

Management of Tuberculosis Training for Health Facility Staff

SECOND EDITION

F. Manage Drugs and Supplies for TB



World Health
Organization



TUBERCULOSIS FOUNDATION

**Management of Tuberculosis
Training for Health Facility Staff
Second Edition**



**MANAGE DRUGS AND SUPPLIES
FOR TB**



**World Health
Organization**



K N C V



TUBERCULOSIS FOUNDATION



WHO Library Cataloguing-in-Publication Data

Management of tuberculosis: training for health facility staff -- 2nd ed.

Contents: Modules: A: Introduction - B: Detect Cases of TB - C: Treat TB Patients - D: Inform Patients about TB - E: Identify and Supervise Community TB Treatment Supporters - F: Manage Drugs and Supplies for TB - G: Ensure Continuation of TB Treatment - H: Monitor TB Case Detection and Treatment - I: TB Infection Control in your Health Facility - J: Field Exercise – Observe TB Management - K: Management of Tuberculosis – Reference Booklet - L: Facilitator Guide - M: Answer Sheets.

1.Tuberculosis, Pulmonary - therapy 2.Health personnel - education 3.Health facilities 4.Teaching materials I.World Health Organization.

ISBN 978 92 4 159873 6

(NLM classification: WF 210)

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Manage Drugs and Supplies for TB

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Acknowledgements

Management of Tuberculosis: Training for Health Facility Staff, 2nd ed.

This second edition of training modules was prepared by the Stop TB Department of the World Health Organization (Geneva, Switzerland) and Patricia Whitesell Shirey of ACT International (Atlanta, GA, USA). The project was coordinated by Karin Bergstrom. Fabio Luelmo and Malgorzata Grzemska were the main technical advisers. The modules were edited by Karen Ciceri. Natacha Barras provided administrative support and coordinated the layout and printing of the modules.

The following organizations contributed to the development of the modules through the Tuberculosis Control Assistance Program (TB-CAP): the American Thoracic Society (ATS), Management Sciences for Health (MSH), the United States Centers for Disease Control and Prevention (CDC), and the KNCV Tuberculosis Foundation.

The original versions of the training modules (published by the World Health Organization in 2003) were field-tested in Malawi through the support of the National Tuberculosis Control Programme of Malawi.

This updated version was tested through the support of the Division of Tuberculosis Elimination of the United States Centers for Disease Control and Prevention.

The United States Agency for International Development financially supported the development of these training modules through its Grant to the World Health Organization and through the sub-agreement to WHO of the Cooperative Agreement with the KNCV Tuberculosis Foundation for the Tuberculosis Control Assistance Program (TB-CAP).

Manage Drugs and Supplies for TB

Introduction

Essential drugs and other supplies for detecting and treating TB in a health facility include:

- drugs for TB treatment (sufficient quantities of oral drugs for complete regimens, plus streptomycin and additional tablets)
- treatment-related supplies, such as syringes, needles and sterile water for injection
- sputum containers
- TB forms and registers.

The health facility must keep sufficient quantities in stock and store them carefully, so that they will be available and effective when they are needed.

The national TB control programme provides complete regimens of anti-TB drugs free of charge for all TB patients. Patients do not have to be concerned with the cost of their drugs, and cost is eliminated as a barrier to taking the correct drugs for the recommended duration.

Today, manufacturers can provide different presentations and methods of packaging anti-TB drugs. WHO recommends the use of fixed-dose combination tablets, or FDCs, in blister packs or strips to facilitate correct drug intake. Drug boxes that contain a full drug regimen for one patient are also recommended to ensure correct drug treatment and prevent interruptions of supply during treatment.

Managing drugs and supplies involves ensuring that sufficient quantities are available, and maintaining good conditions for their storage. Generally, quantities of drugs and supplies to order are calculated as follows:

$$\text{Estimated drug requirements} + \text{reserve stock} - \text{current stock} = \text{amount to order}$$

Whether your health facility places orders for supplies or the district determines the amounts to send, you should be aware of the quantities that should be in stock. Then, if stocks are low, you can respond in time to request a resupply. Good storage and management procedures will keep the drugs and supplies safe from theft, misuse or spoiling.

Objectives of this module

Participants will learn:

Refer to section:

- | | |
|--|---|
| • How to ensure sufficient stock of drugs for TB patients | 1 |
| • How to plan for other supplies | 2 |
| • Good drug management procedures for safe keeping the supply of anti-TB drugs | 3 |

1. Stock sufficient drugs for treatment of all TB cases

1.1 About presentations and packaging of anti-TB drugs

The first-line¹ drugs currently used in standard regimens for treatment of TB (with their standard abbreviations) are:

- rifampicin (R)
- isoniazid (H)
- pyrazinamide (Z)
- ethambutol (E)
- streptomycin (S)

These drugs are manufactured in different presentations. You will use the presentations that are provided to your health facility for treatment of TB patients, but you should be aware of other possible presentations.

Most anti-TB drugs are now manufactured in **fixed-dose combinations** (FDCs) instead of only separate tablets. FDCs are drugs combined in tablet or capsule form, in specific dosages, to facilitate correct drug intake. The following FDCs are becoming widely available:²

- rifampicin–isoniazid–pyrazinamide–ethambutol (RHZE)
- rifampicin–isoniazid–pyrazinamide (RHZ)
- rifampicin–isoniazid (RH)
- rifampicin–isoniazid (RH)₃
- rifampicin–isoniazid–ethambutol (RHE)
- isoniazid–ethambutol (HE)

FDCs have many advantages. They help to reduce mistakes by the health worker or the patient, so that the correct drugs in the correct doses are taken by the patient each day. They reduce the number of tablets to take from 9–12 down to 3–4. They also increase compliance with treatment. FDCs are often cheaper than separate drugs. Use of FDCs is essential for self-administered treatment.

If a country uses some separate tablets, a TB patient on the regimen 2(RH)ZE would receive each day a specific number of rifampicin–isoniazid tablets, pyrazinamide tablets and ethambutol tablets.³

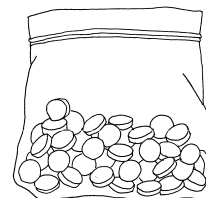
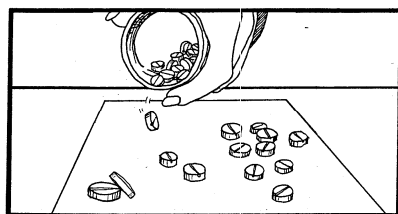
WHO strongly recommends the use of FDCs, and more and more countries are choosing to provide FDCs for treatment of TB patients. If your country is not yet using FDCs, or is using only one FDC such as (RH), you can look forward to using more FDCs for TB patients in the future.

¹ The first drug normally used to treat a particular condition. A second-line drug is a therapeutic agent that is not the drug of choice or the first drug normally used to treat a particular condition. Generally, second-line agents are used when standard “first-line” therapy fails.

² (RHZE), (RHZ), (RH), (RHE) and (HE) are made in dosages for daily administration. (RH)₃ contains the appropriate dosages of each drug for administration 3 times per week.

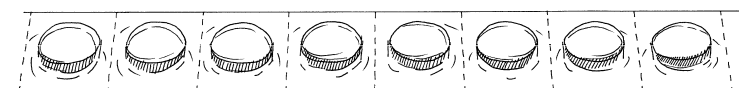
³ See Annex A for a review of how to read the drug code for TB treatment regimens.

Another important development for health workers is the packaging and presentation of anti-TB drugs. In the past, all anti-TB drugs were provided as loose pills in bottles. Health workers had to package these for patients:

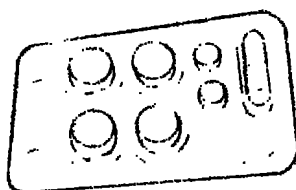


Manufacturers now package anti-TB drugs in some additional ways, including:

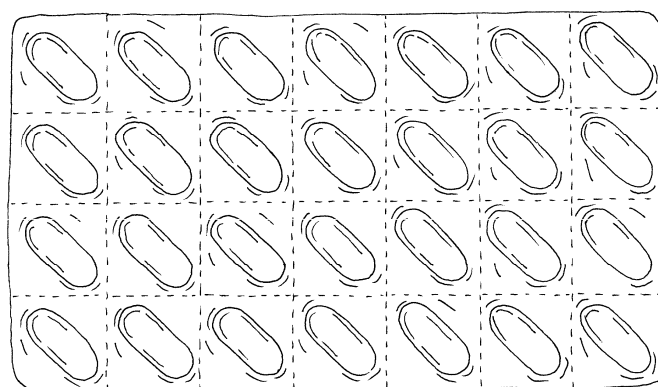
- Strips



- Blister packs of several tablets for a daily dose on one card, or a week's tablets on one card



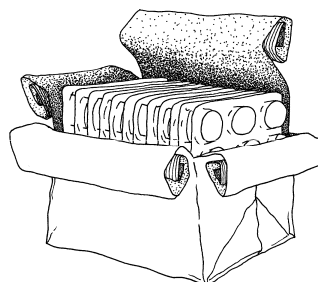
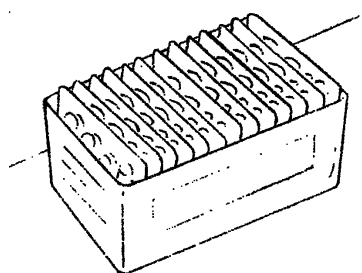
- Blister packs of 28 FDC tablets on a card, such as 28 (RHZE) or 28 (RH) tablets



WHO strongly recommends the use of blister packs or strips, preferably of FDCs.

In addition, some manufacturers package anti-TB drugs in boxes or bags containing a full treatment regimen for one patient. Each box or bag contains the correct number of pre-packaged daily blister packs or envelopes for the regimen. These **drug boxes** are an important tool for ensuring correct drug treatment and avoiding interruptions of supply during treatment. Drug boxes are strongly recommended by WHO.

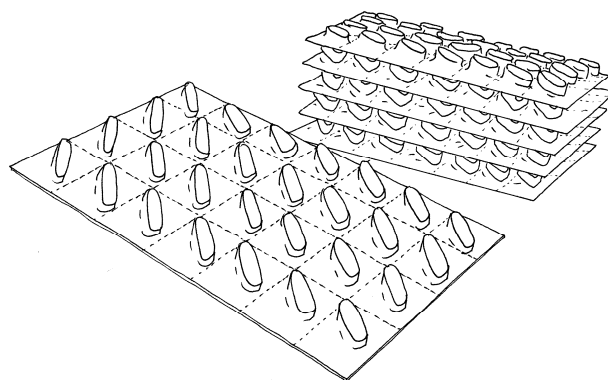
When a TB patient is identified, the health worker specifies the regimen needed and the dosages (based on the patient's body weight). A drug box containing the appropriate regimen is labelled with the patient's name and kept for him or her only. In this way, the health facility is certain to be able to provide the full course of drug treatment needed by the patient. The health worker and the patient can be confident that the patient will never come for treatment to find that the health facility has run out of drugs. Daily drug administration is simplified for the staff because the drugs are labelled for the patient and are pre-packaged in daily doses. Determining when the patient has completed the treatment is also easy, because the patient continues until all the drugs in the box have been taken as recommended.



If your health facility does not receive anti-TB drugs pre-packaged as a complete regimen for one patient, WHO recommends assembling drug boxes.

Health workers may assemble boxes for the New patient regimen and the Retreatment regimen for different body weight ranges ahead of time, or they may partially assemble boxes that will be completed when a TB patient is identified. As soon as a diagnosis of TB is made, a drug box is taken from the shelves. If a suitable box is not already assembled for the weight of the patient, it is quickly assembled. For example, an additional number of tablets may be added to a box to increase the daily dose for a heavier patient. The box is labelled with the patient's name and kept for that patient.

Using the 4-drug FDC (RHZE) greatly simplifies assembly of drug boxes. For example, for the New patient regimen, a patient of average weight needs 3 (RHZE) tablets per day in the initial phase for 2 months. If (RHZE) tablets are provided in blister packs of 28 tablets, the patient's treatment box would contain 3 of these blister packs per month of treatment, or 6 blister packs for the initial phase of treatment.



Making drug boxes with blisters of FDCs is far simpler and more likely to be done correctly than if loose drug tablets (not FDCs) are used. If loose tablets are used, a health worker must assemble 56 envelopes containing 9–12 tablets each for the initial phase.

The Retreatment regimen includes streptomycin, which is usually not placed in the drug box.⁴ However, a supply of streptomycin (56 doses of streptomycin, 5 ml sterile water per gram of streptomycin, sterile needles and syringes) should be available in reserve for each patient on the Retreatment regimen.

To assemble a kit for a child, you must receive information from the clinician or paediatrician on the drugs and doses for the particular child.

There are particular codes for the different (second-line) drugs used to treat MDR-TB. A drug box to treat a patient for MDR-TB should be assembled at the health centre using the special drugs sent for this purpose.

1.2 Estimate the expected number of TB cases that will begin treatment and the drugs needed

Be sure that enough drugs are in stock for all TB cases expected to start treatment during the next quarter. It is assumed that the number of patients next quarter will be the same, or approximately the same, as it was in the previous quarter. At the beginning of each quarter, the District TB Coordinator will determine these numbers from records of current cases and will order drugs to be sent to your health facility to meet the expected need. Though you may not be required to place drug orders each quarter, you should be aware of the usual quantities used, so that you will know whether the supplies you receive are far too much or too little.

The expected number of cases that will begin treatment next quarter (new and retreatment), multiplied by 2, is the number of drug regimens that should be available when your health facility's drug storeroom is fully stocked. (Depending on the practice of your national TB control programme, these regimens may be packaged in patient drug boxes or may be the equivalent in supplies of different anti-TB drugs.) The reserve stock allows for possible increases in the number of cases and extra supplies in case of delay in drug delivery.

Some additional tablets will be needed for heavier adults who need larger than standard doses. Some loose tablets will be needed for patients who need special regimens.

The number of expected TB cases that will begin treatment next quarter, multiplied by 2, is the number of regimens that should be available when your health facility's drug storeroom is fully stocked.

⁴ Boxes for the Retreatment regimen that include streptomycin, syringes and water are available in some areas.

1.3 Check drugs received

When drugs are received from the district or the Essential Drugs Programme, check that the correct drugs were received in the correct quantities. If not, request the missing drugs and return any extra or expired drugs that were sent in error.

Depending on the system used, this can be a fairly simple step, or it may be quite complicated. If your health facility receives boxes or bags containing full treatment regimens for a given patient, the task is just to count the number of boxes of each regimen received and compare with the amount needed.

However, some health facilities receive bulk quantities of all the different drugs that must be counted out and assembled in boxes for each regimen. In this case, there is greater possibility for error in supplies; for example, the shipment could include too many (RH) tablets (rifampicin–isoniazid combination tablets) and no E (ethambutol tablets).

When a drug shipment is received:

- Receive and sort through the drug shipment:
 - Check expiry dates⁵.
 - Identify the number of complete regimens received (drug boxes or the equivalent drugs for treatment).
 - Identify additional tablets received and their strengths.
 - Check the quantities of each received and compare with the amount needed.
- Note discrepancies (such as incorrect number of complete drug regimens – New or Retreatment, incorrect tablet or strength of tablet, insufficient quantity of a particular tablet, expired drugs).
- Request missing drugs, return extra drugs, return or destroy expired drugs.
- Place the drugs in stock, recording them on the stock card for the item and placing them on the shelves behind older stock.

1.4 Periodically, check drug stocks

With experience, you will be aware of the number of TB cases entering treatment each quarter and the quantities of drugs needed to treat them. If you think that the health facility's stocks do not contain sufficient quantities for the quarter, a special order may be needed. Take action or inform the person responsible for drug supplies. A periodic check of drug supplies will also be performed by staff of the Essential Drugs Programme.

⁵ Do not accept expired drugs or drugs that will expire before they can be used. Consider when the tablets will be assembled into drug boxes, when the drug boxes will be used for patients and how long the treatment will last. For example, if (RHZE) tablets received today will be assembled in drug boxes next month, some patients will begin treatment using those boxes in the next quarter, and the initial phase of their treatment will last 2–3 months. Therefore, the (RHZE) tablets must have an expiry date more than 6 months in the future. (RH) tablets will be used in the continuation phase and should have an expiry date at least 12 months in the future.



STOP

Now read Annex B

If your health facility will need to assemble drug boxes for TB patients from supplies of anti-TB drugs in blister packs, strips, loose tablets or some combination of these, turn to page 25 and read Annex B, *Guidelines for assembling drug boxes for TB patients*. When you have finished reading the annex, go back to page 8 and continue reading.

If your health facility will not assemble drug boxes, you do not need to read Annex B. Turn this page and continue reading in the module.

2. Plan for other needed supplies

Make sure that your health facility maintains an adequate supply of sputum containers, disposable needles and syringes, and sterile water for injections⁶. If adequate disposable needles and syringes are not available, the health facility must have reusable needles and syringes and a sterilizer in good working condition.

Estimate the quantities needed of each of these supplies, and periodically check the quantities in the storeroom. If supplies will not meet the needs, request more according to usual procedures.

2.1 Estimate required quantity of sputum containers

A large number of sputum containers are needed to identify and investigate TB suspects and to follow up patients. A shortage of sputum containers is a serious problem.

Estimate quarterly needs for sputum containers based on the expected number of sputum examinations to be done for diagnosis plus the expected number to be done for follow-up. Base estimates on the number of new cases treated last quarter. When estimating and ordering sputum containers, it is recommended to round numbers up.

Example methodology for calculating the number of sputum containers needed next quarter

Organize data on cases in the previous quarter as follows:

| | <i>Smear-positive</i> | <i>Smear-negative</i> | <i>Total</i> |
|--------------------|-----------------------|-----------------------|--------------|
| <i>New</i> | 22 | 6 | 28 |
| <i>Retreatment</i> | 5 | 5 | 10 |
| <i>Total</i> | 27 | 11 | 38 |

The number of sputum containers needed **for diagnosis** may be calculated as follows:

- number of new pulmonary sputum smear-positive cases last quarter
- multiplied by 10 (because on average, 10 TB suspects have been investigated for each new pulmonary sputum smear-positive case detected)⁷
- multiplied by 2 (because 2 sputum samples are needed from each TB suspect)

| | |
|-------------|---------------------------------|
| 22 | new smear-positive cases |
| <u>x 10</u> | |
| 220 | TB suspects |
| <u>x 2</u> | |
| 440 | sputum containers for diagnosis |

⁶ Special supplies needed for management of a patient with MDR-TB (for example, masks, special forms) are not routinely stocked but should be supplied along with the special drugs for the patient.

⁷ This number may vary by country or region depending on case detection activity and TB prevalence in the community.

The number of sputum containers needed **for follow-up** of treatment is calculated as follows:

- number of new sputum smear-positive cases last quarter
- multiplied by 6 (3 follow-up examinations of 2 sputum samples each time)
- number of smear-positive retreatment cases
- multiplied by 6 (3 follow-up examinations of 2 sputum samples each time)
- number of sputum smear-negative cases (new or retreatment)
- multiplied by 2 (one follow-up examination of 2 sputum samples).

| |
|------------------------------------|
| 22 new smear-positive cases |
| <u>x 6</u> |
| 132 containers |
| 5 smear-positive retreatment cases |
| <u>x 6</u> |
| 30 containers |
| 11 smear-negative cases |
| <u>x 2</u> |
| 22 containers |
| 132 + 30 + 22 = 184 containers |

The number of sputum containers needed **for culture and DST** is calculated as follows:

- number of retreatment cases (smear-positive or smear-negative)
- multiplied by 1 (every retreatment case should have a sputum sent for culture and DST at the beginning of treatment)
- number of new and retreatment (total) cases
- multiplied by 20% for culture and DST when follow-up microscopy is positive
- plus 20% for follow-up for culture-positive cases

| |
|--|
| 10 retreatment cases |
| <u>x 1</u> |
| 10 containers |
| 38 new and retreatment cases |
| <u>x 0.2</u> |
| 8 containers for microscopy positives |
| <u>+ 8</u> 20% for follow-up cultures of culture positives |
| 10 + 8 + 8 = 26 containers |

The **total** number of **sputum containers** to order⁸ is calculated as follows:

- number needed for diagnosis
- plus number needed for follow-up examinations
- plus number needed for culture and DST
- plus 10% for additional investigations
- plus 20% for reserve stock
- minus the number of sputum containers in stock at the end of last quarter.

| | |
|-------|-----------------------|
| 440 | for diagnosis |
| + 184 | for follow-up |
| + 26 | for culture, DST |
| 650 | |
| + 65 | 10% for additional |
| 715 | |
| + 143 | 20% for reserve stock |
| 858 | TOTAL needed |
| - 250 | in stock |
| 608 | to order |

⁸ A simplified method to calculate the number of sputum containers to order is as follows: Multiply by 40 the number of new pulmonary smear-positive cases last quarter. Then subtract the number of containers in stock at the end of last quarter.

2.2 Estimate required needles and syringes for streptomycin injections

Streptomycin injections must be given with **sterile** needles and syringes. Avoid transmission of bloodborne diseases (especially HIV infection).

In areas with high prevalence of HIV infection, disposable syringes and needles should be used. If disposables are to be used, the number of **syringes and needles** needed is the same as the number of doses of streptomycin.

Example methodology:

- number of patients on Retreatment regimen (includes streptomycin) last quarter
- multiplied by 56 doses per patient (28 doses per month)
- multiplied by 2 for reserve stock
- minus the number of syringes in stock at the end of last quarter

| | |
|-------------|------------------------------------|
| 8 | patients on streptomycin |
| <u>x 56</u> | doses per patient |
| 448 | doses (and syringes) needed |
| <u>x 2</u> | for reserve stock |
| 896 | syringes needed when fully stocked |
| <u>- 80</u> | in stock |
| 816 | to order |

If reusable needles and syringes will be used, follow normal procedures for estimating need and ordering them. You may need to inform the person responsible for supplies about the estimated number of TB patients who will require streptomycin injections. Recommended procedures for sterilization of needles and syringes must be strictly followed. Make sure that the sterilizer is in good working condition.

Also plan for a sufficient number of vials of sterile water in stock, reserved for TB cases. (For each gram of streptomycin, 5 ml of sterile water is also required.)

2.3 Estimate TB forms and registers needed

The District TB Coordinator will make sure that sufficient forms are available. Generally, forms will be provided once a year to cover the needs for the **entire year**. Estimates are based on the number expected to be used in the year plus 20% to allow for increases in detection of new TB cases and losses through misuse or damage.

- ***TB Treatment Cards***

Some patients will have only one *TB Treatment Card*, while patients who have a community TB treatment supporter will have two cards. Thus, on average, 1.5 *TB Treatment Cards* are needed for each expected patient plus 20% for reserve.

- ***Tuberculosis Identity Cards***

Estimate one per expected TB patient, plus 20% for reserve.

- ***Register of TB Suspects***

Generally, one *Register of TB Suspects* is sufficient for a small or medium-sized health facility for a year (that is, a register book containing 60 pages with 20 lines per page).

- **Request for Sputum Smear Microscopy Examination forms**

Estimate about 15 *Request for Sputum Smear Microscopy Examination* forms per new sputum smear-positive case.⁹

- **Tuberculosis Treatment Referral/Transfer forms**

Referral/Transfer forms are needed for about 3 in 10 TB patients. Calculate 30% of the expected patients, and then add 20% for reserve.

| | |
|---------------|------------------------|
| 325 | expected patients/year |
| <u>x 0.30</u> | |
| 98 | forms |
| <u>+ 20</u> | for reserve (20%) |
| 118 | forms needed |

2.4 Periodically, check stocks of supplies

Periodically, check stocks of needles, syringes, sputum containers, forms and registers. If the facility uses reusable needles and syringes, also check that the sterilizer is in good working condition. If supplies of any of these items will not meet the expected needs for the quarter, alert the person responsible that certain supplies are low, or request more according to usual procedures.

3. Use good storage and management procedures for anti-TB drugs and supplies

Health facility drugs and supplies are kept in the health facility's drug storeroom, which should be well kept and managed by a designated responsible staff member. Good storage and management procedures are important for anti-TB drugs (and all drugs) and supplies kept in the storeroom or cabinet. If you handle drugs and supplies for TB, you should do your part to ensure that good storage procedures are followed. If there are problems that you are not able to correct, you must talk to the person responsible or the medical officer.

3.1 Keep drugs safe

Stocks of anti-TB drugs are stored safely in the main storeroom, which should be locked when not in use. Access to the main drug storeroom should be limited to one or two people who are responsible for its management.

Keep drugs for current TB patients available for when the patients come for directly-observed treatment. This could be in a cabinet or on a shelf in the area where patients are seen. These drug supplies should be available (not be locked up) so that staff can get to them even if the normal treatment provider is not present.

⁹ The factor of 15 is based on the average of 10 diagnostic sputum examinations to detect 1 sputum smear-positive TB case, plus 3 follow-up sputum examinations per smear-positive case, and reserve stock. The factor may be adjusted depending on case detection activity and TB prevalence in the community.

3.2 Keep the storeroom in good condition

The temperature, light and humidity in the main storeroom should be kept moderate. Though anti-TB drugs are very stable, they must be protected from extreme cold or heat, direct sunlight, moisture or rain, as these can cause some drugs to spoil. For instance, some tablets, such as ethambutol, absorb humidity from the air and deteriorate.

Storage conditions can be improved by some simple measures. Collaborate with other staff if needed to improve storage conditions. Temperature can be controlled (maintain temperature below 30 °C¹⁰) by using fans, air vents or windows to increase ventilation, and by using insulating materials for the roof and ceiling. Direct sunlight can be prevented from entering the room by hanging curtains or painting the window glass. Humidity can be controlled by increasing ventilation, creating drainage areas and repairing any roof leaks quickly.

No one should eat, drink or smoke in the storeroom. Do not keep food or drink in the storeroom. This will help to keep the storeroom clean and free of pests.

3.3 Organize drugs and supplies

Stocks of anti-TB drugs in the storeroom (in individual patient drug boxes or stocked by type of drug) should be placed on shelves by expiry date: the drugs that expire soonest should be in front and those that expire later should be behind. When taking drugs off the shelf, use those in front first. These procedures follow the FIFO rule (meaning First In, First Out), so that the oldest drugs are used first. Return expired drugs to the district office or destroy them.

3.4 Recognize and correct storage problems

Periodically check the condition of the anti-TB drugs (those kept in the storeroom and those kept handy for current patients) to identify any problems. When a problem is identified, correct it without delay. For example, if a drug cabinet is in direct sunlight, move it or block the light with curtains. If drugs are stored on the floor, move them onto shelves.

If some expired drugs are found on the shelves, dispose of them and then check the expiry dates of the other drugs.



STOP

Now do Exercise A – Group practical exercise

When you have reached this point in the module, you are ready for Exercise A. Turn to page 20 and read the instructions. When everyone is ready, the facilitator will conduct the exercise.

¹⁰ Refer to the manufacturer's instructions on the drug boxes.

Summary of important points

- Essential drugs and other supplies for detecting and treating TB include:
 - Drugs for TB treatment (sufficient oral drugs for complete regimens, streptomycin and additional tablets)
 - Treatment-related supplies (syringes, needles and sterile water for injection)
 - Sputum containers
 - TB forms and registers.
- Fixed-dose combinations, or FDCs, are drugs combined in tablet or capsule form, in specific dosages, to facilitate correct drug intake. FDCs, preferably in blister packs or strips, reduce mistakes by the health worker, community treatment supporter or patient.
- Be sure that enough drugs are in stock for all TB cases expected to start treatment during the next quarter. The number of expected cases, multiplied by 2, is the number of drug regimens that should be available when your storeroom is fully stocked. Remember that the Retreatment regimen also requires that a sufficient supply of streptomycin, sterile water, sterile needles and syringes be held in reserve for TB patients.
- Drug boxes that contain all the drugs for a full treatment regimen for one patient are an important tool for ensuring correct drug treatment and adherence. If your health facility does not receive boxes of drugs packaged in complete regimens, you will have to assemble drug boxes. Drug boxes should be ready to use or be quickly assembled when new patients are diagnosed.
- When you gather drugs for making drug boxes, check the expiry dates. Use older stock first. Do not use any drugs that have expired or will expire during the treatment period.
- A drug box should contain the entire course of treatment, with each dose in a blister pack or small envelope. Use a *Worksheet for drug box assembly* to plan, for the two phases, the drugs needed, number of tablets for each dose, and the number of doses needed. When a drug box is assembled, clearly label the box as either the New patient regimen or Retreatment regimen, and specify the drug code, patient's weight range and expiry dates of the drugs.
- A large number of sputum containers are needed. Calculate the total number of sputum containers to order for the quarter as follows:
 - number needed for diagnosis
 - plus number needed for follow-up examinations
 - plus number needed for culture and DST
 - plus 10% for additional investigations
 - plus 20% for reserve stock
 - minus the number of sputum containers in stock at the end of last quarter.
- TB forms and registers needed include:
 - *TB Treatment Cards* (average 1.5 per TB patient)
 - *Tuberculosis Treatment Referral/Transfer Form*
 - *Register of TB Suspects*
 - *Request for Sputum Smear Microscopy Examination* forms (about 15 per new smear-positive case).

Self-assessment questions



Answer the self-assessment questions below to check what you have learnt. Then compare your answers to those on page 16.

1. Whether they are delivered to the health facility or assembled at the health facility, _____, which contain all the drugs for a full _____ for one patient, are an important tool to ensure correct drug treatment and compliance.
2. Estimates of anti-TB drugs needed next quarter are based on the expected number of TB patients that will start treatment next quarter. It is assumed that the number of patients who will need each treatment regimen next quarter will be _____.
3. List at least three things to check when you receive a shipment of drugs:
 -
 -
 -
4. A New patient regimen is 2(RHZE)/4(RH)₃. How many total doses are required for the initial phase?

How many for the continuation phase?

(If you do not know the answer to Question 4, refer to Annex C.)

5. List critical supplies for TB management (other than drugs) to stock at a health facility.
 - For sputum examination: (list 1 item)
 - For streptomycin injections: (list 3 items)
 - Forms and registers: (list 4 items)
6. The number of sputum containers needed for the next quarter can be calculated based on the number needed for _____, plus the number needed for _____, plus the number needed for _____. This number is then increased by a percentage for additional investigations and an additional percentage for reserve stock.

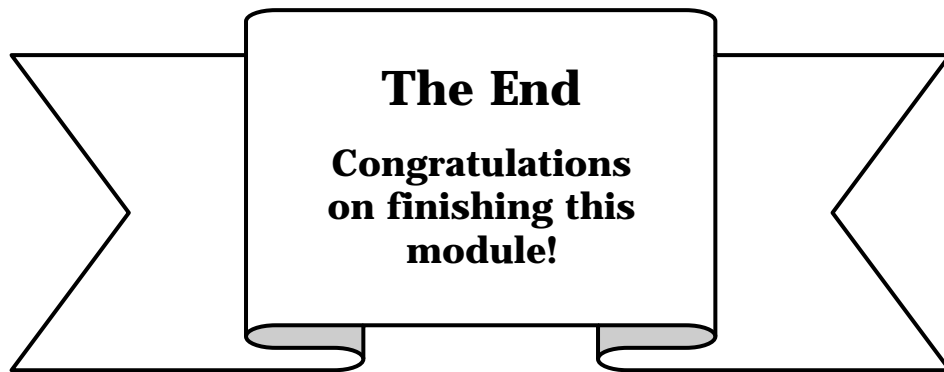
Now compare your answers with those on the next page.



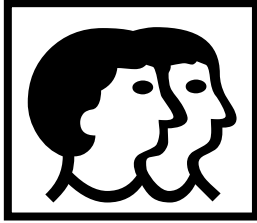
Answers to Self-Assessment Questions

If you had difficulty answering any question, turn back and study the section indicated. If you do not understand something, discuss it with a facilitator.

1. *Whether they are delivered to the health facility or assembled at the health facility, drug boxes , which contain all the drugs for a full treatment regimen for one patient, are an important tool to ensure correct drug treatment and compliance. (See Introduction.)*
2. *It is assumed that the number of patients who will need each treatment regimen next quarter will be the same, or approximately the same, as in the previous quarter . (See 1.2)*
3. *Check:*
 - *expiry dates (drugs not expired or about to expire)*
 - *number of complete regimens received*
 - *additional tablets received and their strengths*
 - *quantities received compared to amounts needed**(See 1.3)*
4. *The initial phase of this regimen is 2 months of daily treatment, which is 56 doses (28 doses per month x 2 months).
The continuation phase is 4 months of 3 times per week treatment, which is 48 doses (12 doses per month x 4 months). (See Annex C)*
5. *Critical supplies for TB management to stock at a health facility include:*
 - *For sputum examination: sputum containers*
 - *For streptomycin injections: Sterile needles, sterile syringes, sterile water for injection. If your health facility uses reusable needles and syringes, you may have listed a sterilizer in good working condition.*
 - *Forms and registers: Register of TB Suspects, Request for Sputum Smear Microscopy Examination forms, TB Treatment Cards, Tuberculosis Treatment Referral/Transfer forms**(See section 2)*
6. *The number of sputum containers needed for the next quarter can be calculated based on the number needed for diagnosis , plus the number needed for follow-up examinations , plus the number needed for culture and DST .
This number is then increased by a percentage for additional investigations and an additional percentage for reserve stock. (See 2.1)*



Exercises for Module F:
Manage Drugs and Supplies for TB



Exercise A

Group Practical Exercise – Examining a drug box for a TB patient

For this exercise, your facilitator will distribute several drug boxes for TB treatment among the group. You will examine a drug box to see how the different drugs look, how they are packaged and how they are labelled. Then there will be a group discussion of how drug boxes are prepared and stored at your health facility.

Part 1 – Examine a drug box

Examine the box that you are given and its contents. Determine the following and write in the blanks:

- Treatment regimen: _____
- The patient's weight (range) for which this box is appropriate: _____
- Size, shape and colour of different anti-TB drugs: _____

- Are drugs separate or combination drugs (FDCs)? _____
- How are each day's tablets packaged (blister packs, envelopes)? _____

- How are they labelled as to regimen and phase? _____
- Number of doses included for the initial phase: _____
- Number of doses included for the continuation phase: _____

Part 2 – Discussion

Write your answers to the questions below in preparation for the discussion.

a) Assembly: Are drug boxes assembled or modified at your health facility? If not, skip to b) below. If so, be ready to describe:

- Formulation and packaging of the drugs as they are provided to the health facility
- How staff plan what goes into each drug box
- How and when assembly of boxes is done

b) Storage and use:

- Where are drug boxes for TB stored at your health facility?
- Are storage conditions for drug boxes satisfactory? Why or why not?
- How do you locate the correct drug box (correct regimen) for a patient who will begin TB treatment among all those on the shelves?
- How do you label a drug box when it is assigned to a new TB patient?

- Where are drug boxes kept for patients who are currently being treated? Are those storage conditions satisfactory? Why or why not?

Tell your facilitator when you are ready for the discussion.



When the group has finished the discussion,
GO BACK to page 13 and read and work to
the end of the module (page 17).

Annexes

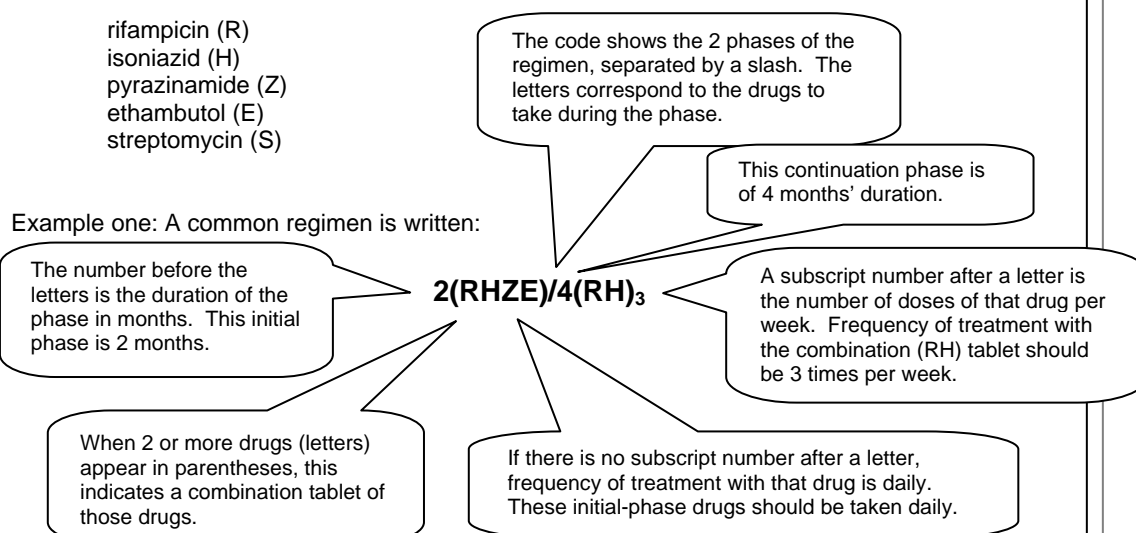
| | |
|--|----|
| A. How to read the drug code for TB treatment regimens | 26 |
| B. Guidelines for assembling drug boxes for TB patients..... | 27 |
| C. Dosages for recommended treatment regimens | 34 |

How to read the drug code for TB treatment regimens

TB treatment regimens are described using a standard code where each anti-TB drug has an abbreviation. Those abbreviations are:

rifampicin (R)
isoniazid (H)
pyrazinamide (Z)
ethambutol (E)
streptomycin (S)

Example one: A common regimen is written:



The above New patient regimen uses 2 fixed-dose combination tablets (also called FDCs). In the initial phase of 2 months, every day the TB patient takes a certain number (depending on the patient's weight) of the combination tablet of rifampicin, isoniazid, pyrazinamide and ethambutol (RHZE).

In the continuation phase, the TB patient would take a certain number of FDCs of rifampicin and isoniazid (RH) three times per week for 4 months.

Example two: **2(RHZE)S/1(RHZE)/5(RH)₃E₃**

The initial phase of this Retreatment regimen is 3 months but has two parts. For 2 months, drug treatment includes an FDC with rifampicin, isoniazid, pyrazinamide and ethambutol (RHZE) administered daily and also a daily injection of streptomycin (S). In the third month, drug treatment is with the combination tablet (RHZE); the streptomycin is not given.

The continuation phase is 5 months. Drug treatment is with the FDC tablet (RH) given 3 times per week (subscript number ₃ after the letters) and ethambutol (E), also given 3 times per week.¹¹

¹¹ If the FDC (RHE) is supplied, the regimen for the continuation phase is 5(RHE) daily.

Guidelines for assembling drug boxes for TB patients

If your health facility does not receive boxes of drugs packaged in complete regimens, you will have to assemble drug boxes. Exactly how to do this will depend on the national TB control programme's recommendations for each regimen, the presentations and packaging of the anti-TB drugs provided to your health facility, and the number of different weight ranges. For example, if one day's dose for the most common weight range is packaged in a blister pack, such as 3 (RHZE) tablets on one card, you will need only to count 56 of these cards for the initial phase and put them into the box. On the other hand, if the health facility is provided (RH) tablets, Z tablets and E tablets, it will take more time and care to prepare a box. You would have to count the number of each tablet needed each day, place the tablets into a small envelope, label it and repeat this to make 56 envelopes for the initial phase.

Staff in some health facilities, particularly those that treat only a few TB patients, wait to assemble a drug box until a new TB patient is ready to begin treatment. The health worker then prepares the correct regimen for the appropriate body weight. If this is the procedure in your health facility, however, you should complete as much assembly as possible ahead of time.

Some health facilities find it more efficient to preassemble several drug boxes for the New patient regimen and the Retreatment regimen in the most common weight ranges. If you choose to do this, take care not to assemble more boxes than will be used in the short term, so that drugs do not expire before they are used and quantities of drugs are not reserved for weight ranges that are not needed.

Some national TB control programmes provide drug boxes with the correct daily dosages of anti-TB drugs for a patient of average weight (38–54 kg), for example, for the New patient regimen, 3 (RHZE) tablets per day. Health staff must modify the boxes as needed for patients who weigh outside the average range. If the patient is lighter than average (30–37 kg), one set of tablets (a blister card with 28 tablets) is removed from the box, leaving 2 tablets per day. If the patient is heavier (55–69 kg), one set of tablets is added, making 4 tablets per day.

Whatever the formulation and packaging of the anti-TB drugs provided to your health facility, work out a procedure for preparing drug boxes so that most of the assembly can be done when the health facility is not busy. A drug box should be ready or very quickly prepared for use whenever a new patient is identified.

1. Plan what will go into one drug box

A drug box should contain the correct number of doses for the entire course of treatment. How each dose is packaged will depend on what drugs are provided by the national TB control programme. You may prepare small envelopes each containing the correct combination of loose tablets for one dose of the regimen. Alternatively, the tablets may be packaged in blisters, such as 28 tablets on one card, or doses for one week on one card. In that case, you would place the correct number of blister cards in a drug box.¹²

Before you can assemble a drug box, you must know:

- the drugs needed
- in what formulation the drugs are provided (the content of FDCs or other tablets)
- the future patient's weight (within a range)
- the number of tablets for each dose
- how many doses to include.

In the standard code for TB treatment regimens, the duration of each phase is stated in months. How many doses is that? The number of doses needed has been standardized as follows:

- One month is considered to be 4 weeks.
- For a daily regimen, a patient needs 28 doses per month (4 weeks x 7 days).¹³
- For a 3 times per week regimen, a patient needs 12 doses per month (4 weeks x 3 doses per week).
- Multiply either 28 or 12 by the number of months in the phase to determine the total doses required.

Standard number of doses for phases of different duration

| For a daily regimen (one month = 28 doses): | For a 3 times per week regimen (one month = 12 doses): |
|--|---|
| 2 months = 56 doses | 4 months = 48 doses |
| 3 months = 84 doses | 5 months = 60 doses |
| 5 months = 140 doses | |

¹² For a Retreatment regimen, which includes streptomycin during the first 2 months, you will not place the streptomycin in the drug box, but must put 56 doses (streptomycin vials, water for injection, sterile needles and syringes) in reserve for use with a TB patient.

¹³ Note that when a patient takes the anti-TB drugs 6 days per week, it will require more than 4 weeks to take 28 doses. This is acceptable; the important thing is for the patient to take all the required doses.

Complete steps a–e below to plan for making a drug box, writing the numbers on a piece of paper or worksheet. An example worksheet is provided on the next page. (A blank worksheet for future use is provided on page 31 in this module and also in the *Reference Booklet*.)

- a) Refer to a table of treatment regimens (such as on page 32) and find the appropriate regimen for the patient. At the top of the worksheet, record the regimen and weight range for which the box will be assembled.
- b) Read the code for the regimen to determine the drugs needed for the initial phase. Record the tablets that will be used for the initial phase, listing each FDC or separate tablet on a different line. Specify the formulation (content and strength) of each tablet. Specify the frequency (daily or 3 times per week). (See Annex A for a review of how to read the drug code for TB treatment regimens.)
- c) Read the table of treatment regimens to find out the number of each tablet per dose for the patient's weight. Record the number of tablets per dose. (See Annex C or your national TB control programme's table of treatment regimens.)
- d) Write the number of doses per month and the number of months in the phase.
 - 28 doses is the standard number of doses per month for a daily regimen.
 - 12 doses is the standard number of doses per month for a 3 times per week regimen.Multiply to determine the number of doses to include for the phase.
- e) Repeat steps b, c and d for the continuation phase. Refer to the code for the regimen to determine the frequency (daily or 3 times per week) and the duration of the phase (in months).

Keep the completed worksheet for reference whenever you need to assemble a drug box for this regimen and weight range.

EXAMPLE

Worksheet for drug box assembly

Box to be made: *New patient*
 Code for regimen: *2(RHZE)/4(RH)₃*
 Patient's weight: *40-54 kg*

a) On table of treatment regimens, find regimen for New patient or Retreatment and record on worksheet. Also record the weight of patient (range).

b) List each tablet on a separate line and note the formulation and strength. Specify frequency.

Initial phase

| Drugs and formulation | Frequency | Number of tablets per dose |
|---|--------------|----------------------------|
| <i>(RHZE)</i> <i>(R 150mg + H 75mg + Z 400 mg + E 275 mg tablet)</i> | <i>daily</i> | <i>3</i> |
| | | |
| | | |

c) From table of treatment regimens, determine number of tablets per dose for this weight range.

| Doses per month | Duration in months | Number of doses |
|-----------------|--------------------|-----------------|
| <i>28</i> | <i>2</i> | <i>56</i> |

d) Write the number of doses per month and duration in months. Then multiply to calculate the number of doses to include in the drug box.

e) Repeat steps b, c and d for the continuation phase to specify the tablets needed for each dose, and calculate the number of doses to include.

Continuation phase

| Drugs and formulation | Frequency | Number of tablets per dose |
|--|-------------------------|----------------------------|
| <i>(RH)</i> <i>(R 150mg + H 150mg tablet)</i> | <i>3 times per week</i> | <i>3</i> |
| | | |

| Doses per month | Duration in months | Number of doses |
|-----------------|--------------------|-----------------|
| <i>12</i> | <i>4</i> | <i>48</i> |

2. Gather together quantities of tablets and preassemble envelopes or packages of tablets

In some health facilities, staff prepare a number of drug boxes ahead of time. In others, particularly in smaller health facilities, staff assemble a box when beginning treatment for a new TB patient, so that the box is prepared with the correct regimen and for the patient's weight. (Note: Do not prepare more drug boxes than the number of patients you expect next quarter to prevent problems with expired drugs in drug boxes.)

However, complete as much assembly as possible ahead of time. For example, have ready a number of empty boxes, and blister packs or envelopes prepared with the usual number of tablets needed. Be familiar with the weight ranges and number of tablets needed for each dose.

Notice that the New patient regimen and the Retreatment regimen use the same daily dose of (RHZE) tablets in the initial phase, but the duration differs (2 months for the New patient regimen and 3 months for the Retreatment regimen.) You may preassemble packages of one month's supply (28 doses) for different weight ranges, such as 3 (RHZE) tablets per dose for 38–54 kg and 4 (RHZE) tablets per dose for 55–69 kg. Then to assemble the initial-phase drugs for the New patient regimen for a patient who weighs 50 kg, you would just have to pick up 2 months' packages of 3 tablets per dose. For a Retreatment regimen for a patient who weighs 50 kg, you would pick up 3 months' packages of 3 tablets per dose. In addition, you would place in reserve 56 doses of streptomycin (and 56 vials of sterile water, and sterile needles and syringes) for the first 2 months of treatment.

To gather quantities of tablets to assemble a number of drug boxes:

- Decide how many drug boxes you need to assemble for each regimen and weight range.
- Refer to a completed *Worksheet for drug box assembly* for each regimen (and weight range) to total the number of different tablets required per box.
- Multiply by the number of boxes that you want to assemble.
- Use this number to estimate the tablets to take out from the storeroom. (Streptomycin is usually not put into each drug box, but is kept in reserve for TB patients, perhaps in a separate place from general stocks of streptomycin.)

When you gather the drugs that you will use, check the expiry dates of the drugs. Use older stock first. Do not use any drugs that have expired or will expire during the treatment period.

3. Assemble a drug box

Refer to a completed *Worksheet for drug box assembly* for the regimen and weight range.

- **Assemble drugs for the initial phase**

Count the tablets for one dose of the initial phase. This may be one blister pack or part of a blister pack, or you may need to put strips or loose tablets for one dose into a small envelope. Then assemble the number of doses needed. If you are assembling envelopes, mark each envelope with an "I" (for initial phase).

- ***Then assemble drugs for the continuation phase***

Count the tablets for one dose of the continuation phase. This may be one blister pack or part of a blister pack, or you may need to put strips or loose tablets for one dose into a small envelope. Then assemble the number of doses needed. If you are assembling envelopes, mark each envelope with a “C”.

- ***Place the envelopes into the drug box***

Put all the blister packs or envelopes into a bag or box, separating the drugs for two phases by putting a divider into the box. Label the box with the regimen and code. In the example on page 28, the label would read “New patient regimen, 2(RHZE)/4(RH)₃.” Also write the earliest expiry date of the drugs included.

An alternative is to put all the doses for each phase into a separate bag, labelled with the regimen, phase and code. Then two bags are required for each patient.

4. Organize the drug boxes for future use

Place the drug boxes in the storeroom (fully assembled or partially assembled). Keep records of:

- the number of new drug boxes of each regimen placed on the shelf
- partially assembled boxes, such as packages of one month’s doses

Label every box or package in the storeroom and organize the boxes so that health workers can easily locate a drug box for each treatment regimen.

When a patient will begin treatment, the health worker will take out a new drug box, label the box with the patient’s name (and District TB Number when available), and place it with the drug boxes for other current TB patients. All drug boxes for current TB patients should be kept in a convenient, safe place that is accessible to the health worker giving directly-observed treatment each day.

Worksheet for drug box assembly

Box to be made:
Code for regimen:
Patient's weight:

Initial phase

| Drugs and formulation | Number of tablets per dose | Frequency |
|-----------------------|-------------------------------|-----------|
| | | |
| | | |
| | | |

| Doses per month | Duration in months | Number of doses |
|-----------------|--------------------|-----------------|
| | | |

Continuation phase

| Drugs and formulation | Number of tablets per dose | Frequency |
|-----------------------|-------------------------------|-----------|
| | | |
| | | |

| Doses per month | Duration in months | Number of envelopes |
|-----------------|--------------------|---------------------|
| | | |

**Recommended TB treatment regimens
(by weight and using fixed-dose combination drugs)**

New patient regimen

| Regimen Patient's weight (kg) | Initial phase (2 months) | Continuation phase (4 months) | |
|--------------------------------------|--|---|--|
| | 2(RHZE) | 4(RH) ₃ | 4(RH) |
| | Daily 56 total doses | 3 times per week 48 total doses | Daily 112 total doses |
| | (rifampicin 150 mg + isoniazid 75 mg + pyrazinamide 400 mg + ethambutol 275 mg) | (rifampicin 150 mg + isoniazid 150 mg) | (rifampicin 150 mg + isoniazid 75 mg) |
| 30–39 kg | 2 | 2 | 1.5 |
| 40–54 kg | 3 | 3 | 2 |
| 55–70 kg | 4 | 4 | 3 |
| Over 70 kg | 5 | 5 | 3 |

Retreatment regimen (for previously treated relapse and default)

| Regimen Patient's weight (kg) | Initial phase (3 months) | | Continuation phase (5 months) | |
|--------------------------------------|--|---|--|---|
| | 2(RHZE)S/1(RHZE) | | 5(RH) ₃ E ₃ | 5(RHE) |
| | Daily 84 total doses of RHZE plus 56 doses of S | | 3 times per week 60 total doses | Daily 140 total doses |
| | (rifampicin 150 mg + isoniazid 75 mg + pyrazinamide 400 mg + ethambutol 275 mg) | streptomycin (vials, IM) 2 months | (rifampicin 150 mg + isoniazid 150 mg) + ethambutol 400 mg | (rifampicin 150 mg + isoniazid 75 mg + ethambutol 275 mg) |
| 30–39 kg | 2 | 0.500g | 2 + 2 | 2 |
| 40–54 kg | 3 | 0.750g | 3 + 4 | 3 |
| 55–70 kg | 4 | 1 g* | 4 + 6 | 4 |
| Over 70 kg | 5 | 1 g* | 5 + 6 | 5 |

* 750 mg for patients aged over 60 years.

