

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action within 48 Hours

Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

Kent Pharmaceuticals Ltd

Betahistine dihydrochloride 8mg Tablets
Betahistine dihydrochloride 16mg Tablets

PL 30464/0019
PL 30464/0020

Product	Batch Number	Expiry Date	Pack Size	First Distributed
Betahistine dihydrochloride 8mg Tablets	EC10619	01/10/2022	84	21/10/2020
	EC10719	01/10/2022	84	09/09/2020
	EC10819	01/10/2022	84	04/05/2020
Betahistine dihydrochloride 16mg Tablets	GY11119	01/10/2022	84	21/04/2020
	GY11219	01/10/2022	84	05/05/2020
	GY11319	01/10/2022	84	23/09/2020

Active Pharmaceutical Ingredient: betahistine dihydrochloride

Brief description of the problem

Kent Pharma has informed us that the affected batches above are contaminated with theophylline due to a cross-contamination issue identified with an excipient that was used in the manufacture of the finished product. Therefore, a decision has been taken to recall the affected batches.

Advice for healthcare professionals

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



Advice for patients

The risk of adverse reactions is low with respect to the level of contamination. However, if patients experience any side effects related to hypersensitivity or those not normally experienced with betahistine, please ensure appropriate clinical advice is sought. Any suspected side effects should also be reported via the [Yellow Card Scheme](#)

Further Information

For stock control enquiries please contact customer.service@kent-athlone.com

For more information or medical information medical@kent-athlone.com

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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

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BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

26th November 2020

Pharmaceutical website: <http://www.hscbusiness.hscni.net>