

This information is for parents and carers of a child who has been prescribed BUCCOLAM® (midazolam oromucosal solution)

Key things to know about BUCCOLAM

BUCCOLAM contains a medicine called midazolam. Midazolam belongs to a group of medicines known as benzodiazepines. BUCCOLAM is used to stop a prolonged, acute, convulsive seizure in infants, toddlers, children and adolescents (from 3 months to less than 18 years of age). In infants from 3 to 6 months of age, BUCCOLAM should only be used in a hospital setting where monitoring is possible and resuscitation equipment is available.¹ This medicine may only be used by the parents/carers of patients who have been diagnosed with epilepsy.

BUCCOLAM is an oromucosal solution that is prepacked in boxes containing 4 pre-filled syringes for oral use. Each syringe contains the same dose and is prepacked in a protective plastic cover:

- is colour-coded according to a particular age range
- is needle-free and designed to help you get BUCCOLAM into the area between the cheek and gum
- contains a single dose

Read and carefully follow the doctor's prescription. The prescription is always personal.

Attached to each tube there is a simple, step-by-step BUCCOLAM administration guide. It includes important safety information.

Do not give this medicine to other people to treat their children. Only give BUCCOLAM to the child who it has been prescribed for.

Storage

Store BUCCOLAM out of the reach and sight of children. Store the syringe in the protective plastic cover. Store protected from frost. Do not freeze. Do not store refrigerated. BUCCOLAM 5 mg, 7.5 mg and 10 mg each has a shelf life of 2 years. BUCCOLAM 2.5 mg has a shelf life of 18 months. Do not administer BUCCOLAM after the expiry date (or EXP) stated on the label on the box, cover and syringe. The expiry date refers to the last day of that month.

Special warnings and precautions

Consult your doctor or pharmacist before you administer BUCCOLAM to your child if he/she has an illness that affects the kidneys, liver or heart and/or a lung disease that regularly causes respiratory difficulties. This medicine can cause loss of memory of events that happen after the medicine has been taken. Patients must be carefully monitored after they have been given this medicine. This medicine must not be given to patients who are addicted to/have been addicted to alcohol or narcotics.

Do not give your child BUCCOLAM if he/she:

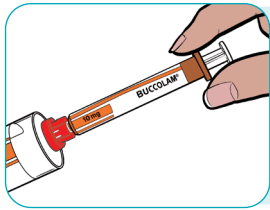
- Is** allergic to midazolam, benzodiazepines (e.g. diazepam) or any other ingredient in this medicine
- Has** a disease in the nerves and muscles that causes muscle weakness
- Has** difficulty breathing when resting (BUCCOLAM can exacerbate respiratory difficulties)
- Has** a disease that causes a large number of respiratory arrests while sleeping
- Has** severe liver problems

1. Buccolam Summary of Product Characteristics. www.fass.se.

◆ There is a risk that habituation may occur.

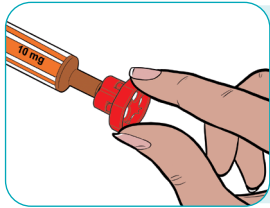
How to give BUCCOLAM (midazolam oromucosal solution)

- Make sure you read the Patient Information Leaflet for BUCCOLAM. There is one inside each pack.
- Check the expiry date before use.
- Do not use if the clear protective plastic tube containing the oral syringe has been previously opened or damaged.



1

Hold the plastic tube, break the seal at one end and pull the cap off. Take the syringe out of the tube.



2

Remove the red cap from the syringe tip and dispose of the cap safely.

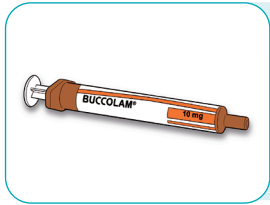


3

Using the finger and thumb gently pinch and pull back the child's cheek. Gently insert the syringe in the space between the inside of the cheek and the lower gum.

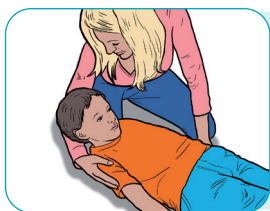
4

Slowly press the syringe plunger until the plunger stops. The full amount of solution should be inserted slowly into the space between the gum and the cheek. If prescribed by your doctor, you can give approximately half the dose slowly into one side of the mouth, then the other half into the other side of the child's mouth.



5

Keep the empty syringe to give to the doctor or paramedic if they have been called. Make a note of the time BUCCOLAM was given and how long the seizure lasted.



6

Stay with them until the seizure is over and they have regained consciousness.

Do not administer more medicine than the doctor has prescribed for the patient.



Call an ambulance immediately if:

- The seizure does not stop within 10 minutes of giving BUCCOLAM
- You cannot administer BUCCOLAM, or cannot give the full dose
- The child's breathing slows down or stops
- The child vomits
- You have administered more BUCCOLAM than you should
- You notice signs of a heart attack

Never administer another dose of BUCCOLAM without consulting a doctor even if:

- The seizure does not stop
- The child vomits or salivates

