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Refusal of the marketing authorisation for KemSu (sufentanil/ketamine)

The European Medicines Agency has recommended the refusal of the marketing authorisation for KemSu, a medicine intended for the management of acute pain in children and adolescents.

The Agency issued its opinion on 23 July 2026. The company that applied for authorisation, Proveca Pharma Limited, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is KemSu and what was it intended to be used for?

KemSu was developed as a medicine to manage acute (sudden, short-term) pain in children aged 1 to less than 18 years. It was to be given as a spray into the nose by a healthcare professional experienced in treating pain and in a setting where resuscitation equipment is available and the patient could be monitored.

KemSu contains the active substances sufentanil and ketamine, which are authorised individually in the EU for pain management and anaesthesia (to prevent pain during surgery and other procedures).

How does KemSu work?

The active substances in KemSu act on different receptors (targets) in the brain that are involved in the perception of pain. Sufentanil is an opioid medicine that acts on mu-opioid receptors, while ketamine acts on receptors called NMDA. When KemSu is sprayed into the nose, the two active substances are absorbed into the bloodstream through the blood vessels in the nose. Once in the bloodstream, sufentanil and ketamine act on the receptors in the brain to help relieve the pain.

What did the company present to support its application?

The company submitted data from a study involving 155 children aged 1 to less than 18 who had sought hospital treatment for an injury and who had moderate to severe pain. The children received one dose of KemSu during the hospital visit; a second dose was given 10 to 15 minutes after the first dose if there was insufficient pain relief. The main measure of effectiveness was the proportion of children with a pain score of 4 or below on an age-appropriate pain rating scale (where 0 is no pain and 10 is the worst possible pain). Pain scores were measured twice in the 30 minutes after the first dose. The study only looked at KemSu; it did not compare KemSu to any other treatment or placebo (a dummy treatment).

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The company also provided supportive data, including from a study involving 220 adults who required pain management after dental surgery. They received either KemSu, intranasal sufentanil alone, intranasal ketamine alone or placebo. All patients received two doses with a 60-minutes interval between the doses. Pain was measured at several time points from before the first dose until 180 minutes afterwards, using a numeric rating scale of 0 to 10. The main measure of effectiveness was the overall reduction in pain during the first 55 minutes.

What were the main reasons for refusing the marketing authorisation?

After assessing the available data, the Agency concluded that it was not possible to confirm that giving sufentanil and ketamine together in a fixed-dose combination was more effective at treating pain in children than giving sufentanil alone. Although the study in children showed that the combination reduced pain, KemSu was not compared with another medicine or placebo. The study in adults, which did include intranasal sufentanil as a comparator, found that the combination was not more effective than sufentanil alone at reducing pain.

In terms of safety, the company claimed that giving ketamine together with sufentanil could reduce the risk of opioid-related side effects, since in adults the observed levels of sufentanil in the body were lower with the combination than when given alone, despite the same dose of sufentanil being administered. However, for children the sufentanil levels were based on models, rather than data collected from people given the medicine. The Agency also considered that the company had not provided sufficient evidence that lower sufentanil levels would result in a better safety profile of the combination medicine compared with sufentanil given alone.

There were further safety concerns about the finished product, given that ketamine and sufentanil are highly potent active substances with strictly controlled access. The nasal spray device lacked a lock-out mechanism to prevent repeat use, which carries a risk of accidental overdosing. In addition, a significant amount of the medicine remained in the bottle after use, which could lead to misuse and diversion of the medicine to unlawful distribution channels.

Therefore, the Agency’s opinion was that the benefits of KemSu did not outweigh its risks and it recommended refusing marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that here are no consequences for patients in clinical trials with KemSu.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.