Example of proposed wording:

for oral use ***~~in a sealed container~~ when sold in the manufacturer's original pack*** *of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 2 years of age except when sold at a transport terminal or aboard a ship or aircraft*

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

See **Appendix A.**

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

The below table shows when medicines containing each sedating antihistamine included in this submission were first approved in New Zealand and the number of products currently available.

Active Pharmaceutical Ingredient	First approved	Number of products available
Brompheniramine	1967	6
Chlorphenamine	1969	31
Cyclizine	1969	5
Dexchlorpheniramine	1969	7
Diphenhydramine	1969	5
Doxylamine	1969	2
Meclozine	1969	5
Mepyramine	1969	1

Pheniramine	1969	1
Promethazine	1969	11

Sales data is not available but given that these products have been grandfathered, they have been around for a long period of time.

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

See Medicines Adverse Reactions Committee (MARC) report, 'Use of oral sedating antihistamines in children for sedation' for the 182nd MARC meeting (attached at **Appendix B**).

See MARC meeting minutes, agenda item '3.2.3 Use of oral sedating antihistamines in children for sedation', for the 182nd MARC meeting (attached at **Appendix C**).

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

Current required warning statements

The Label Statement Database currently requires the labels of oral sedating antihistamines to include/display the below statements (as according to the Label Statements Database accessed on 19 February 2024):

Substance/Group/Class	Conditions	Statements or requirements
Antihistamines, sedating Examples include: • Alimemazine • Brompheniramine • Chlorphenamine • Cyclizine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Ketotifen • Meclozine • Mepyramine • Pheniramine • Promethazine	For oral use	• Do not use in children under 2 years old. • This medicine may cause drowsiness. • Be cautious about driving a vehicle or operating machinery within 8 hours of taking this medicine.
	In cough and cold medicines	• Do not use in children under 6 years of age. • Consult a healthcare professional before using in children aged six years and over. • Do not use with other antihistamines. • Do not use with other medicines intended to treat the symptoms of the common cold except on the advice of a healthcare professional.
	For the treatment of insomnia	• Do not use in children under 12 years of age. • Do not exceed the maximum stated dose.

Substance/Group/Class	Conditions	Statements or requirements
		• This product is for temporary use only. [or] For short term use only. • Consult a doctor if sleeplessness persists.

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

This submission proposes that only changes are made to the classification of sedating antihistamines which are indicated for sedation and insomnia. This submission does not propose changes to sedating antihistamines indicated for other purposes.

PART B – Clinical Context and Implications

14. Indications and dose

There are a number of different indications for sedating antihistamines. Examples are listed below (as taken from the New Zealand Formulary, accessed on 19 February 2024):

- Cough suppressant e.g. brompheniramine, chlorpheniramine, promethazine, diphenhydramine
- Prophylaxis and treatment of nausea and vomiting including motion sickness, vertigo, labyrinthine disorders e.g. cyclizine
- Nausea and vomiting in palliative care e.g. cyclizine
- Treatment and prevention of motion sickness e.g. meclozine hydrochloride, promethazine.
- Allergic rhinitis e.g. dexchlorpheniramine maleate, promethazine
- Allergic conjunctivitis e.g. dexchlorpheniramine maleate
- Allergic skin conditions e.g. dexchlorpheniramine maleate
- Insomnia e.g. diphenhydramine hydrochloride, doxylamine
- Symptomatic relief of insect stings and bites, and nettle rash e.g. mepyramine maleate.
- Sedation e.g. promethazine

15. Presentation

This submission proposes that age restrictions are placed on sedating antihistamines for indications of insomnia or sedation at OTC level. Sedating antihistamines in oral dose forms are the only medicines for use in sedation or insomnia that are available OTC (classified as restricted). Subsequently, this submission only proposes changes to sedating antihistamines in oral dose forms.

This proposal would not result in any additional requirements for disposal of sedating antihistamines.

16. Consumer benefits

Access to OTC sedating antihistamines will remain for sedation (in adults only) or insomnia (in adults and children aged 12 years and over) after a consultation with a pharmacist who will determine if the benefits outweigh the risks for each consumer. For use in children for these indications interaction will a prescribing health professional will be required.

17. Contraindications and precautions

Sedating antihistamines have significant antimuscarinic activity, caution is advised in those with prostatic hypertrophy, urinary retention, susceptibility to angle-closure glaucoma, and pyloduodenal obstruction. Caution is advised in epilepsy (NZ Formulary 2024).

Children and elderly are more susceptible to adverse effects (NZ Formulary 2024).
For contraindications specific to each sedating antihistamine-containing medicine please refer to the New Zealand Data Sheet or, if not available, the published consumer information.

18. Undesirable effects

Sedating antihistamines are able to cross the blood-brain barrier and bind to non-histamine receptors and have less selectivity for peripheral or central H1-receptors. Subsequently, sedating antihistamines tend to cause more adverse reactions than non-sedating antihistamines (Medsafe 2013).

Drowsiness is a significant side effect with sedating antihistamines although paradoxical stimulation may occur, especially with high doses or in children and the elderly. Drowsiness may reduce after a few days of treatment and is less of a problem with the newer non-sedating antihistamines (Medsafe 2020; NZ Formulary 2024).
Adverse effects that are more common with sedating antihistamines include headache, psychomotor impairment and antimuscarinic effects such as urinary retention, dry mouth, blurred vision and gastrointestinal disturbances.
Other rare adverse effects of antihistamines include hypotension, palpitation, arrythmias, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, and hypersensitivity reactions (including bronchospasm, angioedema, anaphylaxis, rash), photosensitivity reactions, blood disorders, liver dysfunction, and angle-closure glaucoma (Medsafe 2020; NZ Formulary 2024).

19. Overdose

Published information on overdose may vary slightly between sedating antihistamines:

- Doxylamine succinate:
  Overdose produces signs and symptoms of anticholinergic toxicity. CNS stimulation is particularly likely in children.
  Fatalities have been reported from doxylamine overdose. Children appear to be at a high risk of cardiorespiratory arrest (Wilson Consumer Products 2019).
- Diphenhydramine hydrochloride:
  Overdose reactions may vary from CNS depression to stimulation. Stimulation is particularly likely in children (Pharmaco (NZ) Ltd 2018).
- Promethazine hydrochloride:
  Symptoms of severe overdose vary. In infants and children, CNS stimulation predominates over CNS depression resulting in ataxia, excitement, tremors, psychoses, hallucinations, convulsions and possible hyperpyrexia, this may be followed by deepening coma and cardiorespiratory collapse (Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics 2022).

In general, CNS stimulation as a result of overdose appears to be more likely in children.

20. Medication errors and abuse/misuse potential

This submission proposes the introduction of age limits for sedating antihistamines when used OTC for insomnia (12 years or older) and sedation (adults only). There are currently no approved products containing sedating antihistamines which have dosing instructions for sedation or insomnia in children under 12 years old on the labelling or data sheets. Use of sedating antihistamines for these purposes in children would be considered off-label use.

However, the classification of sedating antihistamines is not aligned with the current approved indications, MARC recommendations or Medsafe guidance. Therefore, this could cause confusion for industry and/ or health professionals.

21. Communal harm and/ or benefit

See answers to Q.21 and Q.22.

22. Integrated benefit-risk statement.

This proposal relates specifically to OTC use of sedating antihistamines for insomnia and sedation.
The MARC has reviewed information on the benefits and risks of sedating antihistamines when used in children for sedation. The MARC considered that there are more appropriate medicines for indications of sedation in children and that the use of sedating antihistamines for this indication should only occur under the guidance of a medical practitioner.
The labelling and Data Sheets for all products currently approved for insomnia or sedation are aligned with the MARC recommendations and therefore this submission for reclassification will not significantly impact any medicines currently on the market.
Updating the restricted classification of sedating antihistamines to include age limits in line with the MARC will reduce any confusion regarding the safe use of sedating antihistamines in children. This updated classification would also ensure that future new medicines containing sedating antihistamines in New Zealand are classified appropriately and in line with the MARC recommendations.

Conclusion

Based on the MARC report and Medsafe's review, it is proposed that the following change are made:

- Revision of the classification database wording for sedating antihistamines in alignment with the MARC recommendation to restrict the usage so that these medicines are not to be used for sedation in children or insomnia in those under 12 years old.

References

AFT Pharmaceuticals Ltd. 2022. *New Zealand Data Sheet Allersoothe Tablets.* 21 September 2022. URL: https://www.medsafe.govt.nz/profs/datasheet/a/Allersoothetab.pdf (accessed on 22 February 2024).

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Pharmaco (NZ) Ltd. 2018. *New Zealand Data Sheet Unisom SleepGels 50 mg capsules.* 30 November 2018. URL: https://www.medsafe.govt.nz/profs/datasheet/u/unisomsleepgels.pdf (accessed on 19 February 2024).

Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics 2022. *New Zealand Data Sheet Phenergan Tablets and Phenergan Elixir.* 28 July 2022. URL: https://www.medsafe.govt.nz/profs/datasheet/p/Phenergantabelixir.pdf (accessed on 19 February 2024).

Wilson Consumer Products 2019. *New Zealand Data Sheet Dozile 25 mg capsules.* 13 May 2019. URL: https://www.medsafe.govt.nz/profs/datasheet/d/dozilecap.pdf (accessed on 19 February 2024)

Appendixes

Appendix A: Classification Statements in other Countries. *(PDF, 108KB, 7 pages)*
Appendix B: MARC Report- Use of oral sedating antihistamines in children for sedation. *(PDF, 512KB, 21 pages)*
Appendix C: MARC Minutes- 182nd meeting.