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IBSA Pharma issues voluntary nationwide recall of select lots of Tirosint-SOL (levothyroxine sodium) oral solution due to subpotency

At Prime Therapeutics Management, we want to help you receive the best possible care. Visit **[PrimeTherapeutics.com/DrugRecalls](https://www.PrimeTherapeutics.com/DrugRecalls)** to review the latest FDA drug recalls.

IBSA Pharma has posted a 27-lot recall of Tirosint-SOL oral solution.

About this recall:

IBSA Pharma is voluntarily recalling 27 lots of Tirosint-SOL (levothyroxine sodium) oral solution 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% of its labeled amount in levothyroxine sodium (T4) for some lots. This recall does not apply to Tirosint (levothyroxine sodium) capsules.

Tirosint-SOL oral solution is a clear, colorless to slightly yellow solution supplied in a 1 mL white, nontransparent, unit-dose ampule. The dosage strength is identified on the box and the pouch and is associated with a distinct color. Each ampule bears a colored label with the dosage strength and the product name (Tirosint-SOL). For full prescribing information, visit **[TirosintSOL.com](https://www.TirosintSOL.com)**.

What this means to you:

Patients being treated for hypothyroidism (underactive thyroid), who receive subpotent Tirosint-SOL, may experience signs and symptoms of hypothyroidism (underactive thyroid), 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 older patients, should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product. To date, IBSA Pharma has not received any reports of adverse events that have been determined to be related to this voluntary recall.

Tirosint-SOL is indicated for:

- Hypothyroidism - As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism.
- Pituitary thyrotropin (thyroid-stimulating hormone, TSH) suppression - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent, well-differentiated thyroid cancer.

IBSA Pharma is proactively notifying its wholesalers, retailers and health care providers to discontinue distribution of the product being recalled and is arranging for the return of all recalled products.

Patients who are currently taking Tirosint-SOL should not discontinue use without contacting their health care provider for further guidance and/or replacement prescription.

Consumers and health care providers with questions regarding this recall can contact IBSA Pharma by phone at **800.587.3513**, Monday–Friday, 9 a.m.–7 p.m. Eastern Standard Time (EST), or by email at **MedInfo@IBSAPharma.com**. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.