

06/02/2019

Ranitidine 150mg Film-coated Tablets (PL 20075 / 0063), MAH: Accord Healthcare Limited, United Kingdom (06 x 10 tablets): Batch number and expiry date prompts 'LOT' and 'EXP' printed in German on outer (carton) packaging.

Dear Healthcare Professional,

Accord Healthcare Limited, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

- Batches of Ranitidine Tablets 150mg (PL 20075/0063) on the market in the UK have been found to have the batch number and expiry date prompts printed on the carton in German as "Ch. – B" & "Verwendbar bis" instead of "LOT." & "EXP" (see Annex 1 for the list of 31 batches that have been released onto UK market).
- The batch numbers and expiry dates provided on the packaging are correct, and the prompts appear in English on the primary (blister) packs.
- All the batches have been manufactured in accordance with Good Manufacturing Practice requirements and, with exception of the print error on the carton, comply with the terms of the Manufacturing Authorisation.
- The print error on the carton is not anticipated to pose a risk to usability or traceability of product.
- Patients should be reassured that this is an approved UK product at time of dispensing or in case of any queries.

Company contact point

The print error is on the carton only and has no impact on the quality, safety and efficacy of the product. However, for any queries please contact Accord Healthcare Medical Information Department at:

Phone: +44 (0) 1271 385 336 Option 1

Email: medinfo@accord-healthcare.com

Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, UK

Tel: +44 208 863 1427

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Card website – <https://yellowcard.mhra.gov.uk/> or via the Yellow Card app available from the Apple App store or Google Play Store.

Yours Faithfully,

Nilesh Parmer

Vice President – Quality and Qualified Person
Accord Healthcare Limited, UK (MAH)

Enclosures: Annex 1: Batch Details

Annex – 1 Batch details - Ranitidine 150mg Tablets

Sr. No.	Product Name	Batch No.	Mfg. Date	Expiry Date	Quantity involved (in packs)
1	Ranitidine 150mg Tablets	X04380	Mar-18	Feb-21	32729
2	Ranitidine 150mg Tablets	X06035	Mar-18	Feb-21	32778
3	Ranitidine 150mg Tablets	X06050	Mar-18	Feb-21	32702
4	Ranitidine 150mg Tablets	X07018	Apr-18	Mar-21	33024
5	Ranitidine 150mg Tablets	X07114	Apr-18	Mar-21	46261
6	Ranitidine 150mg Tablets	X07323	Apr-18	Mar-21	32999
7	Ranitidine 150mg Tablets	X06046	Mar-18	Feb-21	32615
8	Ranitidine 150mg Tablets	X07894	May-18	Apr-21	40138
9	Ranitidine 150mg Tablets	X07901	May-18	Apr-21	33007
10	Ranitidine 150mg Tablets	X08709	May-18	Apr-21	7985
11	Ranitidine 150mg Tablets	X08711	May-18	Apr-21	33043
12	Ranitidine 150mg Tablets	X08717	May-18	Apr-21	32959
13	Ranitidine 150mg Tablets	X08946	May-18	Apr-21	32823
14	Ranitidine 150mg Tablets	X08947	May-18	Apr-21	32670
15	Ranitidine 150mg Tablets	X09053	May-18	Apr-21	32799
16	Ranitidine 150mg Tablets	X09080	May-18	Apr-21	32856
17	Ranitidine 150mg Tablets	X09367	May-18	Apr-21	32768
18	Ranitidine 150mg Tablets	X09413	May-18	Apr-21	32755
19	Ranitidine 150mg Tablets	X09417	May-18	Apr-21	32972
20	Ranitidine 150mg Tablets	X09418	May-18	Apr-21	32823
21	Ranitidine 150mg Tablets	X09483	May-18	Apr-21	32821
22	Ranitidine 150mg Tablets	X09677	Apr-18	Mar-21	33108
23	Ranitidine 150mg Tablets	X09702	Apr-18	Mar-21	33063
24	Ranitidine 150mg Tablets	X09805	Apr-18	Mar-21	33096
25	Ranitidine 150mg Tablets	X09957	Apr-18	Mar-21	32988
26	Ranitidine 150mg Tablets	X10123	Apr-18	Mar-21	33147
27	Ranitidine 150mg Tablets	X10280	May-18	Apr-21	8801
28	Ranitidine 150mg Tablets	X11042	May-18	Apr-21	32576
29	Ranitidine 150mg Tablets	X13150	Jul-18	Jun-21	32788
30	Ranitidine 150mg Tablets	X13199	Jul-18	Jun-21	20800
31	Ranitidine 150mg Tablets	X13200	Jul-18	Jun-21	32988