



Medicine Supply Notification

MSN/2023/043

Ketamine (Ketalar[®]) 10mg/1ml solution for injection vial (Schedule 2 controlled drug)

Tier 3 – medium impact*

Date of issue: 6/04/2023

Link: [Medicines Supply Tool](#)

Summary

- UK licensed ketamine (Ketalar[®]) 10mg/1ml solution for injection vials are out of stock until July 2023.
- Unlicensed Swiss ketamine (Ketalar[®]) 10mg/1ml solution for injection have been sourced to cover a portion of the out-of-stock period. Trusts will be allocated this stock until June 2023. This stock will be available by w/c 17th April 2023.
- Where unlicensed ketamine (Ketalar[®]) 10mg/1ml solution for injection is unavailable, ketamine 50mg/1ml solution for injection vials will remain available.

Actions Required

All healthcare professionals in primary and secondary care including hospices, who prescribe, dispense or administer ketamine 10mg/1ml solution for injection vials, working with their local Medication Safety Officer (MSO) should be aware of the following advice:

- where UK licensed ketamine 10mg/1ml solution for injection is unavailable, clinicians should consider prescribing unlicensed Swiss ketamine (Ketalar[®]) 10mg/1ml solution for injection sourced from Pfizer (see Supporting information). Trusts are advised to order stock sensibly in accordance with needs;
- consider prescribing ketamine 50mg/1ml solution for injection where needed taking into account that these products are five times more concentrated and ensuring the appropriate patient safety measures are applied to avoid dosing errors (see below);
- where unlicensed Swiss ketamine (Ketalar[®]) 10mg/1ml solution for injection sourced from Pfizer is unavailable and licensed alternatives are not appropriate, consider prescribing unlicensed ketamine 10mg/1ml solution for injection via importers, taking into account that these products could be twice as potent or in different vial sizes (see patient safety advice in Supporting information);
- ensure Trusts have reviewed and amended local guidance that reference use of ketamine 10mg/1ml solution for injection where there is potential for ketamine 50mg/1ml solution for injection to be used instead. In these circumstances, appropriate patient safety measures should be applied to avoid dosing errors and patient harm, for example, before administering patients with ketamine the volume is checked by two appropriate staff members.

*Classification of Tiers can be found at the following link:

<https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>

Supporting information

Clinical Information

Ketamine injection is a Schedule 2 controlled drug (CD POM) and is licensed for:

- use as an anaesthetic agent for diagnostic and surgical procedures.
- induction of anaesthesia prior to administration of other general anaesthetic agents.
- supplementation of other anaesthetic agents.
- use in specific types of procedures or specific areas of application (see SPC for further details)

There is use of ketamine 10mg/1ml solution for injection in frail adult patients and for analgesia where a lower concentration is required. Ketamine is also used commonly for paediatric anaesthesia, particularly when repeated administration is required (such as for serial burns dressings). Occasionally, it is used in theatres for patients with depression of vital functions, or where depression of vital functions must be avoided; and in the asthmatic patient to minimise the risks of bronchospasm.

Off-label use

It has also been used off-label for the treatment of chronic pain refractory to standard therapies. In these situations, practitioners are of the opinion that alternative treatment options are limited. It is also commonly used off-label as an analgesic adjunct for patients having major surgery.

Patient safety issues with using ketamine 50mg/1ml solution for injection as an alternative

Though supplies of ketamine 50mg/1ml injection are available, use of this product may not be appropriate for delivery of lower doses, particularly when used in paediatrics and for analgesia in adults or paediatrics; and the vial is only intended for single use, with any unused product discarded at the end of each operating session.

Dose error mitigation is essential as there is no antidote to an overdose of ketamine; only supportive measures.

Patient safety issues with using ketamine 10mg/1ml solution for injection from unlicensed importers

In the absence of a suitable alternative in certain scenarios, supplies of unlicensed product is available via pharmaceutical importers but there are potential patient safety issues associated with the imported products as follows:

- Ketamine used in the UK is a racemic mixture of two enantiomers. There is a potential for imported versions to be esketamine (s-ketamine), the S-enantiomer of ketamine, which is about twice as potent as the original product, and thus doses should be halved.
- European-sourced ketamine injection may be available at the same concentrations as used in the UK but the volumes of presentation may differ.
- Trusts are advised to check carefully which version of the product they receive and that communication of the relevant issues outlined above to departments (especially theatres) and practitioners is critical so that patients are not exposed to inadvertent overdoses of the drug.

Risk mitigation is essential as there is no antidote to an overdose of ketamine; only supportive measures.

Pfizer imported Swiss ketamine (Ketalor[®]) 10mg/1ml solution for injection

Pfizer imported Swiss ketamine (Ketalor[®]) 10mg/1ml solution for injection can be ordered once available and in accordance with the allocations in place by calling Pfizer Customer Services (Tel: 0345 608 8866 or Freephone Tel: 0800 032 7907).

For further information on hospital allocations, Trusts should contact their Regional Pharmacy Procurement Specialist (RPPS).

Guidance on ordering and prescribing unlicensed imports

- The following specialist importers have confirmed they can source unlicensed ketamine 10mg/ml solution for injection (please note there may be other companies that can also source supplies):
 - Alium Medical
 - Mawdsleys unlicensed
 - Orifarm
 - Target Healthcare
- Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information:
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC),

Further information

[SPC Ketalar 10 mg/1ml solution for injection](#)

[SPC Ketamine 50 mg/1ml solution for injection](#)

[BNF Anaesthesia \(general\)](#)

Enquiries

Enquiries from NHS Trusts in England should in the first instance be directed to your Regional Pharmacy Procurement Specialist, who will escalate to national teams if required.

REGION	Full Name	Email
Midlands	Andi Swain (East Midlands)	andi.swain@nhs.net
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All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team quoting reference number MSN/2023/043

Email: DHSCmedicinesupplyteam@dhsc.gov.uk.