

ALPROSTADIL/PAPAVERINE HCL/PHEHTOLAMINE MESYLATE COMPOUND (TRI-MIX)

What is this medicine?

Alprostadil (al PROS ta dill)

Alprostadil is a prostaglandin analog and vasodilator.

- It may help address symptoms of erectile dysfunction.
- It may also be used for other conditions as determined by your doctor.

Papaverine HCl (pa PAV er een)

Papaverine is a non-selective phosphodiesterase inhibitor that promotes smooth muscle relaxation.

- It may help address symptoms of erectile dysfunction.
- It may also be used for other conditions as determined by your doctor.

Phentolamine Mesylate (fen TOLE a meen meh suh layt)

Phentolamine is an alpha-1 blocker or nonselective alpha-adrenergic receptor blocker.

- It may help address symptoms of erectile dysfunction.
- It may also be used for other conditions as determined by your doctor.

Compounded Drug Forms: Intracavernosal injection

What should the injectable product look like?

Upon visual inspection, the vial contents should appear as a clear to pale yellow solution with no visible particles.

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

- Allergy to alprostadil
- Allergy to papaverine
- Allergy to phentolamine
- History of sickle cell anemia
- History of multiple myeloma
- History of leukemia
- History of arrhythmias
- History of hepatitis
- History of glaucoma
- Pregnant partner
- History of priapism or diagnosis increasing priapism risk
- Penile anatomical deformation or fibrotic condition

How should I use this medicine?

Follow the package directions provided by the pharmacy and by your prescriber. Your dosage is based on your medical condition and response to therapy. Follow the dosing schedule provided carefully.

This medication should be given as an intracavernosal injection as indicated by your healthcare provider. See recommended administration guide for further instruction.

What are the limits to how often I can use this medication?

- Do not inject more than one dose within 24 hours of the last dose.
- Do not inject more than 3 doses per week.

What should I watch for while using this medicine?

- Signs of an allergic reaction: hives blistering, swelling of the mouth, face, lips tongue throat, trouble breathing.

- Injection site reaction: redness or itching around the administration site.
- Injection site changes: bruising, infection, or fibrosis
- Monitor blood pressure, respiratory, orthostasis and heart rate as indicated by your provider.
- Monitor erection duration and detumescence.

What may interact with this medicine?

- Drug interactions exist with this medication.
 - Of note: Phosphodiesterase 5 inhibitors may enhance the adverse effects of alprostadil/papaverine/phentolamine. Avoid combining therapy.
 - May enhance the QTc prolongation effects of QT prolonging agents.
- 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:

- GI upset (nausea, abdominal pain, constipation, diarrhea)
- Appetite changes
- Fatigue
- Loss of strength and energy
- Flushing
- Sweating
- Penile discomfort
- Runny nose
- Injection site pain

What serious events prompt immediate attention?

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

- Signs of liver problems
 - Dark urine, extreme changes in energy or appetite, light colored stools, yellow skin, nausea/vomiting
- Signs of a stroke
 - One-sided weakness, difficulty speaking or thinking, drooping on one side of face, balance changes, blurry eyesight.
- Redness, lumps, swelling, tenderness, or erection curving
- Site irritation
- Chest pain or pressure, fast heartbeat, shortness of breath
- Dizziness or passing out.
- Extreme headache
- Unexplained bruising or bleeding
- Leg vein swelling
- Fast or abnormal heartbeat
- Vision changes
- Painful erection or an erection that lasts longer than 4 hours.

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, and/or trouble breathing.

Contraindications: Complete AV block (heart block); MI or history of MU; coronary insufficiency, angina, or presumed coronary artery disease. Conditions predisposing patients to priapism such as sickle cell anemia, multiple myeloma, or leukemia; presence of anatomical deformation or fibrotic penis conditions such as angulation, cavernosal fibrosis, Peyronie disease; penile implants. **Sexual intercourse with a pregnant patient is contraindicated unless a condom barrier is used.**

Where should I keep my medicine?

- Follow the storage recommendations found on your prescription label.

- Store injectables at refrigeration, between 36 to 46 degrees F, unless otherwise specified on the packaging.
- Protect injectables from light.

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.

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.

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.

References:

1. Alprostadil. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed October 2023.
2. Papaverine. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed October 2023.
3. Phentolamine. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Accessed October 2023.