Australian Government

Department of Health
Therapeutic Goods Administration

[redacted]

SAS No: MB18/0042450
17 May 2018

EXEMPTIONS FOR SPECIAL AND EXPERIMENTAL USES
APPROVAL TO SUPPLY UNDER THE SPECIAL ACCESS SCHEME
UNDER THE THERAPEUTIC GOODS ACT 1989, 19(1)(a)

Medicine: Fesoterodine - Tablet

Patient: [redacted] **DOB:** [redacted] **Sex:** [redacted] **MRN:**

Dosage Regimen: 8mg tablet orally, one daily
Duration: 12 Month(s)
Dose Form: Tablet

Concerning your application to use the above drug in the treatment of the above patient on the grounds that there is no alternative therapy currently supplied in Australia, I, the medically qualified person named below, hereby provide Notification of Approval. The proposed clinical use of this drug must be regarded both medico legally and ethically as experimental. No assurance can be given as to the quality, safety and efficacy in the proposed usage. Your co-operation is required concerning sound data management.

Permission is given for the use of the drug in the above patient for the above duration subject to the following conditions:

1. The doctor and patient, patient's parents or guardian accept responsibility for any adverse consequence of therapy;
2. The product is used within the context of fully informed consent and in accordance with the treatment protocol provided to the TGA with the request.
3. The use of the medicine shall be regarded as experimental, and the principles set out in the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research 2007) shall be observed.
4. Adverse events associated with the use of the medicine are to be reported in accordance with the reporting guidelines set out in the Special Access Scheme: Guidance for health practitioners and sponsors published on the TGA website.
5. The Therapeutic Goods Administration be notified of reasons for discontinuation should this occur;
6. Details of patient response to treatment are submitted to the supplier on completion of treatment ensuring compliance with State, Territory and Australian Government privacy legislation.
7. On completion of treatment all remaining supplies of the above product be returned to the supplier or destroyed should no supplier be present in Australia;
8. The person supplying the drug accepts responsibility for any defects in the drug related to the manufacture, distribution or directions for usage including dosage;

This approval must be used within 12 (twelve) months from the date of this letter, or until revoked or until this product is marketed in Australia, whichever occurs first.

Yours sincerely,

Signed and authorised by
[redacted]
Delegate of the Secretary
Pharmacovigilance and Special Access Branch
Email: sas@health.gov.au
17 May 2018