



Safeguarding public health  
Defective Medicines Report Centre  
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## DRUG ALERT

CLASS 4 CAUTION IN USE

**Additional information following our alerts EL(12)A/08 issued on 28 February 2012,  
EL(12)A/10 issued on 6 March 2012 and EL(12)A/16 issued on 24 April 2012**

**For distribution to hospitals, clinics, wholesalers, GPs and Community Pharmacists**

Date: 23 August 2012

EL(12)A/26

Our Ref: MDR 08-02/12

Dear Healthcare Professional,

### **Special Products Ltd**

**Epistatus, Midazolam 10mg in 1ml Buccal Liquid x 5ml (M11) – unlicensed medicine  
made under Manufacturers Specials licence MS 123.**

As mentioned in our previous alert, EL(12)A/16, Special Products Ltd have now made a final change to the syringe, within the Epistatus packs, to one without a luer tip. The packs containing the new syringe will be distributed from September 2012.

The modifications to the Epistatus packs will be as follows:

- Removal of the luer tip from the syringe
- New bottle adaptor compatible with the syringe without a luer tip

The syringe will be graduated to 1.0ml with a plunger stop at the 1.0ml position. The packs containing this new syringe and dosing adaptor will be identifiable via yellow and black flashing on the carton stating “This pack contains 1ml syringes without luer tip.” This is expected to complete the final change to this product..

It should be noted that Epistatus packs containing the previous versions of the syringes referenced in EL(12)A/08, EL(12)A/10 and EL(12)A/16 will remain within the distribution chain until stock is exhausted.

Contd/...

#### **MHRA Distribution:**

Regional Contacts for NHS Trusts and Provider Units

Chief Pharmacists: England, Scotland, Wales, Northern Ireland

Prison Health Policy Unit (DH)

Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar

Special Hospitals

Healthcare Commission for distribution to Independent Health Care Establishments

Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency (MHRA)

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An executive agency of the Department of Health



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As previously stated Special Products Ltd have requested that all patients are informed that they should use the syringe graduations and not rely on the plunger stop irrespective of the batch number(s) as this is considered good clinical practice.

For Special Products Ltd Medical Information enquiries, please telephone 01932 690325.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to forward this letter to relevant clinics, General Practitioners and Community Pharmacists.

Yours faithfully

Ian Holloway

MHRA DMRC Manager