

PREVENTING TB

People who become infected with TB germs, but do not feel sick have latent TB infection (sleeping TB)



THE AURUM
INSTITUTE

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English | Version 1 | September 2019



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Clinician
Information



MANAGING ADVERSE EVENTS IN PATIENTS TAKING 3HP

Overall 3HP is safe
Minor adverse events are likely to occur in a small proportion of individuals
Rarely serious adverse events may occur, and hence both the health care provider and patient should be vigilant and manage such events rapidly



3HP and Adverse Events (AEs)

Because 3HP is a preventive treatment used to cure persons with no active disease, the risk of AEs should be especially minimized.

Most AEs associated with 3HP are drug reactions due to isoniazid and rifapentine. Some are also due to drug-drug interactions with other concomitant medications.

Active TB, and pregnancy can occur during 3HP use and should be carefully managed. Malaria outcomes can be worse with concomitant 3HP administration.

Drug reactions

The most common drug reactions with 3HP are:

- Liver toxicity (less common than for IPT)
- Flu-like reactions (more common than for IPT)

Drug reactions are usually mild and self-limiting, but occasionally they can be severe.

Children usually tolerate 3HP very well and have much lower rates of drug reactions.

Baseline assessment

Active TB must always be ruled out before commencing 3HP.

3HP is currently not recommended in:

- Pregnancy
- Age <2 years

Consider checking liver enzymes (AST/ALT) to assess baseline liver function in these individuals:

- PLHIV (usually done during antiretroviral initiation)
- Daily alcohol consumption
- Liver disorders including viral hepatitis
- Postpartum period (≤ 3 months after delivery)
- Concomitant use of other hepatotoxic medicines, especially unregulated supplements/herbal medicines

If AST > 3x ULN - 3HP should not be given and the patient should be referred for evaluation

Individuals at higher risk of peripheral neuropathy should be offered vitamin B6 (pyridoxine) supplementation with 3HP. If B6 is not available this should not delay starting a course of 3HP.

Counselling for AEs

Red/orange discoloration of urine and other body fluids while taking 3HP is normal and completely harmless.

Individuals should be alert to the following symptoms:

- Weakness, fatigue, loss of appetite, persistent nausea (early symptoms of hepatotoxicity)
- Flu-like, or other acute symptoms appearing shortly after taking a dose of 3HP
- Symptoms of active TB
- If a person thinks they are having an adverse event based on the symptoms above, they should contact their health care worker as soon as possible

Routine monitoring

Patients taking 3HP should be monitored at monthly visits to assess tolerability and adherence. Essential components of the visit are:

- Screen for active TB
- Screen for AEs and assess tolerability
- Assess adherence and provide support as appropriate
- Assess for new medications that can interfere with 3HP
- Repeat AST for patients who had a raised baseline test

Management of AEs

If an AE occurs while a patient is taking 3HP, they should be advised not to take any further doses until an assessment is made of the severity and nature of the AE.

Assessment should include:

- Screen for active TB
- Past history
- History of the AE: type, onset and duration, severity
- Relevant physical examination

Management of the AE should always be guided by the clinical judgement of the healthcare provider. Suggested management:

- Severe drug reactions: seek urgent supportive care
- Mild/moderate drug reactions: reassurance, symptomatic relief, further assessment
- Pregnancy: discontinue 3HP
- Active TB: discontinue 3HP and start full TB treatment

Recording and reporting

Routine pharmacovigilance procedures should be used for AEs associated with 3HP, where possible and according to national guidelines.

At sentinel sites, AEs should also be reported according to the evaluation protocol.

