

## Shortage of Epistatus® 10mg/1ml pre-filled oral syringe

### **Description of product affected**

Epistatus® 10mg/1ml pre-filled oral syringe (midazolam 10mg), manufactured by Veriton Pharma Ltd.

### **Background to shortage**

Veriton Pharma Ltd. have confirmed a batch release issue with Epistatus® 10mg/1ml pre-filled oral syringe and do not currently have any stock of this product. This is a temporary shortage, however the manufacturer is unable to confirm a date for when normal supply will resume.

### **Background**

Therapeutic indications - Epistatus® is indicated for the treatment of prolonged, acute, convulsive seizures in children and adolescents aged 10 to less than 18 years. Epistatus® must only be used by parents / caregivers where the patient has been diagnosed to have epilepsy: [Epistatus 10 mg Oromucosal Solution - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

Epistatus® is available as two preparations – a multidose 5ml bottle (10mg in 1ml) and pre-filled syringes (2.5mg, 5mg, 7.5mg and 10mg doses). The **Epistatus® 10mg/1ml strength (pre-filled syringe) is licensed** and is the most commonly prescribed strength, including for off-label use in children under 10 years or adults above 18 years of age. **Epistatus® multidose 5ml bottle and Epistatus® 2.5mg, 5mg, 7.5mg pre-filled syringes remain unlicensed.**

The other licensed buccal midazolam product is Buccolam®. This is twice the volume per mg dose compared to Epistatus® and hence there are training requirements when switching from Epistatus® to Buccolam® as the products are not interchangeable.

### **Recommended alternatives until shortage resolves**

**First choice** would be use of the unlicensed Epistatus® 2.5mg, 5mg, 7.5mg pre-filled syringes. These are available as: 2.5mg (in 0.25ml) 5mg (in 0.5ml) 7.5mg (in 0.75ml). The volume administered for a particular dose will remain the same as for the 10mg in 1ml syringe. Using a pre-filled syringe is the preferred option as there is no requirement to draw up the dose.

**Second choice** would be use of the unlicensed Epistatus® multidose 5ml bottle (10mg in 1ml). The dose would need to be drawn up, hence the individual carrying out administration would need to be deemed competent in doing this.

Please note that GPs will need to be contacted in order to discuss prescribing the alternative unlicensed preparation until the shortage resolves. The unlicensed product should not be put on a repeat template.

If you have any queries please contact the Epilepsy Specialist Nurses for advice: Tel: 01442 453017

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