



# URGENT PRODUCT DEFECT ALERT

## **Ospolot® (sulthiame) Tablets 200 mg Bottle** **Product Code: TAB003**

Batch numbers 18003717 & 28811

Expiry date: 5/2021 & 11/2022 AUST R 18848

Phebra Pty Ltd, following consultation with the Therapeutic Goods Administration, is alerting consumers that the current closure system of TAB003 Ospolot (sulthiame) Tablets 200 mg does not meet all the child-resistant packaging requirements for medicines (TGO95). A child-resistant closure system is still in place. Evidence from studies has shown that the majority of children could not open the bottle.

If you have a bottle of Ospolot (sulthiame) Tablets 200 mg from batch 18003717 & 28811, please exercise extra vigilance and caution when storing the medicine. As per the product label information it is imperative that you keep the medicine out of reach of children.

Ospolot (sulthiame) Tablets 200 mg is used as an anticonvulsant for behavioural disorders associated with epilepsy; hyperkinetic behaviour; temporal lobe epilepsy; myoclonic seizures; grand mal attacks; Jacksonian seizures. Should a child have unsupervised access to the Ospolot 200mg tablet bottle and gain access to the medicine, a potentially life threatening health risk is present.

Phebra Pty Ltd sincerely regrets any inconvenience to their customers.

**Phebra Medical Information Manager: (02) 9420 9199**