

20 July 2023

Rapifen Intensive Care 5mg/ml solution for injection (10 x 2ml ampoules): difficulty opening ampoules

Dear Healthcare Professional,

Piramal Critical Care, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you of the following issue with the ampoules impacting Rapifen Intensive Care batches:

Summary

- It has been reported that for Rapifen Intensive Care 5mg/ml batch number 2200509 Exp: 03/2026, healthcare professionals have been unable to open, or found it difficult to open, an ampoule containing the medicine.
- If an attempt is made to open the ampoule without the correct orientation in relation to applying the force, the ampoule will be difficult to open and may shatter.
- This is a hospital product and is administered by trained healthcare professionals (HCPs). In the event of difficulty opening an ampoule, the HCP should retain that ampoule and use another ampoule from the pack.
- Piramal Critical Care commits to replacing any packs that include ampoules that were hard to open ampoule.

Background / brief description of the problem

Rapifen Intensive Care 5mg/ml is a potent opioid analgesic with a very rapid onset of action. It is indicated for analgesia and suppression of respiratory activity in mechanically ventilated patients on intensive care and to provide analgesic cover for painful manoeuvres. Piramal Critical Care has been made aware of difficulties faced by HCPs with opening Rapifen Intensive Care, 2ml ampoules from batch 2200509. Extra force is required to break open the ampoule.

Piramal Critical Care wishes to highlight this issue to assist HCPs in the safe administration of the product. Piramal Critical Care has investigated this reported defect and identified a corrective action at the manufacturing site to address this fault and prevent a future occurrence. The corrective action will be implemented from 31 October 2023.

Advice to healthcare professionals

- If an ampoule is hard to open, follow the instructions in Appendix 1.
- After following the instructions, if the ampoule cannot be opened safely, retain it and select another ampoule from the same pack.
- If this is the last ampoule in the pack, then replace with another ampoule from another pack.
- If this is the last pack, contact your provider and request urgent supply (see returns information below).
- If units have been supplied to any other facilities or departments within your institution, please forward a copy of this letter to them.

Call for reporting

Reporting suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions through the Yellow Card Scheme Website: <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Company contact point

For access to further information, please email medical.information@piramal.com

Replacement and returns

Contact your supplier for returns and replacements following your internal policies. Primal Critical Care has informed suppliers of this potential defect and advised them to treat with urgency any requests for replacements. Primal Critical Care has committed to work with suppliers to replace any returned packs free of charge.

DocuSigned by:
Azhar Salahudeen 20-Jul-2023 | 16:14 BST
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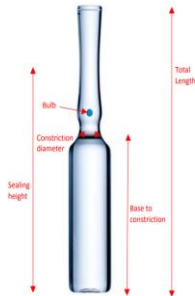
Azhar Salahudeen
Quality Director EU/UK, QP

Appendix 1

Instructions for opening One Point Cut (OPC) ampoules

The ampoules

The medical product is contained in One Point Cut (OPC) ampoules. These ampoules are pre-scored and ready to open without additional scoring. A coloured black dot on the bulbous part of the ampoule indicates the position of the score. OPC ampoules are designed to be opened easily and safely, reducing the risk of splintering and/or sharp edges.



Opening OPC ampoules

- Pick up the ampoule and hold it between your thumb and index finger.



- If there is liquid in the top of the ampoule, gently tap it with a finger of the other hand to get all the liquid into the bottom part of the ampoule.



- Hold the bottom part of the ampoule so that you are looking directly at the coloured dot on the bulbous part of the ampoule. Grasp the top of the ampoule with the other hand: place your thumb onto the black dot and place your index finger from the same hand on the other side (back) of the bulbous part, close to the neck of the ampoule. You are now holding the ampoule with both hands.



- Hold the bottom of the ampoule firmly while pushing the top section away from the black dot with light even pressure. Take care to hold the ampoule in an upright position.
- A light pressure should cleanly snap the ampoule open, whereas using too much force may cause it to shatter. Do not use the medicine if the ampoule shatters.
- If the ampoule does not break as expected, readjust the position of the ampoule in your hands and try again. If the ampoule seems extremely hard to open, do not try to open it by force. Try another ampoule or use an ampoule opener.



Safety advice

- To prevent glass ampoules shattering, take care with the amount of force used.
- Always apply pressure away from the black dot, never in any other direction.
- Avoid any pushing, pulling, or twisting actions while applying pressure on the ampoule to open it.
- If the ampoule does not break as expected, readjust the position of the ampoule in your hands and try again. If the ampoule is extremely hard to open, do not try to open it by force. Try another ampoule or use an ampoule opener.
- Pressure between the index finger and the thumb of either hand can cause the ampoule to break in an unintended manner. This may cause injuries to the operator.
- Do not use the medicine if your ampoule shatters or if the opened ampoule is contaminated with glass after opening.