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Buccal midazolam for seizures in children (Buccolam, Epistatus)

Buccal midazolam is given as an emergency rescue medication during an epileptic seizure (fit).

Empty the contents of the pre-filled oral syringe into the space between the inside of the cheek and the lower gum.

Call an ambulance if the seizure has not stopped within ten minutes of it starting or within five minutes of giving buccal midazolam.

About buccal midazolam

Type of medicine	A benzodiazepine
Used for	Treatment of acute, convulsive seizures in children under 18 years old
Also called	Buccolam®; Epistatus®
Available as	Pre-filled oral syringe (oromucosal solution)

Buccal midazolam is an emergency rescue medication used to stop a seizure if one occurs in a child with epilepsy. This leaflet is for parents or carers who may need to give rescue medication to a child with epilepsy who is having a seizure.

A seizure, also known as a fit or convulsion, is an episode of abnormal electrical activity in the brain. There are different types of seizures with different symptoms depending on which parts of the brain are affected. Seizures can affect your muscles, emotions, sensations, behaviour and consciousness. People with [epilepsy](#) experience repeated seizures and so take medication to help control and reduce the number of seizures.

The most common type of seizure is a generalised [tonic-clonic seizure](#). With this type of seizure your whole body stiffens, you lose consciousness and then your body shakes (convulses) due to uncontrollable muscle contractions.

This type of seizure typically lasts from a few seconds to a few minutes before the person recovers naturally. Once the convulsions finish and the person regains consciousness they will feel confused and sleepy. Sometimes the seizure continues for several minutes and shows no sign of stopping naturally. Emergency rescue medication, such as buccal midazolam, can be used to try to stop seizures that continue for too long. A seizure that does not stop or keeps happening is known as status epilepticus.

Midazolam is a sedative medicine that controls and reduces electrical activity in the brain, thereby helping to stop a seizure. 'Buccal' means that the medicine is administered into the mouth and is absorbed through the lining of the mouth. This means it does not have to be swallowed for it to work; useful if someone is unconscious and cannot swallow. Buccolam[®] and Epistatus[®] come as pre-filled oral syringes that can be emptied into the space between the inside of the cheek and the lower gum (the buccal cavity).

Buccolam[®] and Epistatus[®] can be used by parents and carers to treat seizures in children aged from 6 months to under 18 years of age. The medicines are not licensed for treatment of adults; however, a doctor may prescribe it for an adult if they feel it is suitable.

Before giving buccal midazolam

Some medicines are not suitable for people with certain conditions, and sometimes a medicine may only be used if extra care is taken. For these reasons, before you start using buccal midazolam for your child it is important that their doctor knows:

- If your child has a long-term breathing problem such as asthma or if they have breathing problems whilst sleeping (sleep apnoea).
- If your child has any problems with the way their kidneys or liver work.
- If your child has any problems with their heart.
- If your child has a condition called myasthenia gravis which causes muscle weakness.
- If your child is pregnant or breast-feeding.
- If your child has ever had an allergic reaction to a medicine.
- If your child is taking any other medicines. This includes any medicines which are available to buy without a prescription, as well as herbal and complementary medicines.

How to use buccal midazolam

- Before you start using this treatment, read the manufacturer's printed information leaflet from inside the pack. The manufacturer's leaflet will give you more information about using buccal midazolam and a full list of side-effects which your child may experience from having it.
- Give buccal midazolam exactly as your child's doctor has told you to.

If your child has been prescribed Buccolam®:

- If you are not sure how to use Buccolam® ask your doctor or pharmacist to show you.

- The strength of Buccolam® will depend on your child's age. Make sure you have the right strength of oral syringe for your child. The packaging and the oral syringe are colour-coded to help you:
 - For children aged 3 months to less than 1 year, the dose is **2.5 mg** and the syringe is colour-coded **yellow**.
 - For children aged 1 year to less than 5 years, the dose is **5 mg** and the syringe is colour-coded **blue**.
 - For children aged 5 years to less than 10 years, the dose is **7.5 mg** and the syringe is colour-coded **purple**.
 - For children aged 10 years to less than 18 years, the dose is **10 mg** and the syringe is colour-coded **red**.
- The dose is the full contents of one syringe:
 - Hold the plastic tube and break the seal to pull the cap off.
 - Take the syringe out of the tube and pull the red cap off the tip of the syringe.
 - Put the tip of the syringe into the back of the space between the inside of the cheek and the lower gum.
 - Slowly press the plunger until it stops.
 - For smaller children the doctor may advise you to empty roughly half the syringe on one side of the mouth and the rest of the medicine on the other side.

Clinical Author's note (11/12/2017: MHRA Class 4 Drug Alert: Caution in Use. The manufacturer of Buccolam® reports that a translucent tip-cap sometimes remains on the syringe tip when pulling the red cap off. If this happens, the translucent tip cap needs to be removed manually to enable administration of Buccolam® and to prevent it falling into the patient's mouth when pressure is applied. Parents and carers need to be made aware of this potential problem. This applies to all strengths and all batches of Buccolam®.

If your child has been prescribed Epistatus®:

- If you are not sure how to use Epistatus® ask your doctor or pharmacist to show you.
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- The strength of Epistatus® will depend on your child's age. Make sure you have the right strength of oral syringe for your child. The packaging and the oral syringe are colour-coded to help you:
 - For children aged 6 months to less than 1 year, the dose is **2.5 mg** and the syringe is colour-coded **yellow**.
 - For children aged 1 year to less than 5 years, the dose is **5 mg** and the syringe is colour-coded **blue**.
 - For children aged 5 years to less than 10 years, the dose is **7.5 mg** and the syringe is colour-coded **purple**.
 - For children aged 10 years to less than 18 years, the dose is **10 mg** and the syringe is colour-coded **orange**.
- The dose is the full contents of one syringe:
 - Remove the syringe from the packing case.
 - Unscrew and remove the amber plastic cover.
 - Put the tip of the syringe into the back of the space between the inside of the cheek and the lower gum.
 - Slowly press the plunger about halfway in.
 - Switch to the other side of the mouth and press the plunger the rest of the way.
- Your child's seizure should stop completely within a few minutes of giving buccal midazolam.
- If your child's seizure has not stopped within ten minutes of it starting or within five minutes of giving buccal midazolam, you should call an ambulance. Hold on to the empty syringe so that you can show the paramedic when they arrive.

- You should also call an ambulance if:
 - Your child's breathing slows down or stops or their lips have turned blue.
 - Your child appears to be in pain.
 - You think your child may have injured themselves during the seizure.
 - You are unable to give all the medication or you spill some of the contents of the syringe.
 - You think you have given your child too much medication.
 - Your child starts to experience another seizure despite being given buccal midazolam.
- Do not give a second dose of buccal midazolam unless specifically instructed by a doctor or paramedic.

Getting the most from your treatment

- Try to keep all your regular appointments with your doctor. This is so your doctor can check on your child's progress.
- Making sure that your child's normal epilepsy medication is taken every day at the right times can prevent seizures from happening.
- If your child still experiences seizures despite taking regular medication it may be a sign the medicine is not working properly. Speak with your child's doctor about changing the dose or trying a new medicine.
- You and your child should always carry a supply of midazolam with you in case of an emergency. Also, make sure your child's school has a supply of midazolam for your child and that there are staff members who have been trained in dealing with epileptic seizures.

- **During a seizure:**
 - Note the time the seizure starts.
 - Try not to move your child unless they are somewhere dangerous such as in the road or near water.
 - Do not restrain your child's movements but try to move any dangerous objects out of the way.
 - Place something soft, like a pillow or jumper, under their head to cushion them.
 - If necessary, use the emergency rescue medication, following the instructions that have been given by your child's doctor.
 - Note the time when you give the rescue medication.
- **Once a seizure has stopped:**
 - Note the time the seizure stopped.
 - Roll your child on to their side and into the recovery position.
 - Check that your child's breathing is returning to normal.
 - Stay with your child and reassure them until they are fully recovered. It may take a while for them to wake up fully, especially if you have used emergency rescue medication.
- If you are planning a trip abroad and need to take a supply of buccal midazolam with you, you are advised to carry a letter from your child's doctor to explain that they have been prescribed buccal midazolam for seizures. This is because midazolam is classed as a 'controlled drug' and is subject to certain restrictions
- If your child is having an operation or dental treatment, tell the person carrying out the treatment if they have recently had a seizure and been given buccal midazolam.

Can buccal midazolam cause problems?

Along with their useful effects, most medicines can cause unwanted side-effects although not everyone experiences them. The table below contains some of the most common ones associated with buccal midazolam.

The most likely effect is that your child will feel sleepy after their seizure and after having this medicine. This is normal and helps your child to fully recover from their seizure. Because buccal midazolam is an emergency rescue medication and therefore not taken regularly, most side-effects should wear off relatively quickly. A full list of possible side-effects can be found in the manufacturer's leaflet supplied with the pack.

Common buccal midazolam side-effects	What can I do if my child experiences this?
Drowsiness, feeling sleepy or falling asleep	Stay with your child while they are recovering from the seizure and the effects of this medicine. If you have been shown how, put your child into the recovery position. If your child loses consciousness again after the seizure has stopped, call an ambulance
Feeling sick (nausea)	This should soon pass
Being sick (vomiting)	If your child is sick (vomits) after having a dose of buccal midazolam, do not give any further doses and call an ambulance if their seizure does not stop within ten minutes of it starting

If your child experiences any other symptoms which you think may be due to this medicine, speak with your doctor or pharmacist.

How to store buccal midazolam

- Keep all medicines out of the reach and sight of children.
- Store in a cool, dry place, away from direct heat and light.
- Regularly check the expiry date on the syringe to make sure it remains in date.

Important information about all medicines

Never take more than the prescribed dose. If you suspect that you or someone else might have taken an overdose of this medicine, go to the accident and emergency department of your local hospital. Take the container with you, even if it is empty.

This medicine is for you. Never give it to other people even if their condition appears to be the same as yours.

If you buy any medicines, check with your doctor or a pharmacist that they are suitable for you to take with your other medicines.

Do not keep out-of-date or unwanted medicines. Take them to your local pharmacy which will dispose of them for you.

If you have any questions about this medicine ask your pharmacist.

If you experience side effects, you can report them online through the [Yellow Card website](#).

Further reading

- [Manufacturer's PIL, Buccolam® 2.5 mg, 5 mg, 7.5 mg and 10 mg oromucosal Solution](#); Neuraxpharm UK Ltd, The electronic Medicines Compendium. Dated February 2022.
- [Manufacturer's PIL, Epistatus® 2.5 mg, 5 mg, 7.5 mg, 10 mg Oromucosal Solution](#); Veriton Pharma Ltd, The electronic Medicines Compendium. Dated August 2022.
- [Medicines Complete BNF 87th Edition](#); British Medical Association and Royal Pharmaceutical Society of Great Britain, London.

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Authored by: Michael Stewart, MRPharms	Peer Reviewed by: Sid Dajani	
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