

## TADALAFIL VARDENAFIL COMPOUND

### **What is this medicine?**

Tadalafil (tah DA la fil)

- Tadalafil is a phosphodiesterase type 5 inhibitor.
- It may be used to increase smooth muscle relaxation and blood flow.
- It may also be used for other conditions as determined by your doctor.

Vardenafil (var DEN a fil)

- Vardenafil is a phosphodiesterase type 5 inhibitor.
- It may be used to increase smooth muscle relaxation and blood flow.
- It may also be used for other conditions as determined by your doctor.

**Compounded Drug Forms:** fast-burst sublingual tablet

### **What should I tell my health care provider before I take this medicine?**

- Current or history of heart disease or hypotension
- Current or history of kidney or liver disease
- Current bleeding disorder or peptic ulcer disease
- Presence of anatomical penis deformation
- Presence of hereditary degenerative retinal disorders
- Presence of pulmonary veno-occlusive disease
- Presence of QT prolongation
- Pregnant or think you may be pregnant
- Consult with your provider if you are breastfeeding.

### **How should I use this medicine?**

Follow the package directions provided by Belmar Pharma Solutions and by your prescriber. Your dosage is based on your medical condition and response to therapy. Follow the dosing schedule provided carefully. This medication may be prescribed on an 'as needed' basis as well.

Sublingual formulations should be placed under the tongue or between the cheek and gums and held in place until fully dissolved. Avoid swallowing saliva to ensure the best absorption into the bloodstream. Avoid eating or drinking 15 minutes before or after taking sublingual formulations.

### **What if I miss a dose?**

- If you miss a dose, take it as soon as possible.
- If it is almost time for your next dose, skip the missed dose and continue with your regular dosing schedule.
- Do not take double the dose at once.

### **What should I watch for while using this medicine?**

Belmar Pharma Solutions recommends monitoring blood pressure, heart rate and response to drug. Monitor international prostate symptom score at baseline and up to 12 weeks after medication initiation if appropriate and participate in yearly checkups with your provider.

### **What may interact with this medicine?**

- Drug interactions exist with this medication.
  - Use of nitrates or guanylate cyclase stimulators are contraindicated with PDE-5 inhibitors, like tadalafil and vardenafil.
    - If nitrates are medically necessary, wait at least 48 hours after tadalafil administration. Medical supervision is recommended.
  - Use caution if taking tadalafil with alpha-1 blockers.
    - May require starting tadalafil at a lower dose.
- High fat meals or grapefruit juice may impact efficacy.
- Discuss your medication regimen with your health care provider to determine the best therapy for you.

**What side effects or adverse drug reactions may I notice from receiving this medicine?**

Side effects that may occur and may go away as your body gets used to the medication include:

- Flushing
- Nausea or indigestion
- Headache
- Muscle pain
- Respiratory tract infection

**What serious events prompt immediate attention?**

Contact your doctor immediately or seek medical attention if you experience:

- Sudden hearing loss
  - Auditory impairment may one-sided, and accompany tinnitus and dizziness
- Significant decrease in blood pressure
- Chest pain
- One-sided weakness or difficulty speaking
- Priapism
  - Seek medical intervention for painful erections lasting longer than 4 hours
- Visual disturbances or sudden vision loss

You may experience side effects not listed. Contact your doctor with questions.

An allergic reaction to this medication is unlikely but seek medical attention if it occurs. Symptoms of an allergic reaction include rash, itching, swelling, severe dizziness, trouble breathing.

**Contraindications:** Concomitant use with all forms of nitrates, whether regular or sporadic, due to exaggerated vasodilation risk that may result in an extreme drop in blood pressure. Use of nitric oxide donors or guanylate cyclase stimulators are also contraindicated.

**Where should I keep my medicine?**

Store at room temperature between 59- and 86-degrees F, unless otherwise specified on the packaging.

Additional Information:

- Do not share this medication with others to whom it was not prescribed.
- Keep out of reach of children and pets.
- If an overdose is suspected contact your local poison control center at 1-800-222-1222 or go to the nearest emergency room.

If you have any questions concerning this or any of your medications, a pharmacist is available during normal business hours to answer your questions. You may report side effects to the FDA at 1-800-FDA-1088.

**Do not flush down a toilet or pour down a drain. Check with your pharmacist if you have questions about the best way to dispose of medications. There may be a drug take-back program in your area.**

**Consumer Information Use and Disclaimer:** This information should not be used to decide whether or not to take this medication or any other medication. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does not include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. For questions about the source of any of the information provided herein, pharmacists at Belmar Pharma Solutions are available. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of this medicine.

**References:**

1. Tadalafil. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed June 2023.
2. Vardenafil. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed June 2023.