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

Health
South Eastern Sydney
Local Health District

Prescribing Protocol	
Title	Standard short-course therapy for Tuberculosis (TB) with Fixed Dose Combination 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 *Please note this medication will require an SAS form (Category A and B) to be completed, for both phases of therapy (intensive phase and continuation phase)*
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	*Intensive phase* (Rifampicin 150 mg / isoniazid 75mg / pyrazinamide 400mg / ethambutol 275 mg) <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 *Continuation phase* (rifampicin 150 mg / isoniazid 75 mg) <50kg: 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
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 and Category B 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

AUTHORISATION	
Author (Name)	Adriana Chubaty
Position	Senior Pharmacist, Antimicrobial Stewardship
Department	Pharmacy, Prince of Wales Hospital
Department Contact (for ongoing maintenance of Protocol/Guideline)	Adriana.Chubaty@health.nsw.gov.au (02) 9382 2338
GOVERNANCE	
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