



## **SPONTAN® (vardenafil HCL nasal spray)**

### ABRIDGED IFU - Edition Number: 1.1

#### **Confidentiality Statement**

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#### **Description**

SPONTAN is a clear, colourless nasal spray solution containing vardenafil hydrochloride, the same active ingredient found in vardenafil tablets.

#### **Indication**

SPONTAN is indicated for the treatment of erectile dysfunction (ED).

#### **Dosage**

SPONTAN is administered via a nasal spray device, delivering 2.5 mg of vardenafil hydrochloride per spray. The recommended dosage is 2 sprays (one per nostril).

#### **Contraindications**

Use of vardenafil, including SPONTAN, is contraindicated in patients taking organic nitrates or nitric oxide donors.

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### Warnings and Precautions

The warnings and precautions for vardenafil tablets apply equally to SPONTAN nasal spray:

- **Adverse Drug Reactions:** Common side effects include headache, flushing, rhinitis, dyspepsia, sinusitis, flu syndrome, dizziness, increased creatine kinase, and nausea. Rare cases of vision loss (NAION), sudden hearing loss, and prolonged erections (priapism) have been reported.
- **Drug Interactions:**
  - **Nitrates:** Concurrent use with organic nitrates is contraindicated due to severe hypotension risk.
  - **Alpha-Blockers:** Use with caution due to potential for significant hypotension.
  - **Antihypertensives:** May enhance blood pressure-lowering effects.
  - **CYP3A4 Inhibitors:** Potent inhibitors (e.g., ketoconazole, indinavir, ritonavir) and moderate inhibitors (e.g., erythromycin, azithromycin) increase vardenafil levels and prolong its half-life. Dosage adjustments or avoidance are recommended.
  - **Antiarrhythmics:** Patients on class IA or III antiarrhythmics should avoid vardenafil.
  - **Priapism:** Erections lasting over 4 hours require immediate medical intervention.
  - **Sudden Hearing Loss:** Discontinue use and seek immediate medical attention if sudden hearing loss occurs.
- **Effects on the Eye:** Discontinue use and seek immediate medical attention if sudden vision loss occurs, potentially indicating NAION.
- **QT Prolongation:** Avoid use in patients with QT prolongation or those taking class IA or III antiarrhythmics.
- **Hepatic Impairment:** Not recommended for patients with severe hepatic impairment. Reduced dose advised for moderate impairment.
- **Renal Impairment:** Not recommended for patients on dialysis; no data available for renal impairment use.
- **Pregnancy and Lactation:** Classified as Pregnancy Category B. Not indicated for use in women. No data on excretion in breast milk.
- **Paediatric Use:** Not indicated for use in patients under 18 years.

### Management of Overdose

There is no specific antidote for vardenafil overdose. Management should involve standard supportive care. Renal dialysis is unlikely to be effective due to high plasma protein binding.

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### ► Patient Administration Instructions

#### How to Use SPONTAN Nasal Spray:

##### 1. Preparation

- Ensure your hands are clean and dry before handling the nasal spray.
- Shake the nasal spray bottle gently.

##### 2. Priming the Nasal Spray

- Before using SPONTAN for the first time, you need to prime the spray. Remove the cap and spray it into the air away from your face until a fine mist appears. This usually takes 3-4 pumps.

##### 3. Administration

- **Step 1:** Blow your nose gently to clear the nasal passages.
- **Step 2:** Tilt your head slightly forward.
- **Step 3:** Insert the nozzle of the spray bottle into one nostril, pointing it slightly outward.
- **Step 4:** Press down firmly on the pump to release one spray while breathing in gently through your nose.
- **Step 5:** Repeat the process for the other nostril.

##### 4. Post-Administration

- After administering the spray, avoid sneezing or blowing your nose for a few minutes to allow the medication to be absorbed.
- Replace the cap on the spray bottle after each use.

##### 5. Storage

- Store SPONTAN nasal spray at room temperature away from direct sunlight and moisture.
  - Keep the bottle tightly closed when not in use.
  - Keep out of reach of children and pets.
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### Important Notes

- Use SPONTAN nasal spray only as directed by your healthcare provider.
- Do not share your nasal spray with others, even if they have the same symptoms.
- Contact your healthcare provider if you experience any adverse reactions or if your condition does not improve.