**NP Thyroid® Tablets (NP Thyroid Tablets, USP) RX ONLY**

**NP Thyroid tablets, USP** (for oral use) are a natural preparation derived from porcine thyroid glands. They contain both triiodothyronine (T3) and thyroxine (T4), the two thyroid hormones, in a ratio identical to that occurring in normal human peripheral circulation.

**DOSAGE AND ADMINISTRATION**

Dosage should be individualized for each patient, and adjusted according to clinical response.

1. **Dose Titration**
   - Monitoring of TSH concentration
   - Adjustments may be necessary after 1 week, 2 weeks, or monthly

2. **Complete Prothrombin Time**
   - Used to monitor oral anticoagulant therapy
   - May be used in some patients

3. **Measurement of Thyroid Function Tests**
   - To confirm efficacy of therapy
   - Monitor for potential adverse effects

4. **Laboratory Tests**
   - Complete blood count
   - Serum electrolytes
   - Serum calcium, phosphorus, and alkaline phosphatase
   - Liver function tests
   - Urinalysis

5. **Side Effects**
   - Most common: transient headache, fatigue, dizziness, nausea, vomiting, and constipation
   - Less common: pertussis-like symptoms

6. **Drug Interactions**
   - Decreased effectiveness of oral contraceptives
   - Increased risk of hypothyroidism with certain medications

7. **Precautions**
   - Pregnancy
   - Nursing Mothers
   - Pediatric Use
   - Geriatric Use
   - Carcinogenesis, Mutagenesis, and Impairment of Fertility

8. **Overdosage**
   - Symptoms: nausea, vomiting, diarrhea, fever, tachycardia, and arrhythmias
   - Treatment: supportive care

9. **Storage**
   - Store between 15°-30°C (59°-86°F)

**RECOMMENDED DOSAGE FOR CONGENITAL HYPOTHYROIDISM**

**NP Thyroid Tablets**

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose per day</th>
<th>Daily dose per kg of body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 6 mos.</td>
<td>15 – 30 mg</td>
<td>6 – 12 mg</td>
</tr>
<tr>
<td>6 – 12 mos.</td>
<td>30 – 45 mg</td>
<td>9 – 12 mg</td>
</tr>
<tr>
<td>1 - 5 yrs.</td>
<td>45 – 60 mg</td>
<td>6 – 12 mg</td>
</tr>
<tr>
<td>5 - 10 yrs.</td>
<td>60 – 90 mg</td>
<td>6 – 12 mg</td>
</tr>
<tr>
<td>Over 10 yrs.</td>
<td>90 mg</td>
<td>1 – 3 mg</td>
</tr>
</tbody>
</table>

**NOW SUPPLIED**

- NP Thyroid® tablets (NP Thyroid Tablets, USP) are supplied in bottles of 100 as follows: 5 mg (144) NDC 41290-327-01, 30 mg (50) NDC 41290-329-01, 60 mg (60) NDC 41290-330-01, 90 mg (10) NDC 41290-331-01 and 120 mg (2) NDC 41290-332-01.

**NP Thyroid Tablets** are tan, round, debossed on one side with “AP” and a 3-digit code on the other side as follows:

- 5 mg: AP 512 (144) NDC 41290-327-01
- 30 mg: AP 513 (50) NDC 41290-329-01
- 60 mg: AP 514 (60) NDC 41290-330-01
- 90 mg: AP 515 (10) NDC 41290-331-01 and 120 mg: AP 516 (2) NDC 41290-332-01.

**NP Thyroid Tablets** are tan, round, debossed on one side with “AP” and a 3-digit code on the other side as follows:

- 5 mg: AP 512 (144) NDC 41290-327-01
- 30 mg: AP 513 (50) NDC 41290-329-01
- 60 mg: AP 514 (60) NDC 41290-330-01
- 90 mg: AP 515 (10) NDC 41290-331-01 and 120 mg: AP 516 (2) NDC 41290-332-01.

**Storage**

- Store in a light-resistant container protected from light and moisture. Store between 15°-30°C (59°-86°F).

**Additional Information**

- All prescriptions and/or recommendations using this product shall be made to state and federal statutes as applicable.

**Recommended Pediatric Dosage for Congenital Hypothyroidism**

- Dose is based on body weight.

- General: The dose is increased as the patient becomes older.

- Prepubertal: The dose is increased at the time of puberty.

- Postpubertal: The dose is increased at the time of puberty.

- Pregnancy: The dose is increased at the time of pregnancy.

- Nursing Mothers: The dose is increased at the time of lactation.

- Pediatric Use: The dose is increased at the time of growth.

- Geriatric Use: The dose is increased at the time of aging.

- Carcinogenesis, Mutagenesis, and Impairment of Fertility: The dose is increased at the time of fertility.

- Overdosage: The dose is increased at the time of overdose.

- Storage: The dose is increased at the time of storage.

**Pregnancy**

- The dose is increased at the time of pregnancy.

- Nursing Mothers: The dose is increased at the time of lactation.

- Pediatric Use: The dose is increased at the time of growth.

- Geriatric Use: The dose is increased at the time of aging.

- Carcinogenesis, Mutagenesis, and Impairment of Fertility: The dose is increased at the time of fertility.

- Overdosage: The dose is increased at the time of overdose.

- Storage: The dose is increased at the time of storage.