BUCCOLAM® 2.5 mg oromucosal solution
For children aged 2 years and less than 1 year

BUCCOLAM® 5 mg oromucosal solution
For children aged 2 years and less than 1 year

BUCCOLAM® 7.5 mg oromucosal solution
For children aged 2 years and less than 1 year

BUCCOLAM® 10 mg oromucosal solution
For children aged 2 years and less than 1 year

Please read all of this leaflet carefully, before you give this medicine to your child and save it for future use. If you have any questions, ask your doctor or pharmacist. This leaflet is also shown on the tube label.

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 convulsion (seizure, fit) in children from 3 months to less than 18 years of age.

In infants from 3 months to less than 12 months, BUCCOLAM can only be used in a hospital setting where monitoring is possible and resuscitation equipment is available.

This medicine must only be used by a doctor or a nurse who 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 listed in section 6

• a breathing condition that causes difficulty in breathing (respiratory distress syndrome)

• a severe liver problem (liver failure, cirrhosis)

Talk to your doctor or pharmacist before giving BUCCOLAM if the patient has:

• a lung condition that causes difficulty in breathing

This medicine may cause what happened after the last dose. Therefore, you should avoid giving the medicine.

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

Life threatening incidents in patients with breathing problems are uncommon.

If prescribed by your doctor or pharmacist, BUCCOLAM can be given in hospital or in a hospital setting where monitoring is possible and resuscitation equipment is available.

Do not give BUCCOLAM to patients between 3 months and 1 year, you should not be given to children younger than 1 year of age.

If you are not sure if the above applies to you, please speak to your doctor or pharmacist. This leaflet is also shown on the tube label.

3. How to give BUCCOLAM

Follow the information given by your doctor or pharmacist. Ask your doctor or pharmacist for advice before taking any other medicines.

Give high doses of BUCCOLAM during the last 3 months of pregnancy.

Babies born after this admission may also have poor sucking, breathing and muscle tone at birth.

Breast-feeding

Tell the doctor if the patient is breast-feeding. Even in small amounts into breast milk, it may be stop-breast-feeding after being given this medicine.

Breast-feeding and using BUCCOLAM may make the baby sleepier and affect their performance at a skill, such as riding, driving, or operating machines or driving. After receiving this medicine, the patient should not drive a vehicle or operate machinery until you have recovered. Please discuss this with your doctor or pharmacist.

3. How to give BUCCOLAM

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

Dosage

Your doctor will prescribe the appropriate dose of BUCCOLAM for your patient. In general: the dose will depend on:

• the age and weight of your patient
• the condition that your patient has
• the size of your patient
• the amount of medicine prescribed

Dependent on age, your child will have received one of the following doses, in specified quantities:

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

The dose is the full contents of one oral syringe, oromucosal solution.

4. Possible side effects

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

Serious side effects

Ask your doctor or pharmacist for advice if the patient experiences the following:

• Severe breathing difficulties, e.g. slow or shallow breathing or blue lips

If prescribed by your doctor for the patient’s treatment of epilepsy (i.e. seizures), you can give approximately half the amount of medicine for the patient’s mother.

When to call an ambulance

ALWAYS follow the treatment advice provided by the patient’s doctor, hospital or health professional. If in any doubt, call your doctor or pharmacist.

The seizure does not stop

You give too much BUCCOLAM and there is no stop and do not breathe

You are not able to wake up the patient

If you have any further questions on the use of this medicine, ask your doctor or pharmacist. This leaflet is also shown on the tube label.

5. How to store BUCCOLAM

Keep this medicine out of the sight and reach of children. Do not leave the medicine after the expiry date which is stated on the container, tube and oral syringe label after the expiry date. If prescribed by your doctor or pharmacist, you can give approximately half the amount of medicine for the patient’s mother.

Disposal of oral syringes

Do not throw away any medicines via the waste bin. Ask your pharmacist how to dispose of medicines. These measures will help protect the environment.

6. Contents of the information pack

WHAT BUCCOLAM contains

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 1.0 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.

The other ingredients are water for injection, sodium chloride, sodium hydroxide (for pH adjustment) and sodium carbonate.

WHAT BETADINE looks like and contains

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

3 months to less than 1 year: 5 mg yellow labelled packaging

3 months to less than 1 year: 7.5 mg yellow labelled packaging

3 months to less than 1 year: 10 mg yellow labelled packaging

BUCCOLAM oromucosal solution is a colourless liquid solution. It is supplied in a dispenser syringe (oral syringe). Each oral syringe is in a protective plastic tube (available in cartons containing 4 pre-filled oral syringes/tubes (including one identical to the same dose).}


to 1 in 5 people: 

• Feeling and being sick

• Feeling or being unconscious

• Side effects of this medicine may appear up to 1 in 100 people.

• Rash, hives (itchy, red), lichen

Very rare side effects may affect up to 1 in 10,000 people: Apnea, death, breathing, restless leg syndrome, aggressive, excitation, confusion, feeling of fear, anxiety, agitation, feelings of pain, skin (including areas not under your control), muscle tremors, muscle stiffness, muscle cramps or muscle weakness.

• Sedation

• Dry mouth

• Nausea

• Headache

• Dizziness

• Constipation

• Weakness

• Convulsions

• Fainting

• Unusual tiredness

• High blood pressure

• Low blood pressure

• Loss. How long this lasts depends on the medicine.

• Lowest pressure

• Nearness

• Feeling of nearness

• Sweating

• Swelling

• Swelling of the face, tongue or throat

• Tense

• Trembling

• Unconscious

• Unconsciousness

• Vomiting

• Weakness

• Weakness or numbness