



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesaler Level

Date: 26 November 2020

EL (20)A/55

Our Ref: MDR 133-11/20

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 Pharmaceuticals Ltd 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 letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574**