

Date: 29 March 2023

URGENT MEDICINE RECALL – CLASS II TYPE B

Dear Customer/Healthcare Professional

iNova Pharmaceuticals (Pty) Ltd, in consultation with the South African Health Products Regulatory Authority (SAHPRA) is taking a decision to recall and withdraw the following products from the market based on the safety findings outlined below:

Product name	Registration number	Active Ingredient(s) per 5 ml	Batch numbers	Pack size
Pholtex Junior	29/10.1/0013	Pholcodine 5 mg	All batches	100 ml 200 ml
Pholtex Forte	32/10.1/0116	Pholcodine 15 mg	All batches	100 ml 200 ml
Pholtex Plus	46/16.5/0711	Pholcodine 5 mg; Phenylephrine HCl 3,3 mg	All batches	100 ml 200 ml

The decision to recall pholcodine containing medicines is linked to a recently concluded French clinical study (the ALPHO Study) which reviewed a possible association between pholcodine and very rare but serious anaphylactic reactions to medicines called neuromuscular blocking agents (NMBAs) used in anaesthesia.

Data from the ALPHO study indicates that the use of pholcodine in the 12 months leading up to anaesthesia using NMBAs increases the risk of developing an anaphylactic reaction. The relationship between pholcodine and anaphylactic reactions to NMBAs has been hypothesised over the last decade, however, until the ALPHO study no association had previously been established in any clinical study globally. There is still no evidence showing causal risk.

Based on the available data, there are currently no possible effective risk minimization measures which have been identified to mitigate against this risk, nor to identify a patient population for whom the benefits of pholcodine outweigh the risks.

Due to these considerations and the nature of the adverse reactions (including its unpredictability and clear timelines to onset), SAHPRA has recommended the withdrawal of all pholcodine-containing medicines from the South African market.

Actions to be taken by customers/Healthcare professionals

- Distribution and sale of the above-mentioned products should be ceased immediately.
- Please return all batches of Pholtex Junior, Pholtex Forte and Pholtex Plus to your wholesaler/distributor.
- We request that you retain this letter and place it in a prominent position for one month in case stock is in transit.

Yours Sincerely,



Kristin Holmes

Responsible Pharmacist

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