SPONTAN

SPONTAN® (vardenafil HCL nasal spray)
TGA SPECIAL ACCESS PATHWAYS

Introduction

SPONTAN® (vardenafil HCL Nasal Spray), an intranasal PDE5 inhibitor for erectile dysfunction (ED), is available in Australia via the Therapeutic Goods Administration (TGA) **Special Access Scheme (SAS)**. Healthcare Professionals with prescribing privileges can currently access SPONTAN for their suitable patients through two primary pathways:

- **Authorised Prescriber (AP) Pathway** (Medical Specialists only)
- **SAS Category B (SAS Cat B) Pathway** (for Medical Specialists, GPs and Nurse Practitioners)

This guide provides a step-by-step process for healthcare practitioners to gain access to SPONTAN.

▶ Authorised Prescriber Pathway (Medical Specialists only)

The **Authorised Prescriber Pathway** allows a **Medical Specialist** to prescribe SPONTAN to a specific patient group without requiring separate TGA approval for each individual patient.

Steps to Become an Authorised Prescriber

1. Obtain Ethics Committee Endorsement (HREC Approval)

- An endorsement from a **Human Research Ethics Committee (HREC)** is required.
- Private hospital groups commonly provide these approvals.
- Ethics committees are more likely to support endorsements for Urologists with an active surgical practice at these hospitals.

2. Submit an Authorised Prescriber Application to the TGA

- Complete the **Authorised Prescriber Application Form** via the **TGA Online Portal**.
- Attach the HREC approval letter.

3. TGA Approval

- The TGA assesses the application and issues approval to the Urologist.

4. Prescribe SPONTAN

- Once approved, the Urologist can prescribe SPONTAN to multiple patients within their clinical practice without needing further TGA approval for each prescription.

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▶ SAS Category B Pathway (Medical Specialists, GPs and Nurse Practitioners)

Medical Specialists, GPs and Nurse Practitioners who wish to prescribe SPONTAN must apply for **SAS Category B approval** on a per-patient basis.

Steps to Apply Under SAS Category B

1. Complete the SAS Category B Form

- Available on the **TGA Online Portal**.
- Provide patient details (excluding full name) and medical justification for using SPONTAN.
- Include a clinical rationale explaining why existing ARTG-listed treatments (e.g., oral PDE5 inhibitors) are unsuitable.

2. Submit the Application to the TGA

- Applications must be submitted online via the **TGA SAS Portal**.
- Email confirmation will be sent upon submission.

3. TGA Review and Approval

- The TGA assesses the request and notifies the prescriber of the decision.

4. Prescribe SPONTAN

- If approved, the prescriber can provide SPONTAN to the patient.
- Approval is **patient-specific** and must be renewed for each new patient.
- Cat B approval is valid for the individual patient for 12 months.

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Key Differences Between AP and SAS Cat B Pathways

Feature	Authorised Prescriber (Medical Specialists Only)	SAS Category B (GPs and Nurse Practitioners)
Who Can Apply?	Medical Specialists only	GPs and Nurse Practitioners
Approval Process	One-time ethics approval + TGA application	Case-by-case patient applications
Renewal Requirement	Six monthly patient audit is required for all patients prescribed	New approval required per patient
Timeframe	Typically, 4-8 weeks	Variable, usually processed within 1-2 business days

SPONTAN SAS Category B Product Details (medicine)

Trade name	SPONTAN®
Sponsor/Supplier	LTR Pharma / Mayne Pharma
Active Ingredient	Vardenafil HCL
Dosage Form	Intranasal
Strength	2.5mg per 130ul spray
Route of Administration	Intranasal
Dose and Frequency	Two sprays (one in each nostril as required, maximum daily dose 5mg)
Expected Duration of Treatment	Ongoing

Conclusion

The **Authorised Prescriber Pathway** is only accessible to **Medical Specialists** and is recommended for those seeking a streamlined process to prescribe SPONTAN for multiple patients.

For **GPs and Nurse Practitioners, SAS Category B** offers access to SPONTAN but requires **individual applications per patient**. This pathway will also allow **Medical Specialists** to gain initial experience with the medication prior to, or during, the AP pathway application.

Please refer to the TGA guidance regarding individual patient consent requirements and adverse event reporting responsibilities. For additional guidance, prescribers can contact the TGA Special Access Team at SAS@health.gov.au or visit https://compliance.health.gov.au/sas/.

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