

BUCCOLAM

Oromucosal solution

BUCCOLAM contains the active substance: midazolam

- Each 2.5 mg pre-filled oral syringe contains 2.5 mg midazolam (as hydrochloride) in 0.5 ml solution.
- Each 5 mg pre-filled oral syringe contains 5 mg midazolam (as hydrochloride) in 1 ml solution.
- Each 7.5 mg pre-filled oral syringe contains 7.5 mg midazolam (as hydrochloride) in 1.5 ml solution.
- Each 10 mg pre-filled oral syringe contains 10 mg midazolam (as hydrochloride) in 2 ml solution.

For the list of excipients - see section 6 "Further Information".

Read this package insert carefully in its entirety before using this medicine. This insert contains concise information about the medicine. In case you have any additional questions, please refer to the doctor or the pharmacist.

This medicine has been prescribed for the treatment of your child/patient. Do not pass it on to others. It may harm them, even though it may seem to you that they have a similar medical state.

This medicine is intended for use in children and adolescents aged 3 months and older, but younger than 18 years of age.

If the seizure does not stop within 10 minutes of giving BUCCOLAM:

- **You must telephone for an ambulance immediately.**
- **You must keep the empty oral syringe and give it to the ambulance staff so that they know how much BUCCOLAM has been given to the patient.**
- **Do not give the patient another dose of BUCCOLAM!**

Taking this medicine with other opioids or other medications which suppress the central nervous system (including narcotics) or alcohol, may result in profound sedation, breathing difficulties (respiratory depression), coma and death.

1. What is this medicine used for?

This medicine is used for the treatment of prolonged, acute, convulsive, epileptic seizures in infants, toddlers, children and adolescents (from 3 months to less than 18 years of age).

This medicine must only be used by parents/carers where the child/patient has been diagnosed to have epilepsy.

In infants from 3 months to less than 6 months it should only be used in a hospital setting where monitoring of the infant's condition is possible and resuscitation equipment is available.

Therapeutic group:

Benzodiazepines group

2. Before using this medicine

Do not use this medicine if:

- You\your child are hypersensitive (allergic) to the active substance midazolam, or benzodiazepines (such as diazepam), or to any of the other ingredients of this medicine (listed in section 6).
- The patient has a disease of the nerves and muscles causing muscle weakness (Myasthenia gravis).
- The patient has a severe difficulty breathing at rest (BUCCOLAM can make breathing difficulties worse).
- The patient has an illness causing frequent interruption of breathing during sleep (Sleep apnoea syndrome).
- The patient has severe liver problems.

Special warnings regarding the use of this medicine:

Before treatment with BUCCOLAM, tell the doctor 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 had 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.

Drug-drug interactions

If you or your child are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell 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.

In particular, if you take the following:

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, posaconazole
- 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.

Using BUCCOLAM with food

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.

Using BUCCOLAM and alcohol consumption

The patient must not drink alcohol while taking BUCCOLAM. Alcohol may increase the sedative effects of this medicine and make them very sleepy.

Pregnancy and breast-feeding

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 the 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

Do not drive, ride a bicycle or operate any dangerous machines while using this medicine until you have completely recovered since BUCCOLAM may make you sleepy, forgetful or affect your concentration and co-ordination. This may affect your performance at skilled tasks such as driving, riding a bicycle, or using machines.

As for children, keep them from riding a bicycle or playing by the road etc.

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

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicinal product.

Dosage

The dosage and treatment regimen will be determined by the doctor only. The commonly recommended dose is:

Depending on age, your child will have received one of the following doses, in specifically colour labelled packaging:

- For ages 3 months to less than 1 year: 2.5 mg - package with a yellow label
- For ages 1 year to less than 5 years: 5 mg - package with a blue label
- For ages 5 years to less than 10 years: 7.5 mg - package with a purple label
- For ages 10 years to less than 18 years: 10 mg - package with an orange label

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.

Do not exceed the recommended dose.

Preparing to give this medicine

If the child 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 your child’s head with something soft, such as a cushion or your lap.

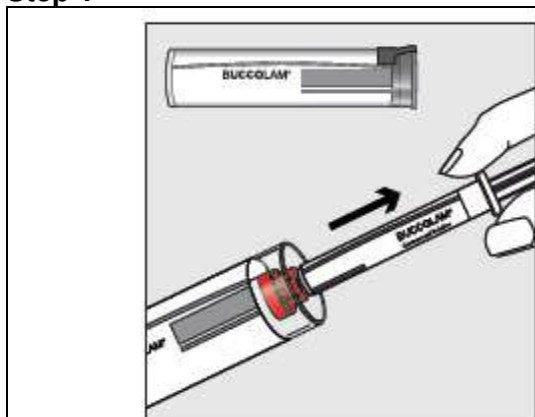
Check that the medicine is the correct dose for your child, according to their age.

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.

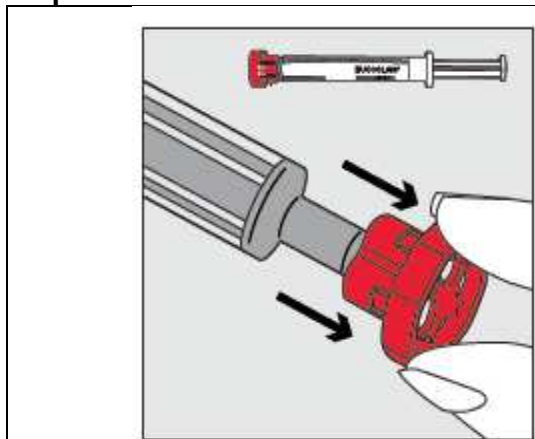
BUCCOLAM must not be injected. Do not attach a needle to the syringe.

Step 1



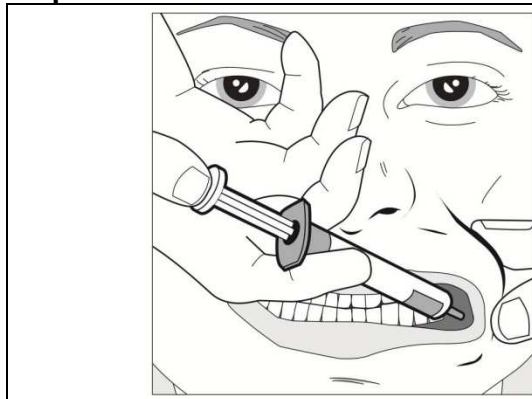
Hold the plastic tube and pull the cap off. Take the syringe out of the tube.

Step 2



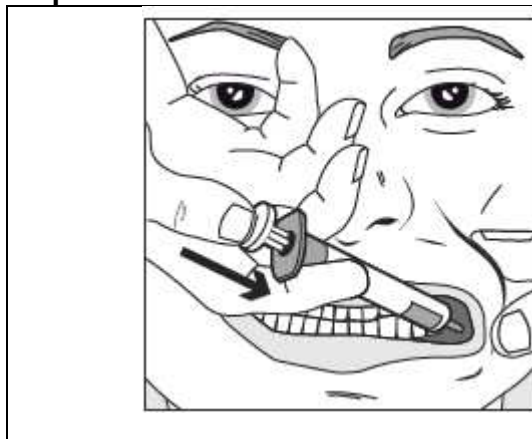
Pull the red cap off the tip of the syringe and dispose of it safely.

Step 3



Using the finger and thumb gently pinch and pull back the child'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 the remaining half dose slowly into the other side of the child's mouth.

You should telephone for an ambulance immediately if any of the following occurs:

- The seizure does not stop within 10 minutes
- You're unable to empty the syringe or you spill some of the contents
- The child'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 child 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 in order to show it to the ambulance staff or the doctor.

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.

Do not give more than the amount of medicine prescribed by a doctor for the patient. If you have an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a doctor or pharmacist.

4. Side effects

Like all medicines, BUCCOLAM can cause side effects in some users.

Do not be alarmed while reading the list of side effects. You may not suffer from any of 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 child'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.

Additional side effects

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

If any of the side effects appear, if any of the side effects worsen, or if you experience any side effects not listed in this leaflet, please consult your doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website

(www.health.gov.il) which links to an online form for reporting side effects, or by the following link:

<https://sideeffects.health.gov.il/>

In addition, you can report by emailing the Registration Holder's Patient Safety Unit at:

drugsafety@neopharmgroup.com

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the carton package, tube and oral syringe labels. The expiry date refers to the last day of that month.
- **Storage:**
Store below 25°C.
Do not refrigerate or freeze.
Keep the oral syringe in the protective plastic tube.
Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Further Information

In addition to the active ingredient, this medicine also contains:
Sodium chloride, Water for injections, Hydrochloric acid and Sodium hydroxide (for pH adjustment).

What the medicine looks like and contents of the pack:

BUCCOLAM oromucosal solution is a clear colourless to yellowish liquid. It is supplied in an amber coloured pre-filled, single-use oral syringe, closed with a syringe cap.

Each oral syringe is individually packed in a protective plastic tube. BUCCOLAM is available in cartons containing 2 and 4 pre-filled oral syringes/tubes (of the same dose).

Not all pack sizes may be marketed.

The presentations available are:

- For ages 3 months to less than 1 year: 2.5 mg - package with a yellow label
- For ages 1 year to less than 5 years: 5 mg - package with a blue label
- For ages 5 years to less than 10 years: 7.5 mg - package with a purple label
- For ages 10 years to less than 18 years: 10 mg - package with an orange label

Registration Holder's name and address: Neopharm Cure (2005) Ltd., Hashiloach 6, Petach-Tikva 49170.

Manufacturer's name and address: Laboratorios Lesvi, S.L., Barcelona 69, 08970, Sant Joan Despí, Barcelona, Spain.

The registration number of the medicine at the national medicines registry of the Ministry of Health:
149 78 33743

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Buccolam Oromucosal Sol PIL vr 03A

