Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 29 January 2020 EL (20)A/03 Our Ref: MDR 141-01/20

Dear Healthcare Professional,

Dr. Reddy's Laboratories (UK) Ltd

Finasteride 5mg Tablets PL 08553/0261

Batch Number	Expiry Date	Pack Size	First Distributed
C706092	Nov 2020	28	21 Feb 2018
C706093	Nov 2020	28	21 Feb 2018
C706094	Nov 2020	28	19 Mar 2018
C706095	Nov 2020	28	01 May 2018
C800262	Dec 2020	28	19 Mar 2018
C800263	Dec 2020	28	19 Mar 2018
C800264	Dec 2020	28	19 Mar 2018
C800483	Dec 2020	28	01 May 2018
C800484	Dec 2020	28	19 Mar 2018
C800485	Dec 2020	28	01 May 2018
C800486	Dec 2020	28	06 Apr 2018
C800506	Jan 2021	28	10 May 2018
C800507	Dec 2020	28	06 Apr 2018
C800508	Dec 2020	28	10 May 2018
C800509	Jan 2021	28	10 May 2018
C800510	Jan 2021	28	01 May 2018
C804932	Jun 2021	28	20 Sep 2018
C804933	Jun 2021	28	20 Sep 2018
C804934	Jun 2021	28	10 Oct 2018
C804935	Jun 2021	28	20 Sep 2018
C804936	Jun 2021	28	20 Sep 2018
C804937	Jun 2021	28	20 Sep 2018
C804938	Jun 2021	28	20 Sep 2018
C804939	Jun 2021	28	16 Oct 2018
C804940	Jun 2021	28	31 Oct 2018
C804941	Jun 2021	28	31 Oct 2018
C806744	Oct 2021	28	18 Mar 2019
C806745	Oct 2021	28	18 Mar 2019
C806746	Oct 2021	28	18 Mar 2019
C806747	Oct 2021	28	18 Mar 2019

Brief description of the problem
Dr. Reddy's Laboratories (UK) Ltd has informed us that the Patient Information Leaflet (PIL) for the above batches is missing the special warning and precautions identified from post-marketing experience that are documented in the Summary of Product Characteristics (SmPC). The change concerns the addition of the following in Section 4.4 Special warnings and precautions for use:

- **Mood alterations and depression:** Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 5 mg. Patients should be monitored for psychiatric symptoms and if these occur, the patient should be advised to seek medical advice.

It is important that any patients who notice the symptoms seek immediate medical advice.

Advice for healthcare professionals

When dispensing this product, please check the Marketing Authorisation Holder and the batch number; if any of the above batch numbers are being dispensed, ensure that patients are aware of any missing information. The current SmPC includes the special warning and precautions:

https://www.medicines.org.uk/emc/product/3493/smpc

Further Information
For more information or medical information queries, please contact:
Dr. Reddy's Laboratories (UK) Ltd Medical Information Department on +44 (0)1748 828873 and DrReddys@professionalinformation.co.uk.

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 community pharmacists and dispensing general practitioners for information.

Yours faithfully

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