



DRUG ALERT

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy and Wholesaler Level Recall

Date: 31 July 2017

EL (17) A/07

Our Ref: MDR 33-07/17

Dear Healthcare Professional,

Torrent Pharma (UK) Ltd

Dutor 20mg Gastro-resistant Capsules, Hard	PL 36687/0185
Dutor 30mg Gastro-resistant Capsules, Hard	PL 36687/0186
Dutor 40mg Gastro-resistant Capsules, Hard	PL 36687/0187
Dutor 60mg Gastro-resistant Capsules, Hard	PL 36687/0188

(Duloxetine)

Strength	Batch Number	Expiry Date	Pack Size	First Distribution
20 mg	BAC5C001	31 Oct 2017	1 x 56	Jun 2016
20 mg	BAC5C002	31 Jul 2018	1 x 28	Jan 2017
20 mg	BAC5C005	31 Aug 2018	1 x 28	Feb 2017
30mg	BAC3C001	31 Oct 2017	1 x 28	Sep 2016
30mg	BAC3C002	31 Oct 2017	1 x 28	Jun 2016
30mg	BAC3C007	31 Aug 2018	1 x 28	Feb 2017
40mg	BAC4C001	31 Oct 2017	1 x 56	Jun 2016
40mg	BAC4C004	31 Aug 2018	1 x 56	Jan 2017
60mg	BAC6C001	31 Oct 2017	1 x 28	Jun 2016
60mg	BAC6C003	31 Jul 2018	1 x 28	May 2017

Torrent Pharma (UK) Ltd is recalling the above batches as a precaution because out of specification results for dissolution were obtained during routine stability testing.

Remaining stock of these batches should be quarantined and returned to the original supplier for credit.

For stock enquiries, please contact Lee Ford on 01293 574184, email: lee.ford@torrentpharma.co.uk

For medical information enquiries, please contact Josephine Ayella on 01293 574183, email: josephine.ayella@torrentpharma.co.uk



Medicines & Healthcare products
Regulatory Agency



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Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional teams: please cascade to relevant clinics, general practitioners and community pharmacies.

Yours faithfully

Alison Bunce

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