

IBSA Pharma – Recall of TIROSINT[®]-SOL (levothyroxine sodium) oral solution

- On February 1, 2023, the [FDA announced](#) a consumer-level recall of 27 lots of IBSA Pharma's [TIROSINT-SOL \(levothyroxine sodium\)](#) oral solution because these lots may be subpotent. The company's analyses show a slight decrease below 95.0% of its labeled amount in levothyroxine sodium (T4) for some lots. This recall does not apply to [TIROSINT[®] \(levothyroxine sodium\)](#) capsules.
 - Other TIROSINT-SOL oral solution products that are not being recalled are available for patients to use.
- Refer to the [press release](#) for the list of recalled products and lot numbers.
- TIROSINT-SOL is indicated as a replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. It is also indicated as adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.
 - TIROSINT-SOL is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients as there are no clinical benefits and overtreatment with TIROSINT-SOL may induce hyperthyroidism.
 - TIROSINT-SOL is not indicated for treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis.
- Patients being treated for hypothyroidism, who receive subpotent TIROSINT-SOL, may experience signs and symptoms of hypothyroidism which may include, fatigue, increased sensitivity to cold, constipation, dry skin, puffy face, hair loss, slow heart rate, depression, swelling of the thyroid gland and/or unexplained weight gain or difficulty losing weight.
- Over- or under-treatment with TIROSINT-SOL may have negative effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, emotional state, gastrointestinal function, and glucose and lipid metabolism.
- Any patients including those who might be pregnant, newborn infants, or elderly patients, should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using recalled TIROSINT-SOL.
- To date, IBSA Pharma has not received any reports of adverse events that have been determined to be related to this voluntary recall.
- Patients who are currently taking TIROSINT-SOL should not discontinue use without contacting their healthcare provider for further guidance and/or until they receive a replacement prescription.
- Anyone with an existing inventory of the recalled product should stop distribution, quarantine the product immediately and arrange for return.
- Consumers and healthcare providers with questions regarding this recall can contact IBSA Pharma by phone at **1-800-587-3513** or by e-mail at medinfo@ibsapharma.com.

- Wholesalers and retailers with questions regarding this recall can contact IBSA Pharma by phone at **1-855-224-0231** or by e-mail at **IBSACS@Eversana.com**.

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