Package leaflet: Information for the user

1000151966-xxx-xx

Buccolam® 7.5 mg oromucosal solution For children aged 5 years to less than 10 years

(midazolam hydrochloride)

The name of your medicine is Buccolam 7.5 mg oromucosal solution but will be referred to as Buccolam throughout this leaflet.
Please note that the leaflet also contains information about other strengths.

Read all of this leaflet carefully, before you start giving this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as those of the patient for whom this medicine has been prescribed.
- If you see any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Buccolam is and what it is used for

Buccolam contains a medicine called midazolam. Midazolam belongs to a group of medicines known as benzodiazepines. Buccolam is used to stop a sudden, prolonged, convulsive, seizure in adults, adolescents, children and infants aged 3 months and above.
In infants from 3 months to less than 6 months it should only be used in a hospital setting where monitoring is possible and resuscitation equipment is available.
This medicine must only be used by parents/carers where the patient has been diagnosed to have epilepsy.

2. What you need to know before you give Buccolam

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 (listed in section 6)
- 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.

Warnings and precautions
Talk to your doctor or pharmacist before giving Buccolam if the patient has:
- A kidney, liver or heart condition
- A lung condition that causes difficulty breathing on a regular basis.

This medicine may cause people to forget what happened after they have been given it. Patients should be observed carefully after being given the medicine.

This medicine should be avoided in patients with a medical history of alcohol or drug abuse.

Life threatening incidents are more likely in patients with breathing difficulties or heart problems, especially when higher doses of Buccolam are given.

Children younger than 3 months: Buccolam should not be given to children younger than 3 months since there is not enough information in this age group.

If you are not sure if any of the above applies to the patient, talk to a doctor or pharmacist before giving this medicine.

Other medicines and Buccolam
Tell your doctor or pharmacist if the patient is taking, or has recently taken, or might take any other medicines. 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. This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved.

The effects of Buccolam may be intensified by medicines such as:
- antiepileptics, (for treating epilepsy) e.g. phenytoin
- antibiotics, e.g. erythromycin, clarithromycin
- antifungals, e.g. ketoconazole, voriconazole, fluconazole, itraconazole, pozaconazole
- anti-ulcer medicines, e.g. cimetidine, ranitidine and omeprazole
- medicines used to treat blood pressure, e.g. diltiazem, verapamil
- some medicines used to treat HIV and AIDS, e.g. saquinavir, lopinavir/ritonavir combination
- narcotic analgesics (very strong pain killers), e.g. fentanyl
- medicines used to reduce fat in the blood, e.g. atorvastatin
- medicines used to treat nausea, e.g. nabilone
- hypnotics (sleep inducing medicines)
- sedative antidepressants (medicines used to treat depression that make you sleepy)
- sedatives (medicines that relax you)
- anaesthetics (for pain relief)
- antihistamines (to treat allergies).

The effects of Buccolam may be reduced by medicines such as:
- rifampicin (used to treat tuberculosis)
- xanthines (used to treat asthma)
- St John's Wort (a herbal medicine). This should be avoided in patients taking Buccolam.

Buccolam may increase the effect of some muscle relaxants e.g. baclofen (causing increased drowsiness). This medicine may also stop some other medicines from working as well, e.g. levodopa (used to treat Parkinson's disease).
Talk to your doctor or pharmacist about medicines the patient should avoid whilst taking Buccolam.

Buccolam with food and drink
The patient must not drink alcohol while taking Buccolam. Alcohol may increase the sedative effects of this medicine and make them very sleepy.
The patient must not drink grapefruit juice while taking Buccolam. Grapefruit juice may increase the sedative effects of this medicine and make them very sleepy.

Pregnancy
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 taking this medicine.
Giving high doses of Buccolam during the last 3 months of pregnancy can cause abnormal heart beat in the unborn child. Babies born after this medicine is administered during childbirth can also have poor suckling, breathing difficulties and poor muscle tone at birth.

Breast-feeding
Tell the doctor if the patient is breast-feeding. Even though small amounts of Buccolam may pass into breast milk, it may not be necessary to stop breast-feeding. The doctor will advise if the patient should breast-feed after being given this medicine.

Driving and using machines
The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to you doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Buccolam may make the patient sleepy, forgetful or affect their concentration and co-ordination. This may affect their performance at skilled tasks such as driving, riding a bicycle, or using machines.
After receiving this medicine, the patient should not drive a vehicle, ride a bicycle or operate a machine until they have completely recovered. Please discuss with your doctor if you need further advice.

Buccolam contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per oral syringe, that is to say essentially 'sodium-free'.

3. How to give Buccolam

Always give this medicine exactly as a doctor has told you. Check with a doctor or pharmacist if you are not sure.

Dosage
The doctor will prescribe the appropriate dose of Buccolam the patient needs, generally according to the patient age. The different doses each have a different colour, which is shown on the carton, the tube and the syringe containing the medicine.
Depending on age, the patient will have received one of the following doses, in specifically colour labelled packaging:

3 months to less than 1 year: 2.5 mg - yellow labelled packaging

1 year to less than 5 years: 5 mg - blue labelled packaging

5 years to less than 10 years: 7.5 mg - purple labelled packaging

10 years and above: 10 mg - orange labelled packaging

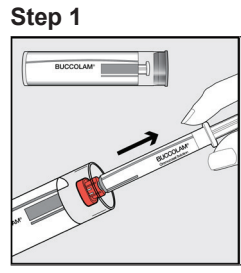
The dose is the full contents of one oral syringe. Do not give more than one dose.

Toddlers aged from 3 months to less than 6 months should only be treated in a hospital setting where monitoring is possible and resuscitation equipment is available.

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, according to their age.

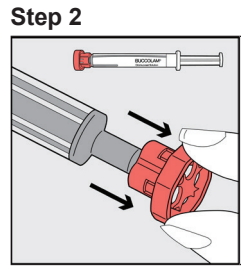
How to give this medicine
Ask a doctor, pharmacist or nurse to show you how to take or administer this medicine. Always check with them if you are not sure. The information on how to give this medicine is also shown on the tube label.
Buccolam must not be injected. Do not attach a needle to the syringe

Step 1



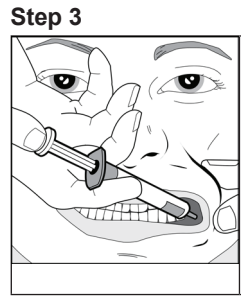
Hold the plastic tube and pull the cap off. Take the syringe out of the tube.

Step 2



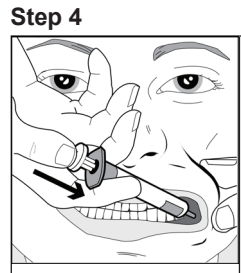
Pull the red cap off the tip of the syringe and dispose of it safely.

Step 3



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.

Step 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 (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 into the other side of the patient's mouth.

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 a doctor or pharmacist.

4. Possible side effects

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 the patient experiences 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 patient's neck and shoulders and down their 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 the patient gets any side effects, talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Common side effects (may affect up to 1 in 10 people):
- Feeling and being sick
- Sleepiness or losing consciousness

Uncommon side effects (may affect up to 1 in 100 people):
- Rash, hives (lumpy rash), itchiness

Very rare side effects (may affect up to 1 in 10,000 people):
- 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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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.

5. How to store Buccolam

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.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

Disposal of oral syringes
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Buccolam contains
- The active substance is midazolam
- Each 7.5 mg pre-filled oral syringe contains 7.5 mg midazolam (as hydrochloride) in 1.5 ml solution.

The other ingredients are sodium chloride, water for injections, hydrochloric acid and sodium hydroxide (for pH adjustment).

What Buccolam looks like and contents of the pack

5 years to less than 10 years: 7.5 mg - purple labelled packaging

Buccolam oromucosal solution is a clear colourless liquid. It is supplied in an amber coloured pre-filled, single-use oral syringe. Each oral syringe is individually packed in a protective plastic tube. Buccolam is available in cartons containing 4 pre-filled oral syringes/ tubes (of the same dose).

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Procured from within the EU by the Product Licence holder Orifarm UK Ltd.,
Ground Floor Suite A2, Breakspear Park,
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HP2 4TZ, UK
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Energivej 15, 5260 Odense S, Denmark

Manufactured by Laboratorios Lesvi, S.L.,
Avda. Barcelona 69, 08970 Sant Joan Despí,
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Buccolam 7.5 mg oromucosal solution
PLGB 45985/0729

POM CD

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Is this leaflet hard to see or read?
Call +45 63 95 27 00
to obtain the leaflet in a format suitable for you.

Buccolam® Prefilled Plastic Syringes: instructions for correct administration

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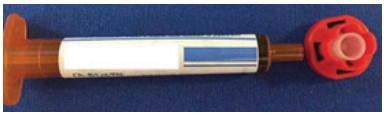
The clear tip-cap of Buccolam syringes can sometimes remain attached to the syringe after the red cap has been taken off. If this happens, the tip-cap can detach in the patient's mouth and they might breathe it in or swallow it. If this happens, this could be a **choking hazard**.

Continue to give Buccolam as your doctor, nurse or pharmacist has told you to.

Buccolam remains **safe to use**. **Before use of Buccolam, you must follow the instructions below:**

Correct

1. Before giving Buccolam, pull the red cap off the end. Check the clear tip-cap is attached to the red cap, as shown.	

Incorrect

2. The clear tip-cap should not be attached to the syringe, as shown.	

3. If the clear tip-cap is still attached to the syringe, you should **pull it off before** giving Buccolam to prevent it from going into the patient's mouth.

! If you think the tip-cap is in the patient's mouth, **do not** insert a finger into the mouth to look for it or remove it. Instead, turn the patient onto their side (recovery position) and make sure they spit it out when they stop fitting.

Call for reporting

If you get any side effects, talk to your doctor, pharmacist or nurse. You should also tell them about any occasions in which the translucent tip-cap remained attached to the syringe.

You can also report side effects directly via the Yellow Card Scheme website https://yellowcard.mhra.gov.uk/ 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.

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