COMMUNICATION

COM-2023-006

03
FEBRUARY
2023

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

02/01/2023

Drug Information:

National Drug Code

Refer to the second page of this notification.

Product Description

TIROSINT™-SOL
(LEVOTHYROXINE SODIUM)

Batch Number

Refer to the second page of this notification.

Expiration Date

Refer to the second page of this notification.

Company:

IBSA PHARMA INC.

QUESTIONS

Call IBSA PHARMA INC. at 1.800.587.3513 Monday – Friday from 9:00 a.m. to 7:00 p.m. ET.

Tirosint™-Sol Oral Solution

It is for this reason that we are notifying you that on 02.01.2023 the US Food and Drug Administration published a drug recall for the following product(s): Tirosint™-Sol (levothyroxine sodium) oral solution.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

IBSA Pharma Inc. is voluntarily recalling 27 lots of Tirosint™-Sol (levothyroxine sodium) oral solution to the consumer level.

The recall is due to these lots potentially being subpotent. The company's analyses show a slight decrease below 95% of its labeled amount in levothyroxine sodium (T4) for some lots. Patients who are being treated for hypothyroidism (underactive thyroid) with subpotent Tirosint™-Sol may experience signs and symptoms of hypothyroidism. These 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.

To date, IBSA Pharma Inc. has not received any reports of adverse events that have been determined to be related to this voluntary recall. The company is proactively notifying its wholesalers, retailers, and healthcare providers to discontinue distribution and is arranging for the return of all recalled products.

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

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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Pharmacy Benefit Management
Expires 12/01/2025

REFERENCES:

1. U.S. Food and Drug Administration. (2023). IBSA Pharma Inc. Issues Voluntary Nationwide Recall of Select Lots of TIROSINT-SOL (levothyroxine sodium) Oral Solution Due to Subpotency. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/ibsa-pharma-inc-issues-voluntary-nationwide-recall-select-lots-tirosintr-sol-levothyroxine-sodium
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda