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EPAR summary for the public

Buccolam

midazolam

This is a summary of the European public assessment report (EPAR) for Buccolam. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Buccolam.

What is Buccolam?

Buccolam is a medicine that contains the active substance midazolam. It is available as 'oromucosal 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 2.5 mg, 5 mg, 7.5 mg or 10 mg of midazolam.

What is Buccolam used for?

Buccolam is used to stop prolonged, acute (sudden) convulsive seizures in children and adolescents (from 3 months to less than 18 years of age).

The medicine can only be obtained with a prescription.

How is Buccolam used?

Buccolam is given in the side of the child's mouth. The recommended dose ranges from 2.5.mg to 10 mg, depending on the child's age.

The full amount of the appropriate prefilled 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.

When given by carers or parents Buccolam should only be used when the child has already been diagnosed with epilepsy.

Carers should only administer one dose. If the seizure has not stopped within 10 minutes of giving Buccolam, they should seek medical help immediately.

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In infants from 3 months to less than 6 months Buccolam should only be used within a hospital and where equipment is available for resuscitation and monitoring of the patient due to an increased risk respiratory depression (inhibition of breathing).

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, Buccolam increases GABA's effects, which will stop a convulsion.

How has Buccolam been studied?

The company presented results of five key studies from the published literature. These studies 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). In four of these studies, oromucosal midazolam was compared with rectal diazepam and the measure of effectiveness was the treatment's ability to stop the seizure within 10 minutes. The fifth study compared buccal midazolam with intravenous diazepam, where the measure of effectiveness was the treatment's ability to stop the seizure within 5 minutes.

What benefit has Buccolam shown during the studies?

Reports from the published literature confirmed that oromucosal midazolam is effective in stopping seizures in children. In the four studies, 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. When comparing buccal midazolam with intravenous diazepam, the results were also very similar.

What is the risk associated with Buccolam?

The most common side effects with Buccolam (seen in more than 1 patient in 10) are sedation, somnolence (sleepiness), depressed levels of consciousness, respiratory depression and nausea (feeling sick) and vomiting. For the full list of all side effects reported with Buccolam, see the package leaflet.

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 has Buccolam been approved?

Based on the results of the studies presented, the CHMP concluded that Buccolam is at least as effective as existing treatments for stopping acute prolonged, convulsive seizures in children. Although intravenous medicines may take less time to start working once injected, it takes time to gain access to the veins, especially in children. Buccolam has the advantage of being quicker and easier to administer 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. The Committee therefore decided that Buccolam's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Buccolam

The European Commission granted a marketing authorisation valid throughout the European Union for Buccolam on 5 September 2011.

The full EPAR for Buccolam can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Buccolam, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2011.