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Defect with Buccolam oral syringes

Translucent cap may remain attached to syringe – parents and carers advised to inspect the syringe before use

A defect has been reported with Buccolam plastic syringes, and parents and carers should carefully inspect the syringes before giving the medicine to children.

Buccolam is an epilepsy medicine for children, which is available as pre-filled oral syringes. Parents or carers giving Buccolam should take the syringe out of the package, pull off the red cap and give the medicine in the side of the child's mouth when the child is having an epileptic seizure (fit).

There have been a few cases where the red cap did not come off completely and a translucent tip-cap remained on the syringe, stopping the medicine from leaving the syringe. This has in some cases resulted in the tip-cap coming off inside the patient's mouth and being inhaled or ingested.

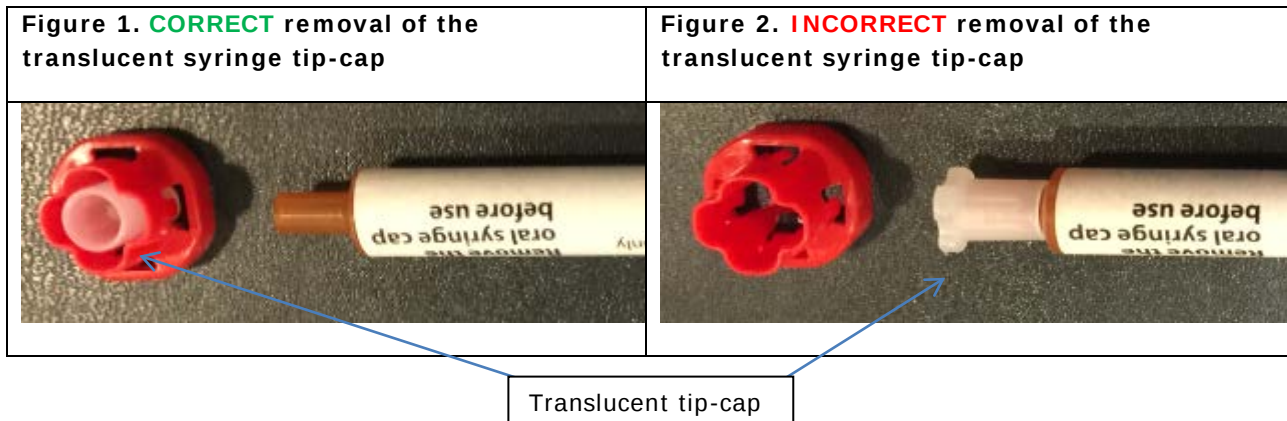
To make sure that the medicine is given correctly and safely, EMA is advising parents and carers to carefully check the syringe before giving Buccolam and to remove the translucent tip-cap if it is still on the syringe after the red cap has been pulled off.

A letter will be sent to all doctors and pharmacists who prescribe and dispense Buccolam, to alert them of this defect and encourage them to share this information with parents and carers of children who are using Buccolam. Practical advice and instructions will also be supplied to parents and carers who are, or have been, dispensed Buccolam.

The company that markets Buccolam is working to resolve this issue for new syringes. However, syringes already on the market in the EU and possibly already dispensed to patients need to be carefully checked before use.

Information for parents and carers

- When giving Buccolam, parents and carers of children with epilepsy should follow the instructions in the package leaflet.
- As an additional step, parents and carers should carefully check that the red cap has been pulled off completely and that the inner translucent tip-cap has come off with the red cap (see Figure 1), and does not remain on the syringe tip (see Figure 2):



- If the translucent tip-cap remains on the syringe tip, parents and carers should pull it off before giving the medicine to the child.
- If the tip-cap is left on the syringe, it will prevent the medicine from coming out, and could also result in the tip-cap ending up in the child's mouth and being accidentally swallowed or inhaled.
- Parents and carers should continue to give Buccolam as advised by the child's doctor.
- Parents and carers who have any questions should speak to their child's doctor or to a pharmacist.

Information for healthcare professionals

- There have been reports of a product defect related to Buccolam plastic pre-filled oral syringes, where the translucent tip-cap remains on the syringe tip when the red cap is pulled off.
- Healthcare professionals that prescribe and dispense Buccolam will receive a letter describing the defect, and highlighting the importance of inspecting the syringe before administering Buccolam. The letter will include an annex with patient/carer instructions for correct administration.
- Healthcare professional should advise parents and carers to check that the translucent tip-cap does not remain on the syringe when pulling off the red cap.
- If the tip-cap is still attached to the syringe, it should be removed before the medicine is given to prevent the tip-cap from coming off into the patient's mouth. Cases have been reported where the tip-cap has been accidentally aspirated or ingested.
- Doctors and pharmacist should share this information with their patients or carers during medical consultations, or dispensing of the product, or at any opportunity for interaction to ensure that they are aware of this issue when handling the product.
- Pharmacists are encouraged to identify patients, parents and caregivers who have been dispensed Buccolam and pass on the information included in the patient/carer instructions.

More about the medicine

Buccolam is a medicine used to stop prolonged, acute (sudden) convulsive seizures (fits) in children and adolescents with epilepsy. Buccolam contains the active substance midazolam and is available as pre-filled syringes containing 2.5 mg, 5 mg, 7.5 mg or 10 mg of midazolam.

More information on Buccolam can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports.