

BUCCOLAM[®] (midazolam) FAQ

Adult Patients' Booklet

This information is provided as a resource for adult patients who have been prescribed BUCCOLAM[®], or individuals who may be required to administer it to them.

Before you need to give this medicine, please also read the BUCCOLAM[®] patient information leaflet for important information about using BUCCOLAM[®], there is one inside each pack. We recommend to do this at regular intervals.

This booklet is developed and funded by Neuraxpharm Ltd.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

BUCCOLAM® Q&A

This information is provided as a resource for adult patients who have been prescribed BUCCOLAM®, or any individuals who may be required to administer it to them. For any medical advice, clarification or information not included in the leaflet, the patient or the individual assisting must refer to the patient's doctor, pharmacist or nurse. For more information, please refer to the Patient Information Leaflet (PIL).

Q1: What is BUCCOLAM®?

BUCCOLAM® is a medicine that contains the active substance midazolam (as hydrochloride). It is available as 'oromucosal/buccal solution' (a solution given in the side of the mouth, into the space between the gum and the cheek) in prefilled syringes. Each syringe contains 10 mg of midazolam.

Q2: What is BUCCOLAM® used for?

BUCCOLAM® is used to stop a sudden, prolonged, convulsive seizure in adults. This medicine must only be used in patients who have been diagnosed to have epilepsy.

(Information on the use of BUCCOLAM® in children is also contained in the PIL.)

Q3-A: How do I give BUCCOLAM®?

Always give this medicine exactly as a doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure. Do not give BUCCOLAM® if the patient has:

- An allergy to midazolam, benzodiazepines (such as diazepam) or any of the other ingredients of this medicine (see Q9)
- A disease of the nerves and muscles causing muscle weakness (myasthenia gravis)
- Severe difficulty breathing at rest (BUCCOLAM® can make breathing difficulties worse)
- An illness causing frequent interruption of breathing during sleep (sleep apnoea syndrome)
- Severe liver problems

If patient has a kidney, liver or heart condition or lung condition which causes difficulty breathing on a regular basis, they should speak to a doctor or pharmacist before being given BUCCOLAM®.

Dosage: The recommended dose for adults is 10 mg. This comes in a prefilled syringe with orange labelled packaging.

The dose is the full content of one oral syringe. Do not give more than one dose.

Q3-B: How should BUCCOLAM® be given?

Please share this information to individuals e.g. family and friends, who may be called upon to administer BUCCOLAM® to you.

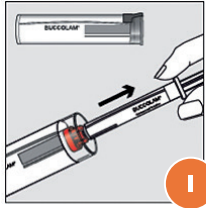
Preparing to give this medicine

- If the patient is having a seizure, allow their body to move freely, do not try to restrain them
- Only move them if they are in danger from, for example, deep water, fire or sharp objects
- Support the patient's head with something soft, such as a cushion or your lap
- Check that the medicine is the correct dose for the patient
- Ask a doctor, pharmacist or nurse to show you how to take or administer this medicine
- Always check with them if you are not sure

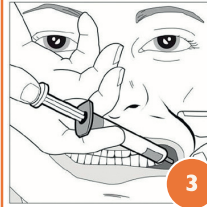
The information on how to give this medicine is also shown on the tube label and the PIL.

BUCCOLAM® must not be injected. Do not attach a needle to the syringe.

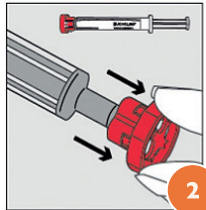
Administration of BUCCOLAM®



Hold the plastic tube and pull the cap off. Take the syringe out of the tube.

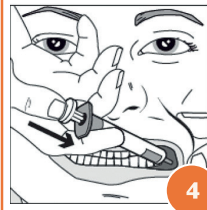


Using the finger and thumb gently pinch and pull back the patient's cheek. Put the tip of the syringe into the back of the space between the inside of the cheek and the lower gum.



Pull the red cap off the tip of the syringe and dispose of it safely.

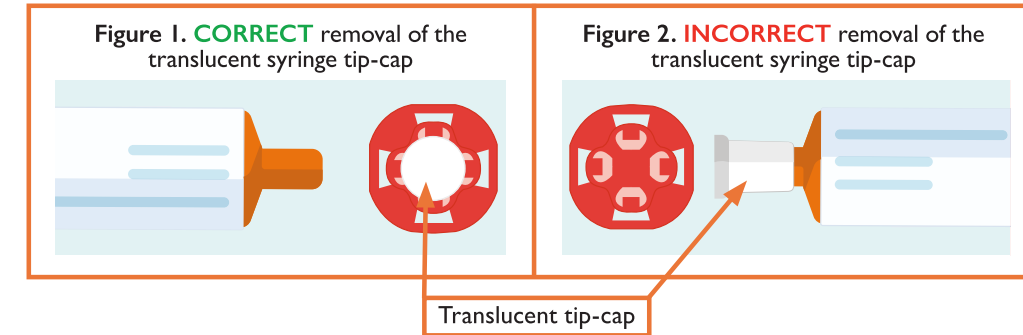
* **Please look at Q3-C: How should BUCCOLAM® be given?**



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 (buccal cavity).
If prescribed by your doctor, (for larger volumes and/or smaller patients), you can give approximately half the dose slowly into one side of the mouth, then the other half of the dose into the other side of the patient's mouth.

Q3-C: How should BUCCOLAM® be given?*

*As an additional step, the individual administering BUCCOLAM® 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, and does not remain on the syringe tip as in the figure below:



Q4: How should BUCCOLAM® be stored?

Keep this medicine out of the sight and reach of children.

Do not give this medicine after the expiry date which is stated on the carton, tube and oral syringe labels after EXP.

The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Keep the oral syringe in the protective plastic tube.

Q5: Can another dose of BUCCOLAM® be given?

Do not give more than the amount of medicine prescribed by a doctor for the patient.

Another dose should not be given without medical advice.

If the seizure does not stop within 10 minutes, call an ambulance.

Q6: When to call an ambulance?

ALWAYS follow the treatment advice provided by the patient's doctor or as explained by a healthcare professional.

If in any doubt, call for immediate medical help if:

- The seizure does not stop within 10 minutes
- You're unable to empty the syringe or you spill some of the contents
- The patient's breathing slows down or stops e.g. slow or shallow breathing or blue lips
- You observe signs of a heart attack which may include chest pain or pain that spreads to the neck and shoulders and down the left arm
- The patient is sick (vomits) and the seizure does not stop within 10 minutes
- You give too much BUCCOLAM® and there are signs of overdose which include:
 - Drowsiness, tiredness, fatigue
 - Confusion or feeling disorientated
 - Absence of knee reflex or a response to a pinch
 - Breathing difficulties (slow or shallow breathing)
 - Low blood pressure (giddiness and feeling faint)
 - Coma

Keep the syringe to show to the ambulance staff or doctor.

Do not give more than the amount of medicine prescribed by a doctor for the patient.

If the patient is sick (vomits)

- Do not give the patient another dose of BUCCOLAM®
- If the seizure does not stop within 10 minutes, call an ambulance

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Q7: Are there any side effects of BUCCOLAM®?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Seek medical advice immediately or telephone for an ambulance if you experience the following:

- Severe breathing difficulties e.g. slow or shallow breathing or blue lips. In very rare cases breathing might stop
- Heart attack. Signs may include chest pain which may spread to the neck and shoulders and down the left arm
- Swelling of the face, lips, tongue or throat which makes it difficult to swallow or breathe, or a pale skin, a weak and rapid pulse, or feeling of loss of consciousness. You may be having a serious allergic reaction

Other side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed here and in the leaflet.

Common side effects (may affect up to 1 in 10 people): <ul style="list-style-type: none">• Feeling and being sick• Sleepiness or losing consciousness	Uncommon side effects (may affect up to 1 in 100 people): <ul style="list-style-type: none">• Rash, hives (lumpy rash), itchiness
Very rare side effects (may affect up to 1 in 10,000 people): <ul style="list-style-type: none">• Agitation, restlessness, hostility, rage or aggression, excitement, confusion, euphoria (an excessive feeling of happiness or excitement), or hallucinations (seeing and possibly hearing things that are not really there)• Muscle spasms and muscle tremors (shaking of your muscles that you cannot control)• Reduced alertness• Headache• Dizziness• Difficulty co-ordinating muscles• Fits (convulsions)• Temporary memory loss. How long this lasts depends on how much BUCCOLAM® was given• Low blood pressure, slow heart rate, or redness of the face and neck (flushing)• Laryngospasm (tightening of the vocal cords causing difficult and noisy breathing)• Constipation• Dry mouth• Tiredness• Hiccups	

Q8: How do I report a side effect of BUCCOLAM®?

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed here. You can also report side effects directly:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

Q9: What are the ingredients?

The active substance is midazolam

- Each 10 mg pre-filled oral syringe contains 10 mg midazolam (as hydrochloride) in 2 ml solution

The other ingredients are sodium chloride, water for injections, hydrochloric acid and sodium hydroxide (for pH adjustment). BUCCOLAM® does not contain alcohol.

Q10: Who will provide training on how to administer BUCCOLAM®?

You and any individuals who will be administering the medication should have been trained to use BUCCOLAM® when it was initiated following your referral to an Epilepsy Specialist. This is usually carried out by the Epilepsy Nurse Specialist.

Q11: Does food and drink affect BUCCOLAM®?

The patient must not drink alcohol or grapefruit juice while taking BUCCOLAM®.

Both these drinks may increase the sedative effects of this medicine and make the patient very sleepy.

Q12: Can I drive, ride a bike or do similar activity after receiving a dose of BUCCOLAM®?

BUCCOLAM® may make the patient sleepy, forgetful or affect their concentration and co-ordination. After receiving this medicine, the patient should not drive a vehicle, ride a bicycle or operate a machine until they have completely recovered. Please read the PIL and discuss with your doctor if you need further advice.

Q13: Can I take BUCCOLAM® on holiday with me?

BUCCOLAM® should always be carried with you.

Q14: When should I order the next box of BUCCOLAM®?

You should order the next box of BUCCOLAM® when you need to replace any of the syringes or if the syringes are approaching expiry.

Q15: Should BUCCOLAM® be included in my care plan?

BUCCOLAM® should be written into the Care Plan so that everyone who is involved with your care is aware of what BUCCOLAM® is, why it has been prescribed and when it might be needed.

Q16: Will my GP know that I have been prescribed BUCCOLAM®?

Your GP will have been sent a copy of the Care plan from the specialist who initiated BUCCOLAM® and may be requested to take over prescribing BUCCOLAM® for you as often as you need it.

Q17: How long will I need to be prescribed BUCCOLAM®?

You will need to be prescribed BUCCOLAM® for as long as your healthcare professional feels it is appropriate to provide this medication to stop sudden, prolonged, convulsive, seizures (PACS) you might have.

This may be over a long period and so it is important to tell your doctor or pharmacist about any changes which may affect the use of BUCCOLAM®.

Tell your healthcare professional about medicines (including herbal or prescription drugs) the patient is taking, or has recently taken, or might take. If you have any doubt about whether any medicine the patient is taking may affect the use of BUCCOLAM®, please speak to your doctor or pharmacist, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

Talk to the patient's doctor or pharmacist about medicines the patient should avoid whilst taking BUCCOLAM®.

If the patient who will be given this medicine is pregnant or breast-feeding, thinks she may be pregnant or is planning to have a baby, ask a doctor for advice before using this medicine.

