

I. GENERAL INFORMATION

Iodine is an essential element. Although its main function is in the production of thyroid hormones by the thyroid gland, other organs in the body have a need for iodine in order to function normally (4).

Several studies have demonstrated a relationship between low iodine intake and fibrocystic disease of the breast (FDB), both in women and laboratory animals (1,2). The minimum amount of iodine required for control and prevention of FDB is equivalent to 0.1mg/kg body weight/day. For example, for a 50 kg woman, the daily amount of iodine would be 5 mg. The thyroid gland needs iodide to function properly. The original study done 80 years ago to control goiter in adolescent girls used 9 mg iodide daily (3).

During the early 1900's, the iodine/iodide solution called Lugol solution was used extensively, effectively and safely in medical practice, for both low activity and above normal activity of the thyroid gland (4). The recommended daily intake for iodine supplementation was 0.1 to 0.3 ml of Lugol solution containing 12.5 to 37.5 mg total iodide. That amount was mentioned as lately as 1995 in a book on Pharmaceutical Sciences (5). Several investigators have shown convincing evidence connecting inadequate iodine intake and breast cancer (6). Japanese women living in Japan consumed a daily average of 13.8 mg total elemental iodine and they experience one of the lowest prevalence (risk) for breast, ovarian and uterine cancer (6). In the 1960's, one slice of bread in the USA contained the full RDA of 0.15 mg iodine. The risk for

breast cancer was then 1 in 20 (7). Over the last 2 decades, iodine was replaced by bromine in the bread making process. Bromine blocks thyroid function and may interfere with the anticancer effect of iodine on the breast (4). Now, the risk for breast cancer is 1 in 8 and increasing 1% per year (7).

The RDA limits for vitamins and minerals were established after World War II. One of the last essential elements included in the RDA system was iodine, established in 1980 and confirmed in 1989 (8). The RDA for iodine was based on the amount of iodine/iodide needed to prevent goiter, extreme stupidity and hypothyroidism (9). The optimal requirement of the whole human body for iodine has never been studied. Therefore, the optimal amount of this element for physical and mental wellbeing is unknown. Based on demographic studies, the mainland Japanese consumed an average of 13.8 mg daily and they are one of the healthiest people on planet earth (6). Lugol solution is a time-tested preparation with a proven track record for over 150 years. Two drops contain 12.5 mg iodine/iodide, an amount very close to the 13.8 mg average intake of mainland Japanese.

II. RATIONALE FOR THIS FORMULATION

Administration of iodine/iodide in liquid solution is not very accurate, may stain clothing, has an unpleasant taste and causes gastric irritation. **Iodorol**[®] is a precisely quantified tablet form containing 5 mg iodine and 7.5 mg iodide as the potassium salt. To prevent gastric irritation, the iodine/iodide preparation was absorbed unto a

colloidal silica excipient; and to eliminate the unpleasant taste of iodine, the tablets were coated with a thin film of pharmaceutical glaze (10).

III. SUGGESTED USE

The suggested daily amount is 1-4 tablets/day as recommended by your physician. Work closely with your physician while on the **Iodorol**[®] program. Report to your physician any history of thyroid surgery and/or radiation, chronic lymphocytic thyroiditis (Hashimoto), and any previous problem with your thyroid. Before starting **Iodorol**[®], your physician (He/She = He) will order blood tests for hematology, blood chemistry and thyroid functions. He will also perform an ultrasound of your thyroid to measure the size and appearance of your thyroid. Depending on the results of the thyroid function tests and ultrasound, he may order some blood tests for thyroid antibodies. If you are taking thyroid hormones, let your physician know about it. Be aware that **Iodorol**[®] enhances the response of your body to thyroid hormones (4,6). Subjects on **Iodorol**[®] feel warmer in cold environments and that is expected. However, you will need to cut down the amount of thyroid hormones if you experience palpitation, anxiety, increased sweating and intolerance to heat. That is because **Iodorol**[®] decreases your need for thyroid hormones. Your physician will guide you in titrating downward the amount of thyroid hormones. Your physician will reevaluate you one month afterward if you are on thyroid hormones, and 3 months if not. Keep a record of what you observe while on **Iodorol**[®] and show it to your physician.

If 4 tablets of 12.5 mg **Iodorol**[®] are required

to achieve and maintain sufficiency, a tablet of 50mg is now available (IOD-50) supplied in bottles of 30 and 90 tablets.

To test whole body sufficiency for iodine, 4 tablets of Iodoral® 12.5 mg or one tablet of 50 mg (IOD-50) are ingested, followed by 24 hr. urine collection. The more deficient a subject is in iodine, the more iodine is retained in the body and the least excreted in the urine. Sufficiency is achieved when 90% or more of the ingested amount is excreted in the urine. In most subjects tested, 3-4 tablets of Iodoral®/day were required to achieve whole body sufficiency within 3 months and the body retained approximately 1.5 gm iodine at sufficiency (4,8). The best response in patients with FDB was observed with ingestion of 4 tablets a day (8). Check with your physician for more information about the loading test.

IV. REFERENCES

1) Ghent, W., et al. Can. J. Surg., 36:453-460, 1993. 2) Eskin, B., et al, Biological Trace Element Research, 49:9-19, 1995. 3) Marine, D., Atl. Med. J., 26:437-442, 1923. 4) Abraham, G.E., The Original Internist, 11:17-36, 2004. 5) Gennaro A.R., Remington: 19th Edition, 1995. Mack Publishing Co, 1267. 6) Abraham, G.E., Flechas, J.D., Hakala, J.C., The Original Internist, 9:30-41, 2002. 7) Epstein, S.S., et al, Breast Cancer Prevention Program Macmillan, NY, 1998, pg5. 8) Abraham, G.E., The Original Internist, 11:(2) 29-38, 2004. 9) Abraham, G.E. Townsend Letter, 245:100-101, 2003. 10) Abraham, G.E., Flechas, J.D., Hakala, J.C., The Original Internist, 9:5-20, 2002.

V. POTENTIAL SIDE EFFECTS

Ingestion of iodine and/or iodide has been associated with certain complaints. If you experience any of the following, stop ingesting Iodoral® and contact your physician:

- acne-like skin lesions in certain areas of your body
- headache in the frontal sinus
- unpleasant brassy taste
- increased salivation and sneezing

If you experience any unusual symptom since starting on Iodoral®, contact your physician.

VI. TABLET POTENCY AND BOTTLE SIZE

Iodoral® 12.5 mg is supplied in bottles of 90 and 180 tablets, a 3 and 6 month quantity if you use one tablet/day.

For the convenience of individuals requiring 4 tablets of 12.5 mg a day, a 50 mg tablet (IOD-50) is now available in bottles of 30 and 90 tablets for a one month and three months supply at one tablet a day.



IODORAL®

**High Potency
Iodine/Potassium Iodide
Supplement**

One tablet of Iodoral® supplies an amount of total elemental iodine, comparable to the average daily intake of this essential element by mainland Japanese, a population with a very low prevalence of fibrocystic disease of the breast and breast cancer.