



Buccal (oromucosal) midazolam

This information sheet should be read in conjunction with any information provided by the manufacturer.

This fact sheet explains about buccal midazolam, how it is given and some of its possible side effects.

What is midazolam?

Midazolam belongs to a group of medicines called benzodiazepines, which are used to treat a number of different conditions, including seizures. If a seizure lasts for more than five minutes, it may be difficult to stop unless treatment is given. It is therefore important that rapid treatment is given to stop the seizures and therefore prevent status epilepticus.

Status epilepticus is a condition where a person has a seizure (convulsion or fit) or a series of seizures that last for 30 minutes or more, without a complete recovery of consciousness.

Midazolam is chemically related to diazepam, which is another medicine used to treat seizures.

How is it given?

The midazolam solution should be placed against the sides of the gums and cheek so that the medicine is absorbed directly into the bloodstream. This is known as the buccal or oromucosal route. If the medicine is swallowed accidentally, it might not work as quickly.

Buccal midazolam is available as:

- Buccolam® contains Midazolam Hydrochloride 5mg in 1ml in pre-filled oral syringes of 2.5mg, 5mg, 7.5mg and 10mg.
- Epistatus® contains Midazolam Maleate 10mg in 1ml. It is a preparation in a 5ml bottle with four oral syringes in the packaging. Epistatus® is also available as pre-filled oral syringes

of 2.5mg, 5mg, 7.5mg and 10mg. This is an unlicensed product, available as a 'special'.

It is important to remember which brand and dose your child uses

Instructions for giving buccal midazolam

- Your local medical team will train you how to prepare and give buccal midazolam.
- Always check the dose and expiry date before use.
- Give the medicine slowly to stop your child swallowing the medicine as this may cause them to choke.
- If buccal midazolam does not control the seizure within five minutes, follow the advice given by your doctor or call 999 for an ambulance.
- If you cannot give buccal midazolam for any reason, give first aid and call 999 for an ambulance.

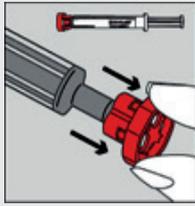
Using Buccolam® pre-filled oral syringes or Epistatus® pre-filled oral syringes

1. Check the dose and expiry date of the pre-filled syringe provided
2. Remove the oral syringe from the packaging

Important safety note about the Buccolam® pre-filled oral syringes only

The pre-filled syringes under the brand name Buccolam® come with a red protective cap on the end of the syringe, which should be removed before giving a dose to your child. Removing the red protective cap should also remove the translucent tip-cap underneath it but occasionally they do not come off together. If the tip-cap is still in place, it will stop the medicine coming out of the syringe and if you push the plunger harder, the tip-cap itself could fall off and land in your child's mouth, where it poses a choking risk.

When you remove the red protective cap, always check that the tip-cap has been removed as well. If it has not come off inside the red protective cap, pull this off separately before giving the dose to your child.



3. Place the syringe into the side of your child's mouth, between the gums and teeth
4. If possible, divide the dose so you give half into one cheek and the remaining half into the other cheek.
5. Slowly push the plunger of the syringe down until the syringe is empty
6. Watch for any breathing difficulties
7. Confirm that the seizure has stopped
8. Dispose of the syringe safely

Using Epistatus® buccal liquid (midazolam maleate 10mg/1ml) 5ml bottle

1. You will need the following:
 - Bottle of Epistatus®
 - Oral syringe provided
2. Check that the liquid is clear with no crystals visible. Discard if you can see crystals.
3. Unscrew the bottle cap, keeping the bottle upright
4. Insert a syringe into the centre of the stopper
5. Turn the bottle upside down

6. Pull the plunger of the syringe back slowly and then push back to prevent any air bubbles
7. Pull the plunger back again slowly and draw up the prescribed amount of liquid
8. Turn the bottle the right way up before removing the syringe
9. Put the cap back on the bottle to stop spillages
10. Place the syringe into the side of your child's mouth, between the gums and teeth
11. If possible, divide the dose so you give half into one cheek and the remaining half into the other cheek.
12. Slowly push the plunger of the syringe down until the syringe is empty
13. Watch for any breathing difficulties
14. Confirm that the seizure has stopped
15. Dispose of the syringe safely

What are the side effects?

- Drowsiness and sedation – recovery is usually fast
- Amnesia or short-term memory loss – your child may not remember having had a seizure
- Breathing difficulties – your child is unlikely to have breathing difficulties if midazolam is given at the correct dosage. If breathing difficulties do develop, seek medical assistance.
- Restlessness, agitation and disorientation – these can occur but are usually rare.

Important information

- Give the medicine as prescribed by your doctor
- If your child stops using midazolam or it passes its expiry date, please return it to your pharmacist. Do not flush it down the toilet or throw it away.
- Keep midazolam in a safe place where children cannot see it or reach it.
- Keep midazolam at room temperature (not in a fridge), away from bright light or direct sunlight and away from heat.
- Always check you have enough medicine and remember to order a new prescription in plenty of time.

Useful numbers

GOSH switchboard: 020 7405 9200

Clinical Nurse Specialist – Complex Epilepsy: ext 5816

Pharmacy medicines information: 020 7829 8608 (Monday to Friday from 9am to 5pm)