Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-011-CG
February 2, 2023

FDA announced that IBSA Pharma Inc. 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 95.0% of its labeled amount in levothyroxine sodium (T4) for some lots.

RECOMMENDATIONS

1. IBSA Pharma Inc. is proactively notifying its wholesalers, retailers and healthcare 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 healthcare provider for further guidance and/or replacement prescription.

2. Consumers and healthcare providers with questions regarding this recall can contact IBSA Pharma Inc. by phone number at 1-800-587-3513 Monday through Friday between the hours of 9:00 am to 7:00 pm (EST), or by e-mail at medinfo@ibsapharma.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

3. Wholesalers and retailers with questions regarding this recall can contact IBSA Pharma Inc. by phone number 855-224-0231 Monday through Friday between the hours of 8:00 am to 5:00 pm (CST), or by e-mail at IBSACS@Eversana.com.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
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IBSA Pharma Inc. Issues Voluntary Nationwide Recall of Select Lots of TIROSINT-SOL (levothyroxine sodium) Oral Solution Due to Subpotency

Summary:

Company Announcement Date:	January 31, 2023
FDA Publish Date:	February 01, 2023
Product Type:	Drugs
Reason for Announcement:	Subpotency
Company Name:	IBSA Pharma Inc.
Brand Name:	IBSA
Product Description:	TIROSINT-SOL (levothyroxine sodium)

Company Announcement

IBSA Pharma Inc. 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 95.0% of its labeled amount in levothyroxine sodium (T4) for some lots.

This recall does not apply to TIROSINT (levothyroxine sodium) capsules.

Risk Statement: 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 elderly patients, should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. To date, IBSA Pharma Inc. has not received any reports of adverse events that have been determined to be related to this voluntary recall.

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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.

TIROSINT-SOL oral solution is a clear, colorless to slightly yellow solution supplied in a 1 mL white, non-transparent, 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).

The product description, NDC numbers, lot numbers, and expiration dates of affected TIROSINT-SOL lots are shown in the table below, and photos of the products can be found at the end of this press release.

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

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Product Description	NDC	Lot Number	Expiration Date
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

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Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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