

Tirosint Soln Oral Solution

On February 1st, 2023 IBSA Pharma Inc. is voluntarily recalling 27 lots of Tirosint-Sol (levothyroxine sodium) Oral Solution due to the consumer-level. This voluntary recall has been initiated 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.

Product Description	NDC	Lot Number	Expiration Date
TIROSINT-SOL 13 mcg/mL 30 units carton-box	71858-0105-5	220409	10/2023
TIROSINT-SOL 13 mcg/mL 30 units carton-box	71858-0105-5	220956	03/2024
TIROSINT-SOL 25 mcg/mL 30 units carton-box	71858-0110-5	220856	02/2024
TIROSINT-SOL 37.5 mcg/mL 30 units carton-box	71858-0112-5	220552	11/2023
TIROSINT-SOL 37.5 mcg/mL 30 units carton-box	71858-0112-5	221055	04/2024
TIROSINT-SOL 44 mcg/mL 30 units carton-box	71858-0113-5	220553	11/2023
TIROSINT-SOL 44 mcg/mL 30 units carton-box	71858-0113-5	221056	04/2024
TIROSINT-SOL 50 mcg/mL 30 units carton-box	71858-0115-5	220407	10/2023
TIROSINT-SOL 50 mcg/mL 30 units carton-box	71858-0115-5	220960	03/2024
TIROSINT-SOL 62.5 mcg/mL 30 units carton-box	71858-0117-5	220556	11/2023
TIROSINT-SOL 62.5 mcg/mL 30 units carton-box	71858-0117-5	221058	04/2024
TIROSINT-SOL 75 mcg/mL 30 units carton-box	71858-0120-5	220853	02/2024
TIROSINT-SOL 88 mcg/mL 30 units carton-box	71858-0125-5	220411	10/2023
TIROSINT-SOL 88 mcg/mL 30 units carton-box	71858-0125-5	220854	02/2024
TIROSINT-SOL 100 mcg/mL 30 units carton-box	71858-0130-5	220413	10/2023
TIROSINT-SOL 100 mcg/mL 30 units carton-box	71858-0130-5	220964	03/2024
TIROSINT-SOL 112 mcg/mL 30 units carton-box	71858-0135-5	220414	10/2023
TIROSINT-SOL 112 mcg/mL 30 units carton-box	71858-0135-5	220852	02/2024
TIROSINT-SOL 112 mcg/mL 30 units carton-box	71858-0135-5	220970	03/2024
TIROSINT-SOL 125 mcg/mL 30 units carton-box	71858-0140-5	220855	02/2024
TIROSINT-SOL 137 mcg/mL 30 units carton-box	71858-0145-5	220415	10/2023

TIROSINT-SOL 137 mcg/mL 30 units carton-box	71858-0145-5	221052	04/2024
TIROSINT-SOL 150 mcg/mL 30 units carton-box	71858-0150-5	220959	03/2024
TIROSINT-SOL 175 mcg/mL 30 units carton-box	71858-0155-5	220416	10/2023
TIROSINT-SOL 175 mcg/mL 30 units carton-box	71858-0155-5	221053	04/2024
TIROSINT-SOL 200 mcg/mL 30 units carton-box	71858-0160-5	220418	10/2023
TIROSINT-SOL 200 mcg/mL 30 units carton-box	71858-0160-5	220560	11/2023

- 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