EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Buccolam (midazolam)
Oromucosal solution (2.5 mg; 5 mg; 7.5 mg and 10 mg prefilled syringes)

Indication	Buccolam is used to stop prolonged, acute (sudden) convulsive seizures in children and adolescents (from three months to less than 18 years of age).
Reason for shortage	In April 2014, Buccolam was recalled from the market in some EU Member States following the detection of deficiencies in the manufacturing process, which raised concerns about a potential risk of contamination with another medicine produced at the same site where Buccolam is produced. The problems have been addressed by the company and the shortage is now resolved.
Member States affected	Temporary supply disruptions occurred in some EU Member States where Buccolam was marketed (Finland, France, Germany, Italy and Spain).
Information to healthcare professionals	• Normal supply of Buccolam (all strengths) has now resumed and Buccolam can be prescribed again to patients. • Additional advice may be available from the national competent authority.
Information to parents and carers	• Problems with the supply of Buccolam are now resolved. • Buccolam (all strengths) may be prescribed again by your doctor. • Parents or carers who have any questions should speak to their doctor or pharmacist. • Additional advice may be available from your national competent authority.
Status	Resolved
Last updated on	30 March 2015

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