NSW Health

Disruption to supply – Azithromycin 200 mg/5 mL powder for oral suspension

SAFETY NOTICE 010/24

Issue Date:	30 May 2024
	Chief Executives; Directors of Clinical Governance.
KEY MESSAGE:	NSW Health facilities are informed of the current disruption to the supply of azithromycin 200 mg/5 mL powder for oral suspension
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	1. Distribute this Safety Notice to all relevant clinicians and clinical departments where azithromycin 200 mg/5 mL powder for oral suspension is held, prescribed, and administered, and include this Safety Notice in relevant handovers and safety huddles. 2. Undertake a local risk assessment and incorporate the below recommendation to manage the disruption to supply. 3. Ensure a system is in place to document actions taken in response to this Safety Notice. 4. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims⁺. 5. Confirm receipt and distribution of this Safety Notice within **72 hours** to: CEC-MedicationSafety@health.nsw.gov.au.
DEADLINE:	COB 4 June 2024
We recommend you also inform:	Directors, Managers and Staff of: • Infectious Disease and Microbiology • Pharmacy • Nursing/Midwifery • Medical Services • Drug and Therapeutics Committees • Respiratory, Paediatric and Emergency Departments All other relevant clinicians, departments and committees.
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	November 2024

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au

Situation

There is a current disruption to the supply of the Australian registered medicine azithromycin (Zithromax) 200 mg/5 mL powder for oral suspension (AUST R: 60049) due to unexpected increases in consumer demand. Refer to the Therapeutic Goods Administration (TGA) Medicine shortage reports database for the most up-to-date information about supply impact dates.

The disruption to supply coincides with an increase in the number of *Mycoplasma pneumoniae* infections in NSW. The increase in cases has also impacted the supply of other macrolide antimicrobials, such as clarithromycin (Klacid) 250 mg/5 mL powder for oral liquid, which has limited availability.

At the time of publication, supply of alternative formulations of azithromycin, including oral tablets and powder for intravenous infusion, remain unaffected. The supply of internationally registered alternatives of azithromycin powder for oral suspension are available via the TGA's Special Access Scheme (SAS). Note that supply of alternative agents via Section 19A (S19A) of the *Therapeutic Goods Act 1989* are under consideration. NSW Health staff are advised to check the TGA website for updates regarding further changes to supply and the TGA S19A approvals database for updates on potential S19A alternatives.

Background

Azithromycin is a macrolide antimicrobial used to treat and prevent infections caused by susceptible bacteria including, but not limited to *Mycoplasma pneumoniae*, *Mycobacterium avium complex* (MAC), and *Bordatella pertussis.*

Azithromycin powder for oral suspension is used in paediatric patients and patients with enteral feeding tubes or swallowing difficulties. It is listed on the NSW Medicines Formulary with a restriction for use in accordance with the local antimicrobial stewardship policy.

Assessment

Remaining supply of the Australian registered azithromycin 200 mg/5 mL powder for oral suspension should be prioritised for paediatric populations and patients where alternative azithromycin formulations are not suitable. International alternatives may be considered for these patients if the Australian registered product is unavailable.

The international alternatives differ to the Australian registered product in presentation, storage requirements and excipients (see Table 1 for comparison and Figure 1 for product images).

In case of a complete disruption to supply of the powder for oral suspension, and alternative formulations of azithromycin are inappropriate, an alternative antibiotic will need to be used.

Recommendations

- Assess the current status and availability of azithromycin 200 mg/5 mL powder for oral suspension in each facility, ensuring all locations of stock are identified.
- Limit supply of azithromycin 200 mg/5 mL powder for oral suspension available in clinical areas (on 'imprest') while ensuring availability outside pharmacy operating hours.
- Ensure back orders based on average usage are placed with preferred wholesalers/suppliers for adequate distribution of stock when it becomes available.
- If international alternatives are used, consider important information provided in Table 1 for example, excipients not present in Australian registered product.

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au

- Reserve remaining supply of azithromycin 200 mg/5 mL powder for oral suspension for use when crushed oral tablet formulations are not suitable, for example:
    - patients requiring a non-solid oral dosage form where the prescribed dose is **not equivalent** to a full or half (scored formulations only) tablet –for example, **paediatric patients**
    - discharge supply.
- Reserve supply of Australian registered product azithromycin (Zithromax) 200 mg/5 mL powder for oral suspension for patients under 6 months of age.
- Use crushed tablets for all other patients who require a non-solid oral dosage form where the prescribed dose is equivalent to a full or half (scored formulations only) tablet. A mask and gloves should be worn when crushing the tablets (see SHPA Don't Rush to Crush, accessible via CIAP for further information).
    - Where crushed tablets are intended, this should be clearly specified on the medication order. For example, as an 'order comment' on the electronic Medication Management (eMM) system.
- Ensure that a suitable quantity is dispensed to the patient considering clinical indication and duration of treatment.
- Regularly review prescriptions for azithromycin for oral suspension and assess ongoing need for use.
- In case of a complete disruption to the supply, clinicians should carefully consider individual patient factors, condition being treated, and microorganism being targeted when selecting an alternative agent. Expert advice should be sought from Infectious Diseases/Microbiology if required.
- Establish regular liaison between Microbiology and Pharmacy Departments to discuss local stock situation and to help inform antibiotic susceptibility testing and reporting.

Figure 1. Image of international alternative product labels (L – R: Epic, Zydus and Teva brands)

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au

Table 1. Comparison between Australian registered azithromycin and international alternatives.

	ARTG listed product	**International alternative**		
	Azithromycin (**Zithromax**) powder for oral suspension	Azithromycin (**Epic**) powder for oral suspension	Azithromycin (**Zydus**) powder for oral suspension	Azithromycin (**Teva**) USP powder for oral suspension
Country of registration	Australia	USA	USA	USA
Current access pathway – *subject to change*	ARTG	SAS	SAS	SAS
Supplier(s)	Pfizer	Link Healthcare, Orspec	Medsurge	Pro Pharmaceuticals
Active ingredient	Azithromycin dihydrate	Azithromycin monohydrate	Azithromycin dihydrate	Azithromycin monohydrate
Final concentration	200 mg/5 mL	200 mg/5 mL	200 mg/5 mL	200 mg/5 mL
Reconstituted volume	15 mL	15 mL	**30 mL**	**30 mL**
Specific patient considerations	Not specified. Australian guidance supports use from birth.	As per US Product Information: *Safety and effectiveness in the treatment of patients under 6 months of age have not been established.*		
Excipients	• Sucrose • Tribasic sodium phosphate • Hyprolose • Xanthan gum • Spray dried artificial cherry 11929 (ARTG PI No 2470) • Spray dried artificial banana 15223 (ARTG PI No 2469) • Crema vaniglia N 11489 Polvere SC613737 AR (ARTG PI No 117797)	• Sucrose • Colloidal silicon dioxide • FD & C Red No. 40 Aluminum Lake • Hydroxypropyl cellulose • Sodium phosphate tribasic anhydrous • Natural and artificial banana flavour • Natural and artificial cherry flavour • Xanthan gum	• Sucrose • Trisodium phosphate anhydrous • Hydroxypropyl cellulose • Xanthan gum • FD&C Red No. 40 • Cherry flavour • Ripe banana flavour	• Sucrose • Amino methacrylate copolymer • banana flavour • cherry flavour • Colloidal silicon dioxide • FD&C Red No. 40 • Hydroxypropyl cellulose • Tribasic sodium phosphate anhydrous • Vanilla flavour • Xanthan gum
Labelling	English	English	English	English
Storage requirements				
Dry powder	Below 30°C	Below 30°C	20 – 25°C	20 – 25°C
Reconstituted suspension	Below 30°C	5 – 30°C	5 – 30°C	5 – 25°C
Shelf life (reconstituted)	Use within 10 days	Use within 10 days	Use within 10 days	Use within 10 days
Lead time	Refer to wholesaler and supplier portals	Contact suppliers for further information on availability and lead times (noting that lead times are variable and can be lengthy).		

Contact: Clinical Excellence Commission
02 9269 5500
CEC-MedicationSafety@health.nsw.gov.au