















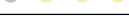









































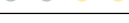



























# Tuberculosis Treatment Guide & Patient Information

1st and 2nd Phase Treatments

A prescribing and treatment guide for the primary treatment of Tuberculosis in adults.

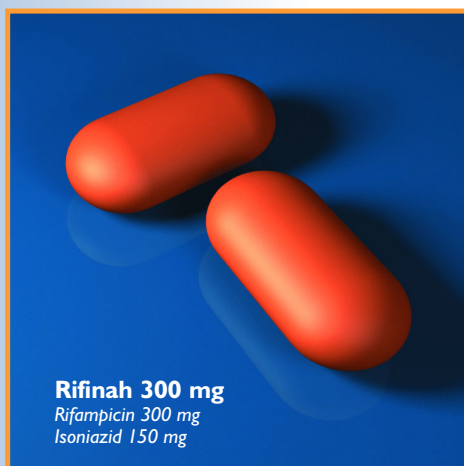
# TB MEDICATION - Dosage Reference Guide

## Phase I<sup>1</sup>

Body weight (Kg)	Ethambutol Hydrochloride 15mg/Kg (actual)	Ethambutol Hydrochloride Dosage	Ethambutol Hydrochloride 400mg (Grey) 100mg (Yellow)	Rifater <small>1 pink tablet tablet contains</small>
40	600mg	600mg	1 + 2 	and 4 
41	615mg	600mg	1 + 2 	and 4 
42	630mg	600mg	1 + 2 	and 4 
43	645mg	600mg	1 + 2 	and 4 
44	660mg	700mg	1 + 3 	and 4 
45	675mg	700mg	1 + 3 	and 4 
46	690mg	700mg	1 + 3 	and 4 
47	705mg	700mg	1 + 3 	and 4 
48	720mg	700mg	1 + 3 	and 4 
49	735mg	700mg	1 + 3 	and 4 
50	750mg	800mg	2 x Grey 	and 5 
51	765mg	800mg	2 x Grey 	and 5 
52	780mg	800mg	2 x Grey 	and 5 
53	795mg	800mg	2 x Grey 	and 5 
54	810mg	800mg	2 x Grey 	and 5 
55	825mg	800mg	2 x Grey 	and 5 
56	840mg	800mg	2 x Grey 	and 5 
57	855mg	900mg	2 + 1 	and 5 
58	870mg	900mg	2 + 1 	and 5 
59	885mg	900mg	2 + 1 	and 5 
60	900mg	900mg	2 + 1 	and 5 
61	915mg	900mg	2 + 1 	and 5 
62	930mg	900mg	2 + 1 	and 5 
63	945mg	900mg	2 + 1 	and 5 
64	960mg	1g	2 + 2 	and 5 
65	975mg	1g	2 + 2 	and 6 
66	990mg	1g	2 + 2 	and 6 
67	1005mg	1g	2 + 2 	and 6 
68	1020mg	1g	2 + 2 	and 6 
69	1035mg	1g	2 + 2 	and 6 
70	1050mg	1.1g	2 + 3 	and 6 
71	1065mg	1.1g	2 + 3 	and 6 
72	1080mg	1.1g	2 + 3 	and 6 
73	1095mg	1.1g	2 + 3 	and 6 
74	1110mg	1.1g	2 + 3 	and 6 
75	1125mg	1.1g	2 + 3 	and 6 
76	1140mg	1.1g	2 + 3 	and 6 
77	1155mg	1.2g	3 x Grey 	and 6 
78	1170mg	1.2g	3 x Grey 	and 6 
79	1185mg	1.2g	3 x Grey 	and 6 
80+	1200mg	1.2g	3 x Grey 	and 6 
If body weight exceeds 80 (Kg) - Dosage must remain the same as that of 80 (Kg)			3 x Grey 	and 6 

# TB MEDICATION - Dosage Reference Guide **Phase 2<sup>1</sup>**

**Phase 2** TB treatment to be implemented **AFTER 2 months** of **Phase 1** TB treatment.  
(ref: page opposite)



\* **Colour coding** refers to TB Patient Medication Leaflets

Information contained in this leaflet was prepared and produced by Genus Pharmaceuticals in partnership with TB Alert



Body weight (Kg)	Rifinah 150 mg (1 pink tablet tablet contains Rifampicin 150 mg Isoniazid 100 mg)	Rifinah 300 mg (1 orange tablet tablet contains Rifampicin 300 mg Isoniazid 150 mg)
40	3 ● ● ●	
41	3 ● ● ●	
42	3 ● ● ●	
43	3 ● ● ●	
44	3 ● ● ●	
45	3 ● ● ●	
46	3 ● ● ●	
47	3 ● ● ●	
48	3 ● ● ●	
49	3 ● ● ●	
50		2 ● ●
51		2 ● ●
52		2 ● ●
53		2 ● ●
54		2 ● ●
55		2 ● ●
56		2 ● ●
57		2 ● ●
58		2 ● ●
59		2 ● ●
60		2 ● ●
61		2 ● ●
62		2 ● ●
63		2 ● ●
64		2 ● ●
65		2 ● ●
66		2 ● ●
67		2 ● ●
68		2 ● ●
69		2 ● ●
70		2 ● ●
71		2 ● ●
72		2 ● ●
73		2 ● ●
74		2 ● ●
75		2 ● ●
76		2 ● ●
77		2 ● ●
78		2 ● ●
79		2 ● ●
80+		2 ● ●
If body weight exceeds 80 (Kg) - Dosage must remain the same as that of 80 (Kg)		2 ● ●

**RIFINAH 150 & RIFINAH 300**

**Presentations:** Tablets containing 150mg of rifampicin and 100mg of isoniazid (Rifinah 150) or 300mg of rifampicin and 150mg of isoniazid (Rifinah 300).

**Indications:** Tuberculosis.

**Dosage & Administration:** Preferably take 30 mins before or 2 hours after food as a single dose. *Adults:* Rifinah 150: patients 50kg or less - 3 tablets; Rifinah 300: for patients 50kg or more - 2 tablets. *Elderly patients:* Use with caution.

**Contra-indications:** Hypersensitivity to rifamycins or isoniazid; presence of jaundice.

**Precautions:** Give under the supervision of a respiratory or other suitably qualified physician. All patients should have pre-treatment LFT. If impaired liver function, only give in cases of necessity with dose reduction and careful monitoring of LFT. Rifinah should be withdrawn if clinically significant changes in hepatic function occur. If impaired liver function, elderly, malnourished patients, and possibly children under 2yrs, caution is recommended if isoniazid is used concurrently. In some patients hyperbilirubinemia can occur in the early days of treatment. Possibility of an immunological reaction with intermittent therapy. Patients should be cautioned that interruption of the dosage regimen should be avoided. If serious complications occur, rifampicin should be stopped and never restarted.

**Interactions:** Rifampicin has enzyme-inducing properties. Reduced activity of anticoagulants, corticosteroids, cyclosporin, digitalis preparations, oral contraceptives (non-hormonal birth control methods are recommended during Rifinah therapy), oral hypoglycaemic agents, dapsone, phenytoin, quinidine, narcotics and analgesics. Diabetes may become difficult to control. Give p-aminosalicylic acid at least 8hrs apart from Rifinah. Isoniazid may decrease excretion of phenytoin or enhance its effects.

**Pregnancy & Lactation:** Only use if potential benefit outweighs potential risk.

**Side effects:** *Rifampicin* - Mild cutaneous reactions and general hypersensitivity reactions involving skin, exfoliative dermatitis, Lyell's syndrome, pemphigoid reactions. Anorexia, nausea, vomiting abdominal discomfort, diarrhoea, pseudomembranous colitis, hepatitis. Thrombocytopenia with or without purpura, eosinophilia, leucopenia, oedema, muscle weakness and myopathy. Discolouration of urine, sputum and tears. Occasional disturbances of the menstrual cycle. Reactions occurring after intermittent dosage regimens include: 'Flu syndrome'; shortness of breath and wheezing; blood pressure reduction and shock; acute haemolytic anaemia; acute renal failure. *Isoniazid* - Hepatitis, eosinophilia, agranulocytosis, anaemia, convulsions.

**Legal Category:** POM

**Marketing Authorisation Number:** Rifinah 150: PL 04425/0041, Rifinah 300: PL 04425/0042

**NHS Price:** Rifinah 150 Tablets x 84 £17.80; Rifinah 300 Tablets x 56 £23.52

Full prescribing information available on request from: Aventis Pharma Ltd., 50 Kings Hill Avenue, West Malling, Kent, ME19 4AH.

**Date of Preparation:** August 2003.

**RIFATER**

**Presentations:** Tablets containing 120mg of rifampicin, 50mg of isoniazid and 300mg of pyrazinamide.

**Indications:** Pulmonary tuberculosis.

**Dosage & Administration:** Rifater is recommended for daily administration during the initial 2-month intensive phase of short course treatment of pulmonary tuberculosis (concomitant administration of ethambutol or intramuscular streptomycin is advised). Preferably take 30 mins before or 2 hours after food as single dose. *Adults:* Patients less than 40kg - 3 tablets o.d., patients 40-49kg - 4 tablets o.d., patients 50-64kg - 5 tablets o.d., patients 65kg or more - 6 tablets o.d.. *Children:* Use only in special cases. *Elderly patients:* Use with caution.

**Contra-indications:** Hypersensitivity to rifamycins, isoniazid or pyrazinamide; presence of jaundice.

**Precautions:** Give under the supervision of a respiratory or other suitably qualified physician. All patients should have pre-treatment LFT. If impaired liver function, only give in cases of necessity with dose reduction and careful monitoring of LFT. Rifampicin should be withdrawn if clinically significant changes in hepatic function occur. In some patients hyperbilirubinemia can occur in the early days of treatment. Use with caution in patients with a history of gout or haemoptysis. Possibility of an immunological reaction with intermittent therapy. Patients should be cautioned that interruption of the dosage regimen should be avoided. If serious complications occur, rifampicin should be stopped and never restarted.

**Interactions:** Rifater has enzyme-inducing properties. Reduced activity of antiarrhythmics, anticoagulants, anticonvulsants, antifungals, antivirals, benzodiazepines, beta-blockers, calcium channel blockers, chloramphenicol, clarithromycin, corticosteroids, cyclosporin, digitalis preparations, tricyclic antidepressants, oral contraceptives (non-hormonal birth control methods are recommended during Rifater therapy), oral hypoglycaemic agents, dapsone, haloperidol, levothyroxine, quinidine, analgesics, tacrolimus and theophylline. Rifater may reduce plasma concentration of atovaquone. Give p-aminosalicylic acid at least 8hrs apart from Rifampicin. Concomitant antacid may reduce absorption of rifampicin. Hepatotoxicity potential increased in combination with an anaesthetic. Diabetes may become difficult to control. Isoniazid may decrease excretion of phenytoin and carbamazepine or enhance its effects. Pyrazinamide antagonises effects of probenecid and sulphapyrazone.

**Pregnancy & Lactation:** Only use if potential benefit outweighs potential risk.

**Side effects:** *Rifampicin* - Mild cutaneous reactions and general hypersensitivity reactions involving skin, exfoliative dermatitis, Lyell's syndrome, pemphigoid reactions. Anorexia, nausea, vomiting abdominal discomfort, diarrhoea, pseudomembranous colitis, hepatitis. Thrombocytopenia with or without purpura, eosinophilia, leucopenia, oedema, muscle weakness and myopathy. Discolouration of urine, sputum and tears. Occasional disturbances of the menstrual cycle. Reactions occurring after intermittent dosage regimens include: 'Flu syndrome'; shortness of breath and wheezing; blood pressure reduction and shock; acute haemolytic anaemia; acute renal failure. *Isoniazid* - Hepatitis, hypersensitivity reactions, eosinophilia, agranulocytosis, anaemia. Convulsions, systemic lupus erythematosus-like syndrome, pellagra. *Pyrazinamide* - active gout, sideroblastic anaemia, arthralgia, anorexia, nausea and vomiting, dysuria, malaise, fever, urticaria, aggravation of peptic ulcer, a range of hepatic reactions.

**Legal Category:** POM

**Marketing Authorisation Number:** PL 4425/0060

**NHS Price:** Rifater Tablets x 100 £23.60

Full prescribing information available on request from: Aventis Pharma Ltd., 50 Kings Hill Avenue, West Malling, Kent, ME19 4AH.

**Date of Preparation:** August 2003.

**ETHAMBUTOL**

**Presentations:** Tablets containing 100mg and 400mg of Ethambutol Hydrochloride (BP).

**Indications:** Primary treatment and re-treatment of tuberculosis, and for prophylaxis in cases of inactive tuberculosis or large-tuberculin-positive reaction. Ethambutol should only be used in conjunction with other anti-tuberculosis drugs to which the patient's organisms are susceptible.

**Dosage & Administration:** The dosage of ethambutol must be adjusted according to the body weight of the patient. *Adults:* For primary treatment and prophylaxis: Ethambutol should be administered in a single daily oral dose of 15mg/kg, concomitant drugs being maintained at their recommended dosage levels. For re-treatment: For the first 60 days of treatment, ethambutol should be administered in a single daily oral dose of 25mg/kg. Thereafter the dosage should be reduced to 15mg/kg, concomitant drugs being maintained at their recommended dosage levels. *Children:* For primary treatment and re-treatment: For the first 60 days of treatment, a single daily oral dose of 25mg/kg. Thereafter the dosage should be reduced to 15mg/kg, concomitant drugs being maintained at their recommended dosage levels. For prophylaxis: A single daily oral dose of 15mg/kg, concomitant drugs being used at their recommended dosage levels. *Elderly:* As for adults. However, patients with decreased renal function may need to have the dosage adjusted as determined by blood levels of ethambutol. In order to obtain maximum effect due to high serum levels, drug administration should be once daily.

**Contra-indications:** Hypersensitivity to ethambutol; patients with known optic neuritis unless clinical judgement determines that ethambutol may be used.

**Precautions:** Patients with decreased renal function may need to have the dosage adjusted as determined by blood levels of ethambutol. As this drug has a unique effect on the eye, it is recommended that patients undergo a full ophthalmic examination before starting treatment. This should include visual acuity, colour vision, perimetry and ophthalmoscopy. Many physicians consider that routine ophthalmological examinations for adults are unnecessary but patients should be informed of the importance of reporting any change in vision. However, routine ophthalmological examinations may be considered desirable when treating young children.

**Interactions:** None.

**Pregnancy & Lactation:** Should not be used unless the potential benefit is considered to outweigh any possible risk.

**Side effects:** Hypersensitivity reactions are rare, although rash, pruritus and urticaria have been reported. There are isolated reports of photosensitive lichenoid eruptions, Stevens-Johnson syndrome, epidermal necrolysis, and bullous dermatitis. Interstitial nephritis and anaphylactoid reactions are extremely rare. Hyperuricaemia has been reported although clinical effects are unlikely. Gastro-intestinal disturbances such as anorexia, nausea, vomiting and diarrhoea have been noted in patients on multiple anti-tuberculosis drug therapy including ethambutol, although not in test patients receiving ethambutol as sole therapy. Reports of thrombocytopenia are rare. Hepatic reactions have been reported in patients treated with multiple drug therapy including ethambutol, and liver function tests should be performed in patients who develop symptoms suggestive of hepatitis or who become generally unwell during treatment. Numbness and paraesthesia of the extremities have been reported. Ethambutol may produce a unique type of visual impairment that is generally reversible and which appears to be due to optic neuritis and to be related to dose and duration of treatment. Less than 1% of patients undergoing treatment with the higher dose regimen of 25mg/kg/day for two months, and 15mg/kg/day thereafter, have exhibited decrease in visual acuity. The change may be unilateral or bilateral and hence both eyes must be tested individually. The effects are generally reversible when administration of the drug is discontinued promptly. In rare cases, recovery may be delayed for up to one year or more and the effect may possibly be irreversible in these cases. Recovery of visual acuity has usually occurred over a period of weeks to months after the drug was discontinued, and patients have then received ethambutol at lower dosages without toxicity.

**Legal Category:** POM

**Marketing Authorisation Number:** Ethambutol Tablets 100mg: PL 17225/0004; Ethambutol Tablets 400mg: PL 17225/0005

**NHS Price:** Ethambutol Tablets 100mg x 56 £11.50; Ethambutol Tablets 400mg x 56 £42.73

Full prescribing information available on request from Further information is available from the Marketing Authorisation Holder: Genus Pharmaceuticals, Benham Valence, Newbury, Berkshire RG20 8LU.

**Date of Preparation:** August 2003.

Date of preparation: September 2003

1 - Ref. Product SmPC

Information contained in this leaflet was prepared by Genus Pharmaceuticals with help from Sandwell Hospital in partnership with TB Alert

