

# PRESCRIPTION MONOGRAPH

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**Compounded Active Ingredients:** Thymosin Alpha 1

**Form:** Injection

**Drug Class:** Synthetic peptide derived from the 28-amino-acid fragment of prothymosin-alpha

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**Mechanism of Action**<sup>1,2</sup>: Thymosin Alpha-1 (Ta1) is a naturally occurring immunomodulatory peptide derived from the thymus gland, the central organ responsible for developing and regulating immune cells. In its bioidentical synthetic form, it is intended to:

- Stimulate the maturation and activation of T lymphocytes to support adaptive immunity.
  - Enhance the function of NK cells, responsible for destroying infected or abnormal cells.
  - Increases immune cytokines while reducing inflammatory mediators to help calm chronic inflammation and promote immune recovery.
  - Strengthen the epithelial immune barrier in the respiratory and gastrointestinal tracts to defend against recurrent respiratory infections.
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## Indications Commonly Prescribed For:

- Chronic viral infections
  - Adjunctive oncology therapy
  - Auto immune/inflammatory modulation
  - Cystic fibrosis
  - Hepatitis B & C
  - HIV/AIDS
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**Before Use:** Let your healthcare provider know if you have had any allergic reactions to injections in the past. Let your healthcare provider know if you are pregnant or breast feeding. Let your healthcare provider know of all supplements you are currently taking, especially corticosteroids and thyroid medications.

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## Contraindications:

- Hypersensitivity to peptide or excipients
  - Severe autoimmune conditions
  - Intentional immunosuppression (organ transplant patients)
  - Liver/kidney disease (use with caution)
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**Cautions:** Take care when injecting the compounded preparation into only specified areas from your healthcare provider. Check the vial for any cloudiness or discoloration before use. Rotate your injection site with each injection to avoid skin problems like thinning, thickening, or lumps.

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## Warnings and Precautions:

- Monitoring is advised for individuals with autoimmune disorders or immune-activation states.
  - Thymosin alpha-1 may cause a temporary rise in liver enzyme (ALT) levels during treatment, monitoring is required.
  - Recent surgery or invasive procedures: closely monitored for signs of infection.
  - Acute kidney or liver injury due to potential toxicity.
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**Adverse Reactions:** If you experience any side effects or adverse reactions, including those not listed, please contact your healthcare provider. Seek emergency care if symptoms are severe

## Common:

- Injection site reaction
- Transient headache, nausea
- Dizziness, fatigue
- Mild flu-like symptoms
- Rash, fever
- Increase in ALT
- Nausea, vomiting

## Serious, but Rare:

- Erythema
  - Transient muscle atrophy
  - Polyarthralgia (pain in 5 or more joints)
  - Hand edema
  - Facial swelling
  - Lung disease
  - Kidney injury
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## Interactions:

- Immune therapies: monitor for over-activation.
  - Immunosuppressants: Tα1 may reduce effects of strong immunosuppression.
  - Vaccines/Adjuvants: Tα1 may enhance response.
  - Limit your alcohol intake or avoid it altogether to minimize risk of side effects.
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## Use in Specific Populations:

- Pregnancy/Lactation: contraindicated
  - Pediatric: Safety not established
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## Storage:

- Refrigerate at 2°C to 8°C (36°F to 46°F)
  - Can be stored at room temperature (up to 30°C or 86°F) for up to 48hrs
  - Do not freeze
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**How to Use This Medication:** This medication is a subcutaneous injection and is delivered in a premixed liquid form. Wash your hands with soap and water before giving the injection. Wipe the rubber stopper of the vial with an alcohol swab. Take a syringe and pull the plunger down to the necessary prescribed amount. This is achieved when the plunger reaches the line for the amount prescribed. Push the needle through the rubber stopper of the vial. Push the plunger down to put air into the vial. Invert the vial and then slowly pull the plunger down past the prescribed dose. If there are bubbles in the syringe, tap the syringe to allow the air bubbles to rise to the top. Slowly push the plunger up until the tip reaches the line for the prescribed dose and removes the bubble of air. Pull the syringe out of the vials rubber stopper. Inject at predetermined injection site as instructed by healthcare practitioner. Discard vial after 28 days from first use.

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## Monitoring Parameters:

- Baseline: CBC with differential, T-cell subsets (CD4/CD8), immunoglobulin levels, relevant viral load, vaccine history, autoimmune screening.
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### Citations:

1. Dominari A, Hathaway Iii D, Pandav K, et al. Thymosin alpha 1: A comprehensive review of the literature. *World J Virol.* 2020;9(5):67-78. doi:10.5501/wjv.v9.i5.67
2. Li J, Liu CH, Wang FS. Thymosin alpha 1: biological activities, applications and genetic engineering production. *Peptides.* 2010;31(11):2151-2158. doi:10.1016/j.peptides.2010.07.026
3. U.S. Food and Drug Administration. *Attachment 5: FDA-2024-N-4777 submission.* Docket No. FDA-2024-N-4777; Attachment 5. 2024. Available from: [https://downloads.regulations.gov/FDA-2024-N-4777-0003/attachment\\_5.pdf](https://downloads.regulations.gov/FDA-2024-N-4777-0003/attachment_5.pdf). Accessed February 18, 2026.
4. Muzavir SR et al., An overview of purification, biological activities and therapeutic applications of thymosin alpha, the health, 2012, 3(3), 75-78, [Accessed on 3rd May 2023][https://applications.emro.who.int/imemrf/Health/Health\\_2012\\_3\\_3\\_75\\_78.pdf](https://applications.emro.who.int/imemrf/Health/Health_2012_3_3_75_78.pdf)
5. Safety information referenced for Thymosin Alpha 1: *Zadaxin (thymalfasin) drug information: description, dosage, side effects* [Internet]. RxList. Updated 2025. Available from: <https://www.rxlist.com/zadaxin-drug.htm#description>. Accessed February 19, 2026.