Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy Level

Date: 09 November 2020 EL (20)A/51 Our Ref: MDR 011-11/20

Dear Healthcare Professional,

Intrapharm Laboratories Ltd

Kolanticon Gel 200ml PL 17509/0084

Batch Number	Expiry Date	Pack Size	First Distributed
AA0620	31/12/2021	1 x 200ml	04 Sep 2020

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

Brief description of the problem
Intrapharm Laboratories Ltd has informed us that there is a difference in dosage instructions between the carton and label. The Patient Information Leaflet (PIL) and bottle label contain the correct instructions.

The carton instructions for dosing read as follows:

- 'Dosage: For Oral use. Two to four 6ml spoonfuls every four hours as required….'

The correct instructions should be:

- 'Dosage: For Oral use. 'Two to four 5ml spoonfuls every four hours as required….'

It was confirmed that the carton with the incorrect dosage instructions had been used to pack only one batch, AA0620. This batch is not being recalled based on a medical risk assessment and consideration that if the maximum daily dosage is taken then an additional 24ml may get consumed in 24 hours. A further consideration is that the standard dosing measurement for a medicine spoon is 5ml; there is no 6ml medicine spoon available. The assessment concluded low risk to patient safety or overdose as a consequence of this dosage instruction error.

Advice for healthcare professionals

- When dispensing or providing this product, please check the Marketing Authorisation Holder and the batch number and ensure that patients are aware of the correct dosing instructions as stated in the PIL and on the bottle label.

In the event that the maximum recommended daily dose is exceeded, the adverse effects expected are likely to be non-serious and may include dry mouth, blurred vision and urinary retention. However, the drug is rapidly cleared by the kidneys and has a half-life of 1.8 hours, so any potential adverse effects are quickly reversed on discontinuation.

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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