

UPDATED: Disruption to supply – rifampicin 300 mg capsules



N SAFETY NOTICE 010/26

Issue date:	21 April 2026
Content reviewed by:	Medication Shortage Assessment and Management Team, Medication Safety Expert Advisory Committee, Antimicrobial Stewardship Expert Advisory Committee, Communicable Diseases Branch – Health Protection NSW, ACI Respiratory Network, Infectious Diseases experts and State Preparedness and Response Unit
Distributed to:	Chief Executives, Directors of Clinical Governance
KEY MESSAGE:	NSW Health facilities are informed of the ongoing disruption to the supply of rifampicin 300 mg capsules, availability of international alternatives, and clinical recommendations for managing this disruption to supply.
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	<ol style="list-style-type: none"> 1. Distribute this Safety Notice to all relevant clinicians and clinical departments where rifampicin 300 mg capsules are 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 recommendations to manage the disruption to supply. Ensure a system is in place to document actions taken in response to this Safety Notice. 3. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims+.
We recommend you also inform:	<p>Directors, Managers and Staff of:</p> <ul style="list-style-type: none"> • Infectious Diseases and Microbiology • Respiratory Departments • Tuberculosis (TB) Services (includes Chest Clinics) • Public Health Units • Emergency Departments • Intensive Care Units • Relevant outpatient clinics • Medical Services • Nursing and Midwifery Services • Pharmacy Services <p>Drug and Therapeutics Committees All other relevant clinicians, departments and committees</p>
Website:	https://www.health.nsw.gov.au/sabs/Pages/default.aspx http://internal.health.nsw.gov.au/quality/sabs/index.html
Review date:	21 October 2026

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What has been updated since SA:004/25?

This Safety Notice replaces SA:004/25 *Critical disruption to supply: rifampicin 300 mg capsules (multiple brands)* which has now been **rescinded**. This Safety Notice has been updated to reflect new information regarding the supply of both Australian-registered and internationally-registered rifampicin products. Recommendations for priority indications have been updated to reflect improvements to the supply chain; all other recommendations remain unchanged.

Situation

There are ongoing disruptions to the supply of rifampicin (Rifadin®) 300 mg capsules due to a global shortage of the active pharmaceutical ingredient (API). Supply is expected to resume by 30 June 2026.

Disruptions to the supply of the alternative Australian-registered rifampicin products (including the 150 mg capsules and oral liquid alternative) have now resolved.

A number of international alternatives are available under the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS) and under Section 19A (S19A) of the *Therapeutic Goods Act 1989*. 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

Rifampicin is a rifamycin-class antimicrobial used to treat and prevent various infections including tuberculosis, leprosy and pulmonary *Mycobacterium avium* complex (MAC) infection.

Rifampicin is restricted on the [NSW Medicines Formulary](#) for 'use as per the *Therapeutic Guidelines OR on the advice of an Infectious Diseases/Microbiology or Respiratory service*'.

Assessment

Wholesaler supply of the Australian-registered rifampicin products has begun to improve, however, access to supply may remain intermittent due to fluctuations in supply chain logistics and consumer demand.

The S19A and SAS alternatives included in **Appendix A** are identical to the Australian-registered product in active ingredient, strength, presentation, and storage requirements. Refer to **Appendix A** for details on differences between the Australian-registered product and international alternatives.

Some rifampicin- and rifapentine-containing fixed dose combination preparations for tuberculosis are available in the NSW Managed Inventory at Link Healthcare. Stock levels will be regularly updated on the [Tuberculosis \(TB\) Treatment Resources webpage](#). Please note, the combination products are not suitable for all patients.

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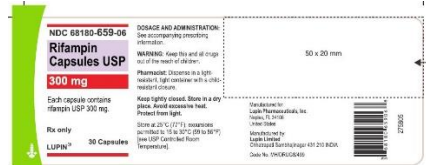
Recommendations

- Supply of rifampicin capsules held by NSW Health facilities **should be prioritised** for the following indications:
 - Treatment of active tuberculosis as part of a multi-drug regimen.
 - Rifampicin-based tuberculosis preventive therapy.
 - *Mycobacterium kansasii* infection.
 - Treatment of leprosy.
 - Staphylococcal and culture negative prosthetic joint infection and residual hardware following surgery.
- Where possible, consider alternative therapies for all other indications as outlined in **Appendix B**.
 - Microbiological findings should guide the treatment of infectious diseases, and expert advice from Infectious Diseases/Microbiology should be sought when necessary.
- Develop a local plan to manage the disruption to the supply of rifampicin capsules that includes (but is not limited to):
 - Assessing the current status and availability of rifampicin in each facility, ensuring all locations where stock is held are identified (for example, stock held in tuberculosis clinics).
 - Determining the ongoing needs for priority indications and ability to obtain supply of alternatives as outlined in **Appendix B**.
 - Dispensing minimum quantities for inpatient use and smaller quantities for outpatient supply (i.e. 2 to 4 weeks at a time) until supply returns to normal.
 - Identification of the most suitable alternative option(s) based on local usage and clinical needs, and account for the lead time/availability of any international alternatives.
 - Ensuring back orders are in place with regular wholesalers/suppliers to ensure supply of the Australian-registered product is received when it is available.
- Ensure clinicians are aware of the differences between the Australian-registered product and the SAS/S19A alternatives, including the difference in pack size and additional excipients.
- Ensure patients receiving supply of the international alternatives for outpatient use are counselled on the differences between these products and their usual brand.
- Regularly review prescriptions for rifampicin and assess ongoing need for use.
- Establish regular communication between Tuberculosis (TB) Services, Infectious Diseases, Microbiology, Antimicrobial Stewardship teams and Pharmacy Departments to regularly review the local supply situation and guide the local response.

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Appendix A: Comparison of Australian-registered product and S19A/SAS alternatives.

	Australian-registered product Rifadin®	International alternative Rifadine® SAS	International alternative Lupin® S19A
Active ingredient	Rifampicin 300 mg		
Excipients	Maize starch Magnesium stearate Titanium dioxide Erythrosine Indigo carmine Gelatin	Corn starch Magnesium stearate Titanium dioxide Erythrosine Indigotine Gelatin	Corn starch Magnesium stearate Titanium dioxide Crospovidone D & C Red no. 28, FD & C Blue no. 1 FD & C Red no. 40 Gelatin Potassium hydroxide Pregelatinized starch Propylene glycol Shellac Sodium lauryl sulphate
Presentation	Capsule		
Pack size	100 capsules – blister pack	50 capsules – blister pack	30 capsules – bottle (via Pro Pharmaceutical Group) 60 capsules – bottle (via Pro Pharmaceutical Group and Medsurge)
Labelled language	English	Non-English (German). Note: active ingredient and strength are clearly distinguishable.	English
Storage	Store below 25°C.		
Product image/artwork			

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Appendix B: Rifampicin indications and suitable alternative(s) where available.

	Indication for use	Recommended alternative(s)	Additional information
Indications where rifampicin are to be used or continued	Treatment of active tuberculosis disease	No alternatives – rifampicin to be used as part of a multi-drug regimen.	4- and 2-drug adult fixed-dose combination tablets for treatment of tuberculosis are available through Link Healthcare and TGA Special Access Scheme .
	<i>Mycobacterium kansasii</i> infection		
	Treatment of leprosy		
	Treatment of latent tuberculosis infection (tuberculosis preventative therapy)	Where available and appropriate, rifapentine plus isoniazid OR isoniazid monotherapy can be used in accordance with the NSW Health Guideline <i>Testing diagnosis and Management of TB Infection (GL_2024_015)</i> . Rifampicin monotherapy or rifampicin plus isoniazid may be used where it is considered the most clinically suitable regimen.	Rifapentine may be available through Link Healthcare and the TGA Special Access Scheme .
Staphylococcal and culture negative prosthetic joint infection and residual hardware following surgery	Use of adjunctive rifampicin may be warranted in combination with pathogen specific antimicrobials as per UpToDate .		

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Appendix B (continued): Rifampicin indications and suitable alternative(s) where available.

	Indication for use	Recommended alternative(s)	Additional information
Indications where alternatives are to be utilised	<i>Amanita phalloides</i> mushroom poisoning	Silibinin or benzylpenicillin as per Therapeutic Guidelines .	Silibinin is available via the TGA Special Access Scheme .
	<i>Bartonella</i> endocarditis	Doxycycline plus gentamicin as per Therapeutic Guidelines .	-
	Brucellosis	Gentamicin plus trimethoprim+sulfamethoxazole (children 1 month to 8 years) or doxycycline (for adults and children 8 years or older) as per Therapeutic Guidelines .	Rifampicin can be considered as a second line option in combination with doxycycline or trimethoprim+sulfamethoxazole if gentamicin is contraindicated.
	Cholestatic itch in palliative care	Sertraline as per Therapeutic Guidelines .	Rifampicin 150 mg is used for this indication.
	<i>Haemophilus influenzae</i> – clearance antibiotics	Ceftriaxone as per Therapeutic Guidelines .	Not applicable
	Leprosy (Hansen’s disease) post-exposure prophylaxis	Rifapentine for patients 10 years and older as per NSW Health Leprosy control guideline .	Rifampicin oral liquid should be used for patients 9 years and younger. Rifapentine is available via the TGA Special Access Scheme .
	Meningococcal disease – clearance antibiotics	Ciprofloxacin or ceftriaxone as per Therapeutic Guidelines .	
	MRSA native bone/joint infection	Clindamycin, doxycycline, or trimethoprim+sulfamethoxazole as per Therapeutic Guidelines .	Rifampicin (in combination with ciprofloxacin or sodium fusidate) to only be considered if resistant to other oral drugs and susceptibility is confirmed.
	<i>Mycobacterium ulcerans</i> infection (Buruli ulcer)	Moxifloxacin plus clarithromycin as per Therapeutic Guidelines .	Not applicable.
	Pulmonary <i>Mycobacterium avium</i> complex (MAC) infection	Use three-drug regimen of azithromycin or clarithromycin plus ethambutol plus rifabutin as per Therapeutic Guidelines . For those who are already on guideline-based therapy, consider switching from rifampicin to rifabutin.	Rifabutin is not suitable for use in an intermittent (3x weekly) regimen. For complex cases, refer to the national NTM reference group.