LTR Pharma

Innovating Better Solutions for Men's Health

Information for Health Care Prescribers

SPONTAN

(vardenafil HCL nasal spray)

Important information for prescribers[1,2]

Clinical Indication:
Erectile Dysfunction (ED)

Intranasal delivery of a **proven oral PDE5 inhibitor,** Vardenafil HCL

Trans mucosal **absorption allows** for:

- Rapid onset of action:
  Tmax median time = 10 mins
- Bypasses the liver and first pass metabolism in the gut
- Benefit for certain patient groups, i.e. Dysphagia
- Now accessible through the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) pathway

Dose delivered from a single spray
= 2.5mg per 130uL

RDD (Recomended Daily Dose) is 5mg prn
(2 applications with one in each nostril)

This information supports healthcare professionals in accessing SPONTAN® (vardenafil HCL intranasal spray) through the Special Access Scheme (SAS) pathways.

Patients may be eligible for intranasal treatment for SPONTAN® if their Erectile Dysfunction (ED) has not been effectively treated by standard treatment methods, and there is clinical evidence suggesting that intranasal therapy could lead to improved outcomes.

Applying for access to SPONTAN® through SAS Category B[3]

- Submit an SAS Category B form to the TGA with patient details and justification.
- Obtain and document patient consent, explaining risks and alternatives.
- Maintain records of the application, consent, and TGA communications.
- Report any adverse events to the TGA

SPONTAN® SAS Category B product details

Medicine ☒ **Biological** ☐

Trade Name (if known) SPONTAN	**Sponsor / Supplier** LTR Pharma / Mayne Pharma
Active ingredient(s) Vardenafil HCL	
Dosage form (e.g. tablet) Intranasal	**Strength** (e.g., 1 mg/ml) 2.5mg per 130ul spray
Route of administration (e.g., IV) Intranasal	**Dose & frequency** 2 sprays (1 each nostril as required)
Expected duration of treatment Ongoing	

How to access SPONTAN® for Patients once SAS approved

SPONTAN® is available nationwide for approved patients under the SAS through Their Pharmacy.

www.SPONTAN.life

Scan to learn more

Authorised Prescriber[2]

- Becoming an Authorised Prescriber allows you to prescribe specific unregistered medicines directly to patients without needing individual SAS applications.
- Obtain approval from a Human Research Ethics Committee (HREC) or your institution's ethics body.
- Submit an application to the TGA, demonstrating expertise in managing patients who may benefit from the unregistered therapy.
- Once approved, you can prescribe the medicine to eligible patients without requiring further TGA approvals for each case.

SPONTAN

(vardenafil HCL nasal spray)

Patients may be eligible for intranasal treatment with **SPONTAN®*** (vardenafil HCL nasal spray) for erectile dysfunction if their Erectile Dysfunction has not been effectively treated by standard treatment methods, and there is clinical evidence suggesting that intranasal therapy could lead to improved outcomes.

If patients meet these criteria, a prescribing clinician may seek approval for this treatment and provide a prescription via the relevant TGA Special Access Scheme (SAS) pathways.

About SPONTAN®

Quick Onset of Action[1,2]

Vardenafil HCL Nasal Spray may offer rapid therapeutic onset, with a Tmax (time to maximum plasma concentration) of approximately 10 minutes.

Efficient Bioavailability[1,2]

With its intranasal administration, Vardenafil HCL Nasal Spray has demonstrated high dose-normalized bioavailability, potentially supporting effective dosing at reduced quantities.

Distinct Safety and Tolerability Profile[1,2]

The intranasal spray has been well-tolerated in studies, showing only mild and transient side effects. Some patients have reported local nasal irritation, which may be a consideration for prescriber and patient discussions around individual tolerance.

***SPONTAN (vardenafil HCL nasal spray) is not registered for general use in Australia and is only available through the Special Access Scheme (SAS) Category B.**

For more information

For More Information about the SAS application process or becoming an Authorised Prescriber please contact LTR Pharma on 1800 519 711 or visit the TGA website by scanning the QR code or by visiting the TGA website at www.tga.gov.au

LTR Pharma

References: 1. Chung,E. (2024) Phase 1 Open-Label, Single-Dose, Randomized Cross-Over Clinical Study Evaluating Pharmacokinetics Profile and Safety Outcomes Between Intranasal and Oral Vardenafil Formulations Administration in Healthy Male Adults. Abstract. USANZ 2024. 2. Data on file. LTR Pharma. 3. Commonwealth of Australia. Special Access Scheme: Guidance for health practitioners V2.0. https://www.tga.gov.au/resources/guidance/special-access-scheme-sas-guidance-health-practitioners-accessing-unapproved-therapeutic-goods March. 2024.

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