



## Direct Healthcare Professional Communication

4th October 2021

### **Chlorpromazine Elixir BP 25mg/5ml Oral Solution : Indications for the management of anxiety and tension states, agitation, depression, behavioural disturbances and subnormality.**

Dear Healthcare Professional,

Pinewood Healthcare, would like to update you on the return of Chlorpromazine our licensed product (PA0281/124/001). The estimated supply date is now the end of January 22, stability data of 3 months has been established and the variation submission will be submitted during the month of October 21 in relation to the change in the cap. In the interim period, the unlicensed product will continue to be made available, this will assist you in delivering continuity to your patients.

Highlighted below are three differentiations between both the Unlicensed and the Licensed version.

The unlicensed product contains Sunset Yellow E110 and is sucrose free, and it is packed in a 150ml bottle. The licensed product contains Tartrazine and sucrose and is packed in a 1Ltr bottle.

For further information a summary of the product characteristics (SmPC) can be obtained by following the link below.

<https://www.medicines.org.uk/emc/product/4558/smpc#gref>

In the event of any adverse reactions please see below.

#### Call for reporting

Healthcare Professionals are asked to report any suspected adverse reactions via HPRA, Pharmacovigilance, Earlfort Terrace, IRL Dublin 2 ;

Tel : +353 1 6764971 ; Fax : + 353 1 6762517

Website : [www.hpra.ie](http://www.hpra.ie) ; email : [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates and product brand name.

#### Company contact point

Address : Pinewood Healthcare, Ballymacarbry, Clonmel, Co Tipperary.

Tel : +353 (0)52 6186000



*Annexes*

[https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC\\_PA0281-124-001\\_06122017152037.pdf](https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA0281-124-001_06122017152037.pdf)

<https://www.medicines.org.uk/emc/product/4558/smpc#gref>

Kind Regards,

Jeffrey Walsh,

Head of Sales Pinewood Healthcare.

---