PRODUCT INFORMATION: PZL-DEPOT (Poly-Zinc-Liothyronine)

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1. NAME OF THE MEDICINE

Poly-Zinc-Liothyronine (PZL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pre-filled syringe contains 25 µg of Liothyronine (as Poly-Zinc-Liothyronine coordination complex) in 0.5 mL of aqueous suspension.

- **Active moiety:** Liothyronine (T_3).
- **Matrix:** Zinc-coordinated supramolecular polymer. Each dose contains approximately 2.5 mg of elemental Zinc (as part of the coordination complex).

3. PHARMACEUTICAL FORM

Suspension for Injection (Subcutaneous). A white to off-white, sterile, aqueous suspension for sustained release.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of primary and secondary hypothyroidism. PZL-Depot is specifically indicated for patients with impaired T_4-to-T_3 conversion or those who require stable physiological T_3 levels and have demonstrated intolerance or poor clinical response to levothyroxine (T_4) monotherapy.

4.2 Dose and Method of Administration

Administration: For subcutaneous injection only. Do not administer intravenously or intramuscularly. **Dosage:** The standard adult dose is 25 µg (one syringe) administered once every 30 days. **Switching from Oral Liothyronine:** When transitioning from daily oral T_3 tablets, the first dose of PZL-Depot should be administered 24 hours after the last oral dose. Close monitoring of serum TSH and free T_3 is recommended during the first 60 days of transition.

4.3 Contraindications

- Hypersensitivity to liothyronine, zinc-coordination compounds, or any of the excipients.
- Untreated adrenal insufficiency.
- Acute myocardial infarction.

4.4 Special Warnings and Precautions for Use

Narrow Therapeutic Index: Liothyronine has a narrow therapeutic index. Small variations in dose or circulating levels may lead to sub-therapeutic response or symptoms of toxicity (thyrotoxicosis). **Cardiovascular Disorders:** Exercise extreme caution in patients with cardiovascular disorders, including angina, coronary artery disease, and hypertension. The sustained-release nature of PZL-Depot is designed to minimise Cmax-related tachycardia, but patients should be monitored for cardiac strain.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics

Mechanism of Action: PZL-Depot provides a sustained release of triiodothyronine (T3), the metabolically active thyroid hormone. The T3 is released from the Zinc-coordinated matrix via slow ligand exchange with physiological ions at the site of injection.

5.2 Pharmacokinetics

Absorption: Following subcutaneous injection, PZL-Depot creates a localised mucosal/tissue depot. **Release Kinetics:** Unlike oral liothyronine, which reaches Tmax in 2-3 hours, PZL-Depot reaches a stable plateau (Tmax) between 4 and 9 hours, maintaining steady-state serum levels for 28–30 days. **Elimination:** Once released from the complex, the liothyronine follows natural metabolic pathways (deiodination) and is excreted primarily via the kidneys.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sodium chloride, Monobasic sodium phosphate, Polysorbate 80, Water for injections.

6.2 Shelf Life

24 months at recommended storage conditions.

6.3 Special Precautions for Storage

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.