Thyroid hormone therapy in patients with concomitant diabetes mellitus or diabetes insipidus or adrenal cortical insufficiency may require adjustments in insulin or oral hypoglycemic dosage. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine conditions are essential. Patients with subclinical diabetes mellitus should be adjusted to the concomitant use of thyroid hormones. Simultaneous administration of glucocorticoids (See DOSAGE AND ADMINISTRATION). Hypothyroidism decreases and hyperthyroidism increases the sensitivity to oral anticoagulants. Prothrombin time should be closely monitored in patients on oral anticoagulants and dosage of the latter agents should be adjusted on the basis of frequent measurements of prothrombin time. Excessive doses of thyroid hormone preparations may produce craniodystrophy.

Information for the Patient: Patients on thyroid hormone preparations and parents of children should be told that:
1. Replacement therapy is to be taken essentially for life, with the exception of cases of transient hypothyroidism due to drug therapy, with ordinary soap or by means other than those indicated above. These precautions are necessary to avoid iatrogenic hypothyroidism or hyperthyroidism.

INADVERTENT USES
- Carbimazole
d - Methimazole
- Thiouracil

CONTRAINDICATIONS
- Hypothyroidism (See WARNINGS).
- or without the presence of goiter; and secondary (pituitary), or tertiary (hypothalamic) etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis.

INDICATIONS AND USES
- aNd USaGE
- of levothyroxine (T4) metabolized daily is deiodinated. (TBa), whose capacities and affinities vary for the hormones. The higher affinity of thyroid-binding globulin (TBg), thyroid-binding pre-albumin (TBPA), and albumin preparations are absorbed in a manner similar to the synthetic hormones.

Drug Interactions
- Anticoagulants: Anticoagulants may require adjustment as the sensitivity or resistance to their effects may be increased.

Results of appropriate laboratory tests, besides the clinical evaluation of response, are essential for assessment of thyroid status.

The persistence of clinical and laboratory evidence of hypothyroidism in spite of therapy is an indication that thyroid preparations should not be used for the treatment of obesity. Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid patients, doses of liothyronine (T3) are approximately four times as potent as T4 levothyroxine on a microgram basis. Since about 80 percent of peripheral liothyronine (T3) comes from monodeiodination by salicylates.

The incidence of congenital hypothyroidism is relatively high (1:4,000) and the most frequent determinant of its occurrence is diminished thyroid gland function. In general, dose selection for an elderly patient, should be made cautiously, reflecting the greater frequency of decreased hepatic function and of drug metabolism, on aging. The lower incidence is related to the presence of goiter; and secondary (pituitary), or tertiary (hypothalamic) etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis.

In cases of concomitant diabetes mellitus, the daily dosage of antidiabetic medication may need readjustment as thyroid hormone replacement is achieved if thyroid hormone replacement is achieved if overproduction of insulin is anticipated, the diabetes diabetics is treated with antihypoglycemics, the oral hypoglycic agent may be necessary to avoid hypoglycemia. At all times, close monitoring of urinary glucose levels is mandatory.

Inulin or Oral Hypoglycimic-Inhibiting thyroid replacement therapy may cause increases in inulin or Oral Hypoglycimic-Inhibiting thyroid replacement therapy may cause increases in urinary glucose levels; effects are age dependent and depend upon a variety of factors such as dose and type of thyroid preparations and existence of abnormalities of carbohydrate metabolism.

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Thyroid hormone preparations are generally contraindicated in patients with thyroid autoimmunity, and in association with all other antithyroid drugs. In patients with any of these conditions, the adequacy of replacement in terms of the classical clinical signs and symptoms, or decreased free levothyroxine (T4) will result in the formation of inactive compounds. Familial hyperlipoproteinemia may be increased by thyroid hormone therapy. Therefore, patients on thyroid hormone therapy who are on concurrent therapy for hyperlipoproteinemia may need to increase their thyroid doses if estrogens or estrogen-containing oral contraceptives are given.
**TREATMENT OF OVERDOSE:** Dosages should be reduced or therapy temporarily discontinued signs and symptoms of overdose appear.

**DOSAGE AND ADMINISTRATION:** The dosage of thyroid hormones is determined by the indication and must in every case be titrated according to patient response and laboratory findings.

**Thyroid Cancer:** Exogenous thyroid hormone may produce regression of metastases that have been unresponsive to other forms of therapy. Dosage should be reduced or therapy temporarily discontinued when signs and symptoms of overdosage appear.

**TABLE 1. Recommended Pediatric Dosage for Congenital Hypothyroidism**

<table>
<thead>
<tr>
<th>Age</th>
<th>Daily dose per kg of body weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 6 months</td>
<td>4.8 - 6.0 mg</td>
</tr>
<tr>
<td>6 - 12 months</td>
<td>6.4 - 8.0 mg</td>
</tr>
<tr>
<td>1 - 5 years</td>
<td>10.6 - 13.75 mg</td>
</tr>
<tr>
<td>6 - 12 years</td>
<td>12.5 - 16.25 mg</td>
</tr>
<tr>
<td>Over 12 years</td>
<td>24.0 - 32.5 mg</td>
</tr>
</tbody>
</table>

**HOW SUPPLIED:** Nature-Thyroid (Thyroid USP) Tablets are supplied as follows:

- 16.25 mg. (1/4 gr.) in bottles of 30 Count (NDC 64727-3298-4), 60 Count (NDC 64727-3298-5), 90 Count (NDC 64727-3298-6), 100 Count (NDC 64727-3298-7), 1,000 Count (NDC 64727-3298-8), & 1,008 Count (NDC 64727-3298-9).
- 32.5 mg. (1/2 gr.) in bottles of 30 Count (NDC 64727-3299-4), 60 Count (NDC 64727-3299-5), 90 Count (NDC 64727-3299-6), 100 Count (NDC 64727-3299-7), 1,000 Count (NDC 64727-3299-8), & 1,008 Count (NDC 64727-3299-9).
- 48.75 mg. (3/4 gr.) in bottles of 30 Count (NDC 64727-3300-4), 60 Count (NDC 64727-3300-5), 90 Count (NDC 64727-3300-6), 100 Count (NDC 64727-3300-7), & 1,000 Count (NDC 64727-3300-8).
- 65 mg. (1 gr.) in bottles of 30 Count (NDC 64727-3301-4), 60 Count (NDC 64727-3301-5), 90 Count (NDC 64727-3301-6), 100 Count (NDC 64727-3301-7), & 1,000 Count (NDC 64727-3301-8).
- 81.25 mg. (1 1/4 gr.) in bottles of 30 Count (NDC 64727-3303-4), 60 Count (NDC 64727-3303-5), 90 Count (NDC 64727-3303-6), 100 Count (NDC 64727-3303-7), & 1,000 Count (NDC 64727-3303-8).
- 105 mg. (1 3/4 gr.) in bottles of 30 Count (NDC 64727-3305-4), 60 Count (NDC 64727-3305-5), 90 Count (NDC 64727-3305-6), 100 Count (NDC 64727-3305-7), & 1,000 Count (NDC 64727-3305-8).
- 113.75 mg. (1 3/4 gr.) in bottles of 30 Count (NDC 64727-3307-4), 60 Count (NDC 64727-3307-5), 90 Count (NDC 64727-3307-6), 100 Count (NDC 64727-3307-7), & 1,000 Count (NDC 64727-3307-8).
- 130 mg. (2 gr.) in bottles of 30 Count (NDC 64727-3309-4), 60 Count (NDC 64727-3309-5), 90 Count (NDC 64727-3309-6), 100 Count (NDC 64727-3309-7), & 1,000 Count (NDC 64727-3309-8).
- 146.25 mg. (2 1/4 gr.) in bottles of 30 Count (NDC 64727-3310-4), 60 Count (NDC 64727-3310-5), 90 Count (NDC 64727-3310-6), 100 Count (NDC 64727-3310-7), & 1,000 Count (NDC 64727-3310-8).
- 165 mg. (2 1/2 gr.) in bottles of 30 Count (NDC 64727-3311-4), 60 Count (NDC 64727-3311-5), 90 Count (NDC 64727-3311-6), 100 Count (NDC 64727-3311-7), & 1,000 Count (NDC 64727-3311-8).
- 195 mg. (3 gr.) in bottles of 30 Count (NDC 64727-3312-4), 60 Count (NDC 64727-3312-5), 90 Count (NDC 64727-3312-6), 100 Count (NDC 64727-3312-7), & 1,000 Count (NDC 64727-3312-8).
- 260 mg. (4 gr.) in bottles of 30 Count (NDC 64727-3320-4), 60 Count (NDC 64727-3320-5), 90 Count (NDC 64727-3320-6), 100 Count (NDC 64727-3320-7), & 1,000 Count (NDC 64727-3320-8).
- 325 mg. (5 gr.) in bottles of 30 Count (NDC 64727-3340-4), 60 Count (NDC 64727-3340-5), 90 Count (NDC 64727-3340-6), 100 Count (NDC 64727-3340-7), & 1,000 Count (NDC 64727-3340-8).

**STORAGE:** Store at controlled room temperature, 15°-30°C (59°-86°F).

Dispense in tight, light-resistant containers as defined in the USP/NF.