HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

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IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

6th December 2022

European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) recommends that pholcodine-containing medicinal products are no longer marketed

Dear Pharmacist,

The HPRA wishes to inform you that the European Medicines Agency's Pharmacovigilance Risk Committee (PRAC) has recommended that the marketing authorisations for all **pholcodine-containing medicinal products** be withdrawn so that these medicines can no longer be marketed in the EU. This follows a review by PRAC which concluded there is a link between pholcodine use within the previous 12 months preceding general anaesthesia where neuromuscular blocking agents (NMBAs) are administered and a risk of anaphylactic reaction to NMBAs.

The PRAC could not identify effective measures that would sufficiently reduce this risk in patients exposed to pholcodine-containing medicinal products. Pholcodine is authorised for use in the symptomatic treatment of non-serious and self-limiting conditions, and as a patient population could not be identified for whom the benefits of pholcodine outweigh its risks, the PRAC recommended that pholcodine-containing medicinal products should be withdrawn from the European Union market.

The PRAC recommendation is not the final step in the regulatory process. The recommendation will now be sent to the EUs Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a position. The marketing authorisations for pholcodine-containing products remain valid until that time.

However, the HPRA wishes to highlight the current PRAC recommendation to withdraw the marketing authorisations and to provide the following advice to pharmacists pending finalisation of the regulatory process.

- **Day Nurse Capsules (Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg Pholcodine 5mg),** indicated for the relief of the major symptoms of colds and influenza for 16 year olds and over, are currently the only pholcodine- containing medicinal product marketed in Ireland.

- In preparation for the upcoming unavailability of pholcodine containing medicinal products, pharmacists can advise patients of the available alternatives for the treatment of the symptoms of cold and flu, including cough.

- If a patient has taken pholcodine and has concerns, they can be informed that a recent study has shown that use of pholcodine-containing medicines is linked to a risk of serious allergic reactions to muscle relaxant medicines that are used during general anaesthesia. If due to undergo anaesthesia (such as for surgery), patients can inform their healthcare professional (anaesthesiologist) that they have taken pholcodine in the past 12 months and discuss any questions they may have with them.

- Further communication will follow in the coming days with instructions for a pharmacy level recall of **Day Nurse Capsules (Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg Pholcodine 5mg).**

The HPRA continues its oversight of this issue at both national and European level. Further information is available on www.ema.europa.eu

Should you have any further queries please send these to medsafety@hpra.ie

Yours sincerely,

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