



Issue Date:1st December 2017

SAFETY ALERT NOTICE.

Buccolam (midazolam) prefilled syringes – all formulations.

Identified Issue / Concern / Problem/ Evidence of harm.

Shire Services the manufacturer of Buccolam Prefilled syringes has informed NAS/DFB of a potential product defect.

In a small number of cases, the translucent tip-cap has remained on the syringe tip when pulling the red cap off.

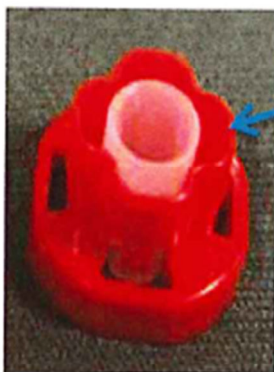
If the translucent tip cap remains on the syringe tip it will prevent the administration of BUCCOLAM.

Actions Required / Risk Treatment strategy

When administering BUCCOLAM, check that translucent cap has been removed with red cap.

If the cap has not been removed, remove it manually.

Please report any occurrence of this hazard with batch number through normal pathway.



Translucent tip-cap

Issued by: Drugs and Therapeutics Committee.