

Critical disruption to supply: rifampicin 300 mg capsules (multiple brands)



! SAFETY ALERT 004/25

Issue Date:	27 June 2025
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 current disruption to the supply of rifampicin 300 mg capsules, availability of international alternatives, and clinical recommendations for managing this disruption to supply (including need for urgent action to ensure supply is preserved for priority indications).
ACTION REQUIRED BY:	Chief Executives, Directors of Clinical Governance
REQUIRED ACTION:	<ol style="list-style-type: none"> 1. Distribute this Safety Alert to all relevant clinicians and clinical departments where rifampicin 300 mg capsules are held, prescribed, and administered, and include this Safety Alert 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 Alert. 3. Report any incidents associated with this disruption to supply into the local incident management system e.g., ims+. 4. Confirm receipt of this Safety Alert by 30 June 2025 via return email to CEC-MedicationSafety@health.nsw.gov.au.
DEADLINE:	30 June 2025
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:	February 2026

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Situation

There is a current disruption 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 January 2026.

The alternative Australian-registered product, rifampicin (Rimycin®) 300 mg capsules, is also unavailable due to increased demand. Additionally, the supply of rifampicin 150 mg capsules (both Rifadin and Rimycin brands) and rifampicin oral liquid (Rifadin) are limited and are also expected to be impacted.

Sanofi® has received approval under Section 19A (S19A) of the *Therapeutic Goods Act 1989* to import supply of rifampicin (Rifadine®) 300 mg capsules from Belgium until 28 February 2026, with limited supply available. International alternatives are also available through the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS) from Belgium via Medsurge, and from the USA via Pro Pharmaceuticals Group and Medsurge.

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 in accordance with the local antimicrobial stewardship policy'.

Assessment

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 S19A alternative.

Both S19A and SAS alternatives are expected to have limited and uncertain ongoing availability due to continued global manufacturing issues resulting from the API shortage. CEC and HealthShare NSW are partnering on the procurement of international alternatives. Supply of the Section 19A product has been allocated to NSW by the drug sponsor and will be managed by HealthShare NSW.

Urgent action is required to ensure that the supply of rifampicin capsules is preserved for priority indications where alternatives are not readily available or suitable.

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 at the [TB Treatment Resources webpage](#). Please note, the combination products are not suitable for all patients.

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Recommendations

- All remaining supply of rifampicin capsules held by NSW Health facilities **is to be prioritised** for the following indications:
 - Completion (only) of 4 months of rifampicin TB preventive therapy which has already been commenced.
 - Treatment of active tuberculosis as part of a multi-drug regimen.
 - *Mycobacterium kansasii* infection.
 - Treatment of leprosy.
 - Staphylococcal and culture negative prosthetic joint infection and residual hardware following surgery.
- Facilities **must use alternative therapies for all other indications wherever possible** 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 ARTG products 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 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 SAS alternatives.

	<i>Australian-registered product</i> Rifadin®	<i>International alternative</i> Rifadine®	<i>International alternative</i> Lupin®
Supply arrangements	Australian Register of Therapeutic Goods (ARTG)	S19A via Sanofi SAS via Medsurge	SAS via Pro Pharmaceutical Group and Medsurge
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.		
Additional notes	-	Medsurge (SAS) – lead time of 15 business days	Medsurge (SAS) – lead time of 15 business days
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 Pharmaceuticals and TGA Special Access Scheme.
	<i>Mycobacterium kansasii</i> infection		
	Treatment of leprosy		
	Treatment of latent tuberculosis infection	<p>Patients that have already commenced 4 months of rifampicin TB preventive therapy should remain on this therapy wherever possible.</p> <p>For patients commencing on TB preventive therapy – use rifapentine plus isoniazid OR isoniazid as per NSW Health Guideline <i>Testing diagnosis and Management of TB Infection (GL_2024_015)</i>.</p>	<p>Where possible, other regimens should be used for TB preventive therapy, or TB preventive therapy deferred.</p> <p>Rifapentine/Isoniazid 300mg/300mg fixed dose combination tablets are available through Link Pharmaceuticals and TGA Special Access Scheme.</p> <p>Rifapentine 150mg may be available via the TGA <u>Special Access Scheme</u>.</p>
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 <u>UpToDate</u> .		

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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 <u>Therapeutic Guidelines</u> .	Silibinin is available via the TGA <u>Special Access Scheme</u> .
	<i>Bartonella</i> endocarditis	Doxycycline plus gentamicin as per <u>Therapeutic Guidelines</u> .	-
	Brucellosis	Gentamicin plus trimethoprim+sulfamethoxazole (children 1 month to 8 years) or doxycycline (for adults and children 8 years or older) as per <u>Therapeutic Guidelines</u> .	Rifampicin to only 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 <u>Therapeutic Guidelines</u> .	Rifampicin 150 mg is used for this indication.
	<i>Haemophilus influenzae</i> – clearance antibiotics	Ceftriaxone as per <u>Therapeutic Guidelines</u> .	Not applicable
	Leprosy (Hansen’s disease) post-exposure prophylaxis	Rifapentine for patients 10 years and older as per <u>NSW Health Leprosy control guideline</u> .	Rifampicin oral liquid should be used for patients 9 years and younger. Rifapentine is available via the TGA <u>Special Access Scheme</u> .
	Meningococcal disease – clearance antibiotics	Ciprofloxacin or ceftriaxone as per <u>Therapeutic Guidelines</u> .	
	MRSA native bone/joint infection	Clindamycin, doxycycline, or trimethoprim+sulfamethoxazole as per <u>Therapeutic Guidelines</u> .	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 <u>Therapeutic Guidelines</u> .	Not applicable.
	Pulmonary <i>Mycobacterium avium</i> complex (MAC) infection	Use three-drug regimen of azithromycin or clarithromycin plus ethambutol plus rifabutin as per <u>Therapeutic Guidelines</u> . 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.