



MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 03 February 2021

EL (21)A/01

Our Ref: MDR 349-01/21

Dear Healthcare Professional,

Intrapharm Laboratories Ltd

Kolanticon Gel 500ml

PL 17509/0084

Batch Number	Expiry Date	Pack Size	First Distributed
AC0620	31/12/2021	1 x 500ml	23/11/2020

Active Pharmaceutical Ingredients: dicycloverine hydrochloride, aluminium hydroxide, light magnesium oxide, simethicone

Brief description of the problem

Intrapharm Laboratories Ltd has received a number of complaints that the product consistency is lumpy. The investigation has confirmed through review of the retained samples that the consistency of the complaint samples are similar and the retained samples for this batch show the same homogeneity issue.

Advice for healthcare professionals

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

Further Information

For more information or medical information queries, please contact: medinfo@intrapharmlabs.com or telephone +44 (0)330 1359 437.

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

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

Yours faithfully

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