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Physicians' Desk Reference®

To Pharmaceutical Specialties and Biologicals

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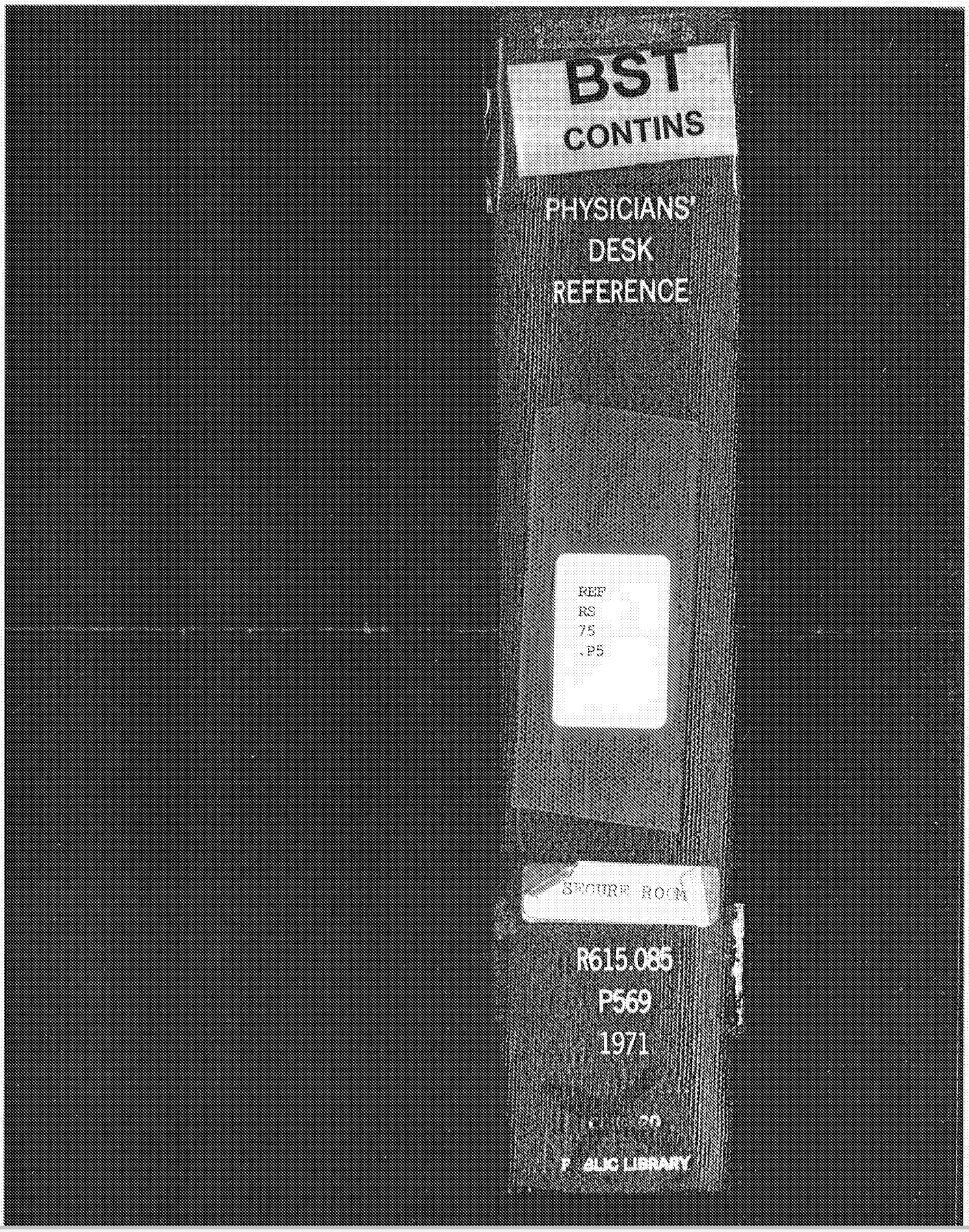

Flint—Cont.

ous history of asthma. Resumption of PIROMEN (pseudomonas polysaccharide) therapy in this individual has not produced a recurrence of such an attack.

A separate heat sterilized syringe and needle or gas sterilized disposable unit should be used for each individual patient to prevent transmission of homologous serum hepatitis and other infectious agents from one person to another.

Side Effects: There are a few and relatively minor side effects associated with PIROMEN (pseudomonas polysaccharide) therapy. An occasional patient may complain of a slight headache or myalgia and rare cases of nausea have been reported. Aspirin will relieve much of the discomfort and any of the usual antipyretic agents may be used if desired. Several investigators have indicated that a sense of euphoria is associated with PIROMEN (pseudomonas polysaccharide) therapy.

Administration and Dosage: PIROMEN (pseudomonas polysaccharide) may be injected by any parenteral route. Intravenous injection produces the most rapid results, although satisfactory results are reported when the drug is given intramuscularly, subcutaneously and intradermally.

Each individual has a different response threshold to PIROMEN (pseudomonas polysaccharide). For this reason initial doses of one or two micrograms intravenously are recommended for allergies and dermatoses, with subsequent doses being increased by one microgram per injection until a clinical response is obtained. Most patients will obtain the most beneficial response when the dose borders the febrile level. If the patient should have a febrile response, the next dose should be reduced by one-half to one microgram from the amount which induced the febrile reaction. Maintenance doses may be given by any parenteral route.

Dosage should be maintained at the level which produces the greatest clinical response. When instituting PIROMEN (pseudomonas polysaccharide) therapy, the second injection should be given approximately 48 hours after the initial administration. Patients generally respond to a program of three injections the first week followed by weekly injections for as long as is necessary. Some cases may require two or three injections weekly to obtain the most beneficial response.

How Supplied: PIROMEN (pseudomonas polysaccharide) is supplied in 10 ml. vials containing 4 micrograms per ml. and in 10 ml. vials containing 10 micrograms per ml. PIROMEN (pseudomonas polysaccharide) is also available in 2 ml. vials containing 50 micrograms per ml. for those desiring a more concentrated dosage form, or where the specific indication requires a higher dosage than usual. The drug should be kept under refrigeration (preferably at a temperature of 2-8° C.).

SYNTHROID® INJECTION (sodium levothyroxine) R

Composition: SYNTHROID (sodium levothyroxine) INJECTION contains the active principle of the thyroid gland, prepared synthetically in pure crystalline form as the monosodium salt.

Action and Uses: SYNTHROID (sodium levothyroxine) INJECTION is specific replacement therapy for diminished or absent thyroid function resulting from primary or secondary atrophy of the gland, congenital defect, surgery, excessive radiation, or antithyroid drugs. It is indicated in myxedematous coma or other thyroid dysfunctions where rapid replacement of the hormone is required or when a patient does not respond to oral therapy.

Administration and Dosage: In myxedematous stupor or coma, with no evidence of severe heart disease, 200 to 400 mcg. of SYNTHROID (sodium levothyroxine) INJECTION may be administered intravenously utilizing a solution containing 100 mcg. per ml. Detectable effects are usually observed by the sixth hour after injection and are fully appreciated during the following day. A repeat injection of 100 to 200 mcg. may be given on the second day if significant improvement has not occurred. Decision to begin thyroid treatment can be guided by serum PBI levels (the normal range in males is 4.5–7.5 mcg%; females 5.5–8.5 mcg%).

Precautions: As with other thyroid preparations, overdose may cause diarrhea or cramps, in addition to metabolic effects such as nervousness, tremors, tachycardia, vomiting, and continued weight loss. In such cases, medication should be stopped for 2–6 days, then resumed at a lower dosage level. In patients with diabetes mellitus, look for possible changes in metabolic activity which may decrease insulin or other antidiabetic drug dosage requirements. If hypothyroidism is accompanied by adrenal insufficiency such as Addison's disease (chronic adrenocortical insufficiency), Simmonds's disease (panhypopituitarism), or Cushing's syndrome (hyperadrenalism), these dysfunctions must be corrected prior to and during SYNTHROID (sodium levothyroxine) therapy. Caution must be exercised in the administration of this drug to patients with cardiovascular disease, and the development of chest pains or other aggravation of the cardiovascular disease requires a reduction of dosage.

Side Effects: Side effects are relatively slow in being manifested and when they do occur are secondary to increased body metabolism—sweating, heart palpitations with or without pain, leg cramps, and weight loss. Diarrhea, vomiting, and nervousness also have been reported. Myxedematous patients with heart disease have died from abrupt increases in dosage of thyroid drugs. In most cases with side effects, reduction of dosage followed with a more gradual upward adjustment is effective.

Contraindications: Thyrotoxicosis, acute myocardial infarction.

How Supplied: SYNTHROID (sodium levothyroxine) INJECTION is supplied in 10 ml. vials containing 500 mcg. of lyophilized active ingredient and 10 mg. of Mannitol, N.F., a 5 ml. vial containing Sodium Chloride Injection, U.S.P. is provided as diluent.

Directions for Reconstitution: Aseptically add the 5 ml. Sodium Chloride Injection, U.S.P. to the 10 ml. vial of lyophilized sodium levothyroxine. Shake vial to insure complete mixing. **Use immediately** after reconstitution. Discard any unused portion.

Literature Available: Upon request.

SYNTHROID® TABLETS R (sodium levothyroxine)

Composition: SYNTHROID (sodium levothyroxine) TABLETS contain the active principle of the thyroid gland, prepared synthetically in pure crystalline form as the monosodium salt.

Action and Uses: SYNTHROID (sodium levothyroxine) TABLETS are specific replacement therapy for diminished or absent thyroid function resulting from primary or secondary atrophy of the gland, congenital defect, surgery, excessive radiation, or antithyroid drugs. The TABLETS are indicated for conditions of the hypothyroid state such as myxedema, hypothyroidism without myxedema, hypothyroidism in pregnancy, pediatric and geriatric hypothyroidism, hypopituitary hypothyroidism, simple [illegible] goiter, and reproductive disorders associated with hypothyroidism.

Administration and Dosage: The [illegible] a 0.1 mg. SYNTHROID (sodium levothyroxine) TABLET is equivalent to [illegible] one grain thyroid, U.S.P. Administration [illegible] gle dose, preferably after breakfast. [illegible] to begin thyroid treatment can be [illegible] serum PBI levels (the normal range [illegible] is 4.5–7.5 mcg.%; females 5.5–8.5 [illegible] hypothyroidism without myxedema [illegible] al initial adult dose is 0.1 mg. daily, [illegible] be increased by 0.1 mg. every 30 days [illegible] proper metabolic balance is attained. [illegible] maintenance dosage will usually range [illegible] 0.2 to 0.4 mg. daily, although some [illegible] er doses are necessary. In patients [illegible] thyroid with SYNTHROID (sodium [illegible] roxine), it is not unusual to find PBI [illegible] 8 to 10 mcg.%.

In adult myxedema, starting dose [illegible] 0.025 mg. daily, increased after two weeks [illegible] 0.05 mg., and to 0.1 mg. at the end of [illegible] two weeks. The daily dose may be [illegible] creased at two-month intervals by [illegible] til the optimal maintenance dose is [illegible] usually 0.2 to 0.3 mg. daily but [illegible] range from 0.1 to 1.0 mg. daily.

The initial dose for children with [illegible] severe hypothyroidism is the same [illegible] adult myxedema, but all intervals [illegible] should be made every two weeks. [illegible] growing child, final dosage requirements [illegible] be greater than in the adult. In cases [illegible] cretinism is discovered after the [illegible] weeks of life, overdosage of SYNTHROID [illegible] dium levothyroxine) therapy is [illegible] ferred to under-treatment, in order to [illegible] ate growth rate.

Precautions: As with other thyroid [illegible] tions, overdose may cause diarrhea [illegible] cramps, in addition to metabolic effects [illegible] ds nervousness, tremors, tachycardia, [illegible] ing, and continued weight loss. In such [illegible] medication should be stopped for 2-4 [illegible] then resumed at a lower dosage level. [illegible] verse effects may not become apparent [illegible] 1-3 weeks so patients receiving the [illegible] should be kept under close observation [illegible] signs of thyrotoxicosis. In patients with [illegible] tes mellitus, look for possible changes [illegible] metabolic activity which may decrease [illegible] lin or other antidiabetic drug dosage [illegible] ments. If hypothyroidism is accompanied [illegible] adrenal insufficiency, such as Addison's [illegible] ease (chronic adrenocortical insufficiency), [illegible] Simmonds's disease (panhypopituitarism), [illegible] Cushing's syndrome (hyperadrenalism), [illegible] dysfunctions must be corrected prior to and during SYNTHROID (sodium levothyroxine) therapy. Caution must be exercised in the administration of this drug to patients with cardiovascular disease, and the development of chest pains or other aggravation of the cardiovascular disease requires a reduction of dosage.

Side Effects: Side effects are relatively slow in being manifested and when they do occur are secondary to increased body metabolism—sweating, heart palpitations with or without pain, leg cramps, and weight loss. Diarrhea, vomiting, and nervousness also have been reported. Myxedematous patients with heart disease have died from abrupt increases in dosage of thyroid drugs. In most cases with side effects, reduction of dosage followed with a more gradual upward adjustment is effective.

Contraindications: Thyrotoxicosis, acute myocardial infarction.

How Supplied: SYNTHROID (sodium levothyroxine) TABLETS are supplied in bottles of 100 and 500 scored tablets in 7 strengths labeled as follows with their approximate equivalent of desiccated thyroid U.S.P.: