Prescribing Protocol SESLHDPR/657
Standard short-course therapy for Tuberculosis (TB) with Fixed Dose Combination (FDC) tablets

Health
South Eastern Sydney
Local Health District

Prescribing Protocol	
Title	Standard short-course therapy for Tuberculosis (TB) with Fixed Dose Combination (FDC) tablets
Areas where Protocol/ Guideline applicable	Hospital inpatients Outpatients seen by Respiratory tuberculosis (TB) clinic or Infectious Diseases (ID) clinic
Areas where Protocol/ Guideline not applicable	Paediatrics
Authorised Prescribers	Respiratory physician, Infectious Diseases physician
Indication for use	Standard short course treatment of patients with fully susceptible tuberculosis (TB)
Clinical condition	Tuberculosis (TB) – fully susceptible
Contra-indications	Multi-drug resistant tuberculosis Patients with some specific medical conditions (e.g. intolerance to certain TB drugs, liver or renal function impairment) are likely to **require individual medication dose adjustment which can be done with separate drug formulations only** Hypersensitivity Jaundice (rifampicin) Some antiretroviral drugs for HIV infection (rifampicin) Gout (pyrazinamide) Optic neuritis (ethambutol)
Precautions	Seizures (isoniazid)
Place in Therapy	Standard short-course therapy for TB, 1st line, fully susceptible TB or awaiting sensitivities.
Dosage	Fixed dose combination (FDC) tablet component dosages should approximate the dosages that would be prescribed in separate medications. Some important points to consider: • avoid overdose of Ethambutol (use caution in the range 15-20mg/kg; and do not exceed 20mg/kg) • avoid under-dosing of other components i.e. may need to add single agents to the FDC tablet • if regimen becomes too complex or fails to approximate required doses, do not use FDC tablet(s) *Tablet: rifampicin 150 mg / isoniazid 75mg / pyrazinamide 400mg / ethambutol 275 mg* **For use in the intensive phase of therapy** <50 kg: Use separate drug formulations or seek TB specialist advice 50-70 kg: 4 tablets a day >70 kg: Use separate drug formulations or seek TB specialist advice

	Tablet: rifampicin 150 mg / isoniazid 75 mg **For use in the continuation phase of therapy** <50 kg: Use separate drug formulations or seek TB specialist advice 50-70 kg: 4 tablets a day Note: The tablets are film-coated to mask the bitter taste, but can be crushed for patients with swallowing difficulties. Alternatively, the dispersible tablet formulation can be used. *Dispersible tablet: rifampicin 75 mg / isoniazid 50 mg* **For use in patients with swallowing difficulties** <42 kg: Use separate drug formulations or seek TB specialist advice 42-48 kg: 6 tablets dissolved in 60 mL water and given once a day 49-56 kg: 7 tablets dissolved in 70 mL water and given once a day >56kg: 8 tablets dissolved in 80 mL water and given once a day Note: If the dispersible tablet is used in the intensive phase of therapy, pyrazinamide and ethambutol will need to be given separately.
Duration of therapy	Two months of intensive phase, then four months of rifampicin and isoniazid continuation phase.

Other criteria	All patients commenced on fixed dose combination TB regimens require completion of SAS Category A form for both phases of therapy.
Important Drug Interactions	Rifampicin is a potent CYP enzyme inducer. Doses of CYP substrates will need to be adjusted accordingly. Some drugs are contraindicated – refer to TGA Product Information for rifampicin for details.
Administration instructions	Administer at least one hour before or two hours after a meal Pyridoxine supplementation also required for patients at increased risk of peripheral neuropathy (isoniazid)
Monitoring requirements	EUCs, LFTs, FBCs, serum uric acid Visual acuity (ethambutol)
Management of complications	As per current management with separate TB drug formulations.
Basis of Protocol/Guideline (including sources of evidence, references)	Guidelines for treatment of drug-susceptible tuberculosis and patient care, 2017 update. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO. Latent tuberculosis infection: updated and consolidated guidelines for programmatic management. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.
Groups consulted in development of this protocol	Dr Hazel Goldberg – POWH/SGH Respiratory Physician A/Prof Jeffrey Post and Dr Kristen Overton – POWH ID Physicians Medication Safety Pharmacist and ID Pharmacist, POWH

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GOVERNANCE	
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