

Guidelines for use of Pediatric Patient Wise boxes under the Revised National Tuberculosis Control Programme

The Revised National Tuberculosis Control Programme (RNTCP), which was initiated in 1997, included the treatment of pediatric cases according to body weight. Until now, the same strategy has been continued. The regimen recommended for treating the pediatric cases had been 2R₃H₃Z₃ / 4R₃H₃ for children less than 6 years of age. For all children above 6 years, the same regimen was recommended as for adults. In early 2004, in consultation with Indian Academy of Pediatrics, the recommendations were revised whereby Ethambutol was included for treatment of pediatric cases even under 6 years of age.

The Programme had been getting feedback in regard to the difficulty in administering the drugs to smaller children as the available formulations needed to be broken up to meet the patients' individual weights. To overcome these problems, RNTCP in consultation with IAP, has taken steps to make the pediatric drugs available in patient-wise boxes (PWBs) similar to those supplied for adult patients under RNTCP. With the availability of pediatric PWBs, all new pediatric patients diagnosed and registered for treatment under RNTCP, would be initiated on pediatric patient wise boxes. This will enable optimum dosage for the patients, without resorting to further breaking of the tablets, as per the respective weight bands. Further, Rifampicin would be available in tablet form, which will enable easier swallowing of the drug by the pediatric patients.

The new formulations to be used in RNTCP are:



- Rifampicin – 75 /150 mg
- Isoniazid – 75 /150 mg
- Ethambutol – 200 /400 mg
- Pyrazinamide – 250 / 500 mg

For the purpose of treatment, the pediatric population is divided into four weight bands:

- 6 – 10 kgs
- 11 – 17 kgs
- 18 – 25 kgs
- 26 – 30 kgs

The anti-TB drugs for pediatric patients will be available in the form of 2 generic patient wise boxes i.e. Product Code 13 and Product Code 14. Product Code 15 and 16 would be available for the prolongation of the intensive phase, if required and also to facilitate conversion of the boxes into Category II and for reconstitution, if required.

The composition of product codes 13 to 16 is given below:

	<p>Product Code 13 - Treatment box for pediatric weight band category (6-10 Kg). Each treatment box containing 24 Combi-packs of Schedule-5 in one pouch and 18 multi-blister calendar Combi-pack of Schedule-6 in another pouch</p> <p>The intensive phase consists of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol to be given under direct observation thrice a week on alternate days for 2 months (24 doses).</p> <p>The continuation phase consists of 4 months (18 weeks; 54 doses) of Isoniazid and Rifampicin given thrice a week on alternate days - the first dose of every weekly blister being directly observed.</p>
	<p>Product Code 14 - Treatment box for pediatric weight band category (11-17 Kg). Each treatment box containing 24 Combi-packs of Schedule-7 in one pouch and 18 multi-blister calendar Combi-pack of Schedule-8 in another pouch</p> <p>The intensive phase consists of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol to be given under direct observation thrice a week on alternate days for 2 months (24 doses).</p> <p>The continuation phase consists of 4 months (18 weeks; 54 doses) of Isoniazid and Rifampicin given thrice a week on alternate days - the first dose of every weekly blister being directly observed.</p>

	<p>Product Code 15 - Treatment box for prolongation of intensive phase of pediatric cases (6-10 kg and 18-25 kg). Each box containing 5 pouches and each pouch containing 12 blister Combi pack of Schedule-5.</p> <p>The pouch consists of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol to be given under direct observation thrice a week on alternate days for 1 month (12 doses).</p>
	<p>Product Code 16 - Treatment box for prolongation of intensive phase of pediatric cases (11-17 kg, 18-25 kg and 26-30 kg). Each box containing 5 pouches and each pouch containing 12 blister Combipacks of Schedule-7</p> <p>Prolongation Pouch consists of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol to be given under direct observation thrice a week on alternate days for 1 month (12 doses).</p>

The composition of all Product Codes is enclosed at Annexure – I

The generic patient wise boxes, i.e. product code 13 and 14, according to weight band would be used for the pediatric patients in the following manner.

- A patient weighing 6 – 10 kg would require 1 box of Product Code 13.
- A patient weighing 11 – 17 kg would require 1 box of Product Code 14
- A patient weighing 18 – 25 kg would require 1 box of Product Code 13 and 1 box of Product Code 14.
- A patient weighing 26 – 30 kg would require 2 boxes of Product Code 14.

The boxes have been designed to suit the requirements of Category I cases which are expected to dominate the patients belonging to pediatric age group. In case, any patients are to be placed on Category II or III, the following steps will have to be taken to convert the generic boxes into a Category II or III box:

Category II – Re-treatment Cases

For children to be placed on Category II, PPs would be added for prolongation of IP. For the extra 1 month of CP, a PP would be added after removing the Pyrazinamide tablets from the PP. For the other 4 months of CP blisters, Ethambutol tablets will need to be added which can be used from the supplies of loose drugs under the Programme.

SM Inj (750 mg) supplied under the programme shall be used for such patients and the dosage would be as per body weight.

Category III cases

For children who are to be put on Category III, the Ethambutol tablets will be removed from the IP blisters.

Categorization and duration of therapy

Categorization of pediatric cases will be as per RNTCP policy. The treatment regimens recommended under RNTCP are the same for adult and pediatric cases. The duration of therapy will be as per the treatment regimen. If required, the duration of therapy may be extended within the current RNTCP guidelines.

Use of Prolongation Pouches

Sputum positivity in the pediatric patients of lower weight categories is usually not found and it is also difficult to get a sputum sample in such children. However, for the older patients, sputum samples can be obtained and prolongation of intensive phase may be required. For such patients, prolongation pouches will be required. In addition, PP would also be required for the purpose of reconstitution of the PWBs of patients who have died, defaulted, transferred out and indoor patients who also would be treated under RNTCP using PPs.

Chemoprophylaxis

Asymptomatic children under 6 years of age, exposed to an adult with infectious (smear-positive) tuberculosis from within the same household, are to be given 6 months of Isoniazid (5 mg per kg daily) as chemoprophylaxis. Loose tablets of INH 100 mg would continue to be supplied for this purpose as was previously done.

Use of Pediatric Patient Wise Boxes for under weight adult patients (<30 Kgs)

One adult patient <30 kg would require two generic boxes of the PC 14. These boxes would be used according to the category of the patient, if required, after making alterations in the boxes as given above.