



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 30 January 2020

EL (20)A/04

Our Ref: MDR 068-12/19

Dear Healthcare Professional,

Wockhardt UK Ltd

Levothyroxine 100micrograms/5ml Oral Solution

PL 29831/0495

Batch Number	Expiry Date	Pack Size	First Distributed
I53481	31/03/2020	1 x 100ml	15/04/2019
I54522	31/05/2021	1 x 100ml	03/10/2019

Active Pharmaceutical Ingredient: levothyroxine sodium

Wockhardt UK Ltd is recalling specific batches of the above products from pharmacies and wholesalers as a precautionary measure due to notification of the impurity liothyronine exceeding the specification limit. Liothyronine is a degradant of Levothyroxine and can be used to treat the same conditions but with a faster onset and considered to be more potent than levothyroxine. This potency difference will result in different pharmacodynamic effects for patients.

Advice for healthcare professionals

- Stop supplying the above products immediately. Quarantine all remaining stock and return it to your original supplier using your supplier's approved process.

Further Information

Liothyronine is a breakdown product that is present in Levothyroxine formulations. Liothyronine, the synthetic form of the natural thyroid hormone tri-iodothyronine, can itself be used to treat an underactive thyroid but is generally reserved to treat more severe forms of the condition. This is because liothyronine has a faster onset of action and is also more potent than levothyroxine. These differences in action mean there is a higher risk of adverse effects with increasing liothyronine content and is why this is controlled within strict limits within levothyroxine preparations.



Company contacts for further information

For medical Information enquiries, please contact Medical Information on 01978 661261 or email drug.safety@wockhardt.co.uk.

For enquiries relating to stock returns please contact Wockhardt UK Ltd Customer Services on 01978 661261 or email customer.services@wockhardt.co.uk.

- Levothyroxine 100micrograms/5ml Oral Solution - PL 29831/0495 - PIP code: 123-0051

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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