

# Phentolamine and PGE1 (4mg/1mg/mL) Intraurethral Gel

# **Visually Impaired**

If you are visually impaired and need help reading your label we can help. At your request, a prescription reader is available to patients in need. If you need help, please contact the pharmacy at 727-498-1228 and speak to a technician or pharmacist who will be able to advise you on your options and the cost. Additional charges do apply.

### What is this medication?

This is a compounded intraurethral gel that combines Phentolamine (4 mg/mL) and Prostaglandin E1 (PGE1 or Alprostadil, 1 mg/mL). It is used to treat erectile dysfunction (ED) by improving blood flow to the penis through local vasodilation when applied directly into the urethra.

# What are the ingredients?

Phentolamine 4 mg/mL and Prostaglandin E1 (Alprostadil) 1 mg/mL. If you have any further questions or concerns about the ingredients used in your customized,

compounded formulation, please contact one of our pharmacists at 727-498-1228.

# What should I tell my healthcare provider before I take this medication?

Tell your provider if you:

Have penile implants or deformities (e.g., Peyronie's disease)

Are allergic to phentolamine, prostaglandins, or any components of the formulation Have a history of priapism (prolonged erections)

Are using medications for blood pressure, ED, or alpha-blockers

#### How should I use this medication?

Use the prefilled syringe to apply the gel into the tip of the penis (urethra) as instructed by your provider. Wash hands and dry thoroughly before and after application. Hold the penis upright, gently insert the tip of the syringe into the urethra, and slowly dispense the gel.

Massage the penis gently for 1–2 minutes to distribute the medication. Apply approximately 5–10 minutes before sexual activity or as prescribed.

Important: Use only as directed. Do not reuse or share syringes.



#### What if I miss a dose?

This medication is used on an as-needed basis. If you forget to use it, apply before your next anticipated sexual activity.

# What may interact with this medication?

Nitrates (e.g., nitroglycerin). Other erectile dysfunction medications (e.g., sildenafil, tadalafil) Alpha-blockers or blood pressure medications. Anticoagulants (e.g., warfarin, aspirin)

Always check with your provider before starting or stopping any medication, including non-prescription products.

### What side effect:

Some individuals may experience mild side effects after using this medication. These can include:

- A gentle burning or tingling sensation where the gel is applied
- Redness or a feeling of discomfort in the penis
- Headache or a light feeling of dizziness
- Minor spotting or bleeding from the urethra

While most side effects are temporary and manageable, you should seek immediate medical care if you notice:

- An erection that lasts longer than 4 hours (this could be a sign of priapism and needs urgent attention)
- Intense pain, swelling, or bruising of the penis, or trouble urinating
- Any symptoms that suggest an allergic reaction, such as skin rash, swelling, or difficulty breathing

This list may not describe all possible side effects. Call your doctor for medical advice about side effects and any unusual problems while taking this medication. If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program, online (www.fda.gov/Safety/MedWatch) or by phone (1-800-332-1088)



# What should I watch while using this medication?

Report any difficulty achieving or maintaining an erection. Avoid vigorous physical activity immediately after application. Do not engage in sexual activity if irritation, pain, or bleeding occurs. If you or your partner experience burning or discomfort, inform your provider. Do not use more than prescribed to avoid the risk of priapism.

# Where should I keep my medication?

This medication should be stored in the refrigerator at a temperature between 36°F and 46°F (2°C to 8°C). Do not freeze the medication, and keep it away from direct light or heat. Keep out of reach of children and pets.

<u>Disposal</u>: Do not flush it or pour it down the drain. The best option is to use a DEA-authorized drug take-back location, which you can find at <u>rxdrugdropbox.org</u>. If that's not available, mix the medication (still in its vial or drawn into a syringe) with an undesirable substance like used coffee grounds or cat litter, seal it in a plastic bag, and discard it in the household trash—after removing any personal information from the label. Used syringes must be placed in an FDA-cleared sharps container and taken to an appropriate sharps disposal site. If you're unsure, contact your pharmacist at 727-498-1228 for guidance.

### OFFER TO COUNSEL NOTICE

You are receiving this notice because you or your physician recently requested a compounded prescription to be filled by our pharmacy. You are entitled to receive medication counseling from one of our pharmacists regarding the following: Name and description of medication. Dose, route of administration, and duration of medication. Intended use of medication and expected action. Special directions and precautions for use. Common adverse effects or interactions. Techniques for self-monitoring. Proper storage. Prescription refill information.

You may contact a pharmacist at (727) 498-1228 Monday through Friday, 9AM to 5PM EST and Saturday 9AM-1PM EST.

PharmaLabs' notice of Privacy Practices may be viewed on the company website. You may view and acknowledge receipt of these offers or refuse your right to be counseled online at: http://www.plabrx.com/offer

Our pharmacists will be happy to discuss any additional questions or concerns you may have.

**NOTE:** This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.