PINEWOOD
HEALTHCARE
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1st November 2024

Pinewood Laboratories Limited
Ballymacarbry, Clonmel
Co Tipperary
Ireland

Important information for healthcare professionals

Change in legal status of Codinex 150 ml pack size to Prescription Only Medicine

Codeine phosphate
Codinex Codeine Phosphate 15 mg/5 ml Oral Solution
PA0281/005/001

Dear Healthcare Professional,

Pinewood Laboratories Limited would like to inform you of the following:

Codinex Codeine Phosphate 15 mg/5 ml Oral Solution **150 ml pack** is to be reclassified from a non-prescription to a **Prescription Only Medicine (POM)** due to concerns relating to the risk of misuse and abuse**.** This reclassification will be implemented on the 3rd December 2024. From this date, the 150 ml pack must only be dispensed with a medical prescription and must no longer be supplied as an over the counter (OTC) product.

As a result, the 150 ml pack carton and label will be updated to remove detailed instructions for dosage, and instead state 'Dosage: as directed by physician'. It will also include serialisation in accordance with the Falsified Medicines Directive.

As product manufactured and available on the Irish market before the 3rd December 2024 will be packaged in OTC labelling and will not be serialised, pharmacists will be unable to scan this stock when dispensing. This is an interim measure. All product manufactured after this date will be serialised, facilitating scanning under FMD legislation. This serialised stock will be available to the market from early 2025.

In addition to the above-mentioned changes, section 4.1 of the SmPC and sections 2 and 3 of the PIL have been updated to clarify a maximum daily dose of 30 mls in any 24 hours, and that treatment should not exceed 3 days without medical advice.

Of note, Codinex Codeine Phosphate 15 mg/5 ml Oral Solution 100 ml pack will continue to be classified as a non-prescription medicine.

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated to all relevant parties.

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance using the report form on the HPRA website, www.hpra.ie.

Adverse events should also be reported to Drug.Safety@pinewood.ie.

If you have any questions, please contact
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Yours faithfully,

Jeffrey Walsh

Head of Sales, Retail Division