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Buccolam (*midazolam*)

An overview of Buccolam and why it is authorised in the EU

What is Buccolam and what is it used for?

Buccolam is a medicine used to stop prolonged, acute (sudden) convulsive seizures in adults and children from 3 months of age. It must only be given by parents or carers when the patient has already been diagnosed with epilepsy.

In infants from 3 months to 6 months of age, Buccolam should only be given in a hospital setting where resuscitation equipment is available and the patient can be monitored.

Buccolam contains the active substance midazolam.

How is Buccolam used?

Buccolam can only be obtained with a prescription and is available as an oromucosal solution (a solution given in the side of the mouth, into the space between the gum and the cheek) in pre-filled syringes.

The dose depends on the patient's age. The full amount of the appropriate pre-filled syringe should be given slowly into the space between the gum and the cheek. If necessary, the dose can be divided between both sides of the mouth.

Carers should only give one dose of Buccolam. If the seizure has not stopped within 10 minutes of giving Buccolam, they should seek medical help immediately. If seizures re-occur after an initial response, medical advice should always be sought before giving a second dose.

For more information about using Buccolam, see the package leaflet or contact your doctor or pharmacist.

How does Buccolam work?

The active substance in Buccolam is midazolam, a benzodiazepine, which acts as an anti-convulsant medicine. Convulsions are caused by excessive electrical activity in the brain. Buccolam attaches to the receptors for the neurotransmitter GABA in the brain and activates them. Neurotransmitters such as GABA are chemicals that allow nerve cells to communicate with each other. In the brain, GABA is involved in reducing the electrical activity. By activating its receptors, midazolam increases GABA's effects, which will stop a convulsion.

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What benefits of Buccolam have been shown in studies?

Children

Five main studies from the published literature looked at children with acute convulsions and compared the effects of oromucosal midazolam with those of diazepam (another benzodiazepine) when given intravenously (into a vein) or rectally (into the rectum). Four of these studies compared oromucosal midazolam with rectal diazepam and showed that oromucosal midazolam was effective in stopping a seizure within 10 minutes in 65 to 78% of children compared with 41 to 85% of children who received rectal diazepam. The fifth study compared buccal midazolam with intravenous diazepam, and both treatments were similarly effective in stopping the seizure within 5 minutes.

Adults

A study was carried out to see how Buccolam behaves in the body, taking into account differences such as weight, age and other factors that can affect how the medicine works. The data showed that when the medicine is given to adults at the recommended doses, the levels of midazolam in the blood are comparable to those seen in children. Based on these data, the medicine is expected to work in a similar way in adults as in children.

What are the risks associated with Buccolam?

For the full list of side effects and restrictions with Buccolam, see the package leaflet.

The most common side effects with Buccolam (which may affect up to 1 in 10 patients) include sedation (induce sleepiness), somnolence (sleepiness), reduced levels of consciousness, respiratory depression (breathing difficulties), nausea (feeling sick) and vomiting.

Buccolam must not be used in people who may be hypersensitive (allergic) to midazolam, benzodiazepines or any of the other ingredients. It must not be used in patients with myasthenia gravis (a disease causing muscle weakness), severe respiratory insufficiency (lung conditions that cause difficulty breathing), sleep apnoea syndrome (frequent interruption of breathing during sleep) or severe liver problems.

Why is Buccolam authorised in the EU?

Based on the results of the studies presented, the European Medicines Agency concluded that Buccolam is at least as effective as existing treatments for stopping acute prolonged, convulsive seizures in children. Although medicines given intravenously may act faster once injected, it takes time to gain access to the veins, especially in children. Buccolam has the advantage of being quicker and easier to give than rectal or intravenous medicines.

With regard to side effects, the medicine may cause respiratory depression, as is the case with other comparable medicines, but is generally well tolerated. Based on how the medicine works, the effectiveness and safety profile in adults are considered to be the same as in children. The European Medicines Agency therefore considered that Buccolam's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Buccolam?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Buccolam have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Buccolam are continuously monitored. Suspected side effects reported with Buccolam are carefully evaluated and any necessary action taken to protect patients.

Other information about Buccolam

Buccolam received a marketing authorisation valid throughout the EU on 5 September 2011.

Further information on Buccolam can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/buccolam.

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