MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Barium sulfate oral suspension products – 22 August 2023 (UPDATED)	
Details of affected product(s)	Barium sulfate (READI-CAT 2) 2% w/v oral suspension – ARTG 129553 Barium sulfate (LIQUIBAR) 125% w/v oral suspension – ARTG 29913 Barium sulfate (LIQUIBAR CT) 2.2% w/w oral suspension – ARTG 58226 Barium sulfate (X-OPAQUE-HD) 976.5 mg/g powder for oral suspension – ARTG 29912
Reason for communication	Disruption to supply due to manufacturing issues. Medication Safety Communication has been **UPDATED** to reflect current alternatives available via the TGA Special Access Scheme (SAS) and under Section 19A (S19A) of the Therapeutic Goods Act.
Date issue made apparent	24 May 2022
Supply impact dates	Unclear

Main indications and use

Barium sulfate oral suspension is a radiographic contrast agent used for double-contrast examinations to visualise the oral, pharyngeal and gastrointestinal (GI) tract in patients.

Situation

Sponsors of the Australian registered barium sulfate products have been unable to provide consistent supply to the market over the past 18 months due to manufacturing issues, with no expected date of resolution available. All oral barium sulfate products registered for use in Australia are impacted by this disruption to supply.

Alternative agents

Medsurge have received approval under Section 19A (S19A) of the Therapeutics Goods Act to import supply of an alternative product Barium sulfate (E-Z-HD) 98% w/w powder for oral suspension from the United States of America until **28 February 2024**. See TGA S19A approvals database for further information.

Other alternative products registered internationally are available via the Therapeutic Goods Administration's Special Access Scheme (SAS) from multiple suppliers e.g., Link Healthcare, Pro Pharmaceuticals Group, Reach Pharmaceuticals and Medsurge Healthcare.

International alternatives may differ from the ARTG listed products with regard to presentation, storage and excipients. It is recommended that a review of the included Product Information occur prior to use. For example, the S19A alternative, E-Z-HD, is presented as powder for oral suspension and requires reconstitution prior to administration.

Precautions, safety issues and other considerations associated with alternatives

To ensure timely access to international alternatives available via S19A and SAS, it is recommended that:

- Sites have accounts set up with the relevant suppliers to enable timely access to these alternatives.
- Supplier and product details are set up in Oracle to allow for smooth ordering and receipting of products that may not have been held before.
- Sites consider the lead time to process orders and are proactive in placing orders. This may include placing back orders with suppliers. As products are being imported from international locations, lead times may be variable and considerable e.g., 14 business days.

If utilising SAS stock, **the relevant paperwork** (available on this page) must be filled out for each individual patient and submitted to the TGA within 28 days. Prescribers may have the SAS form submitted to the TGA on their behalf by another health practitioner. It is recommended that local protocols regarding the submission of SAS forms be consulted.

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Impacts of this communication on clinical practice

Actions to address the disruption to supply of barium sulfate oral suspension should be coordinated and implemented by the local Drug and Therapeutics Committee and Clinical Product Managers. SAS alternatives are available and can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy references

PD2022_032 Medication Handling

PD2019_019 Coordination of responses to urgent system-level medicine or medical device issues

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
HealthShare NSW (Category Manager – Strategic Procurement) – Noman.Masood@health.nsw.gov.au