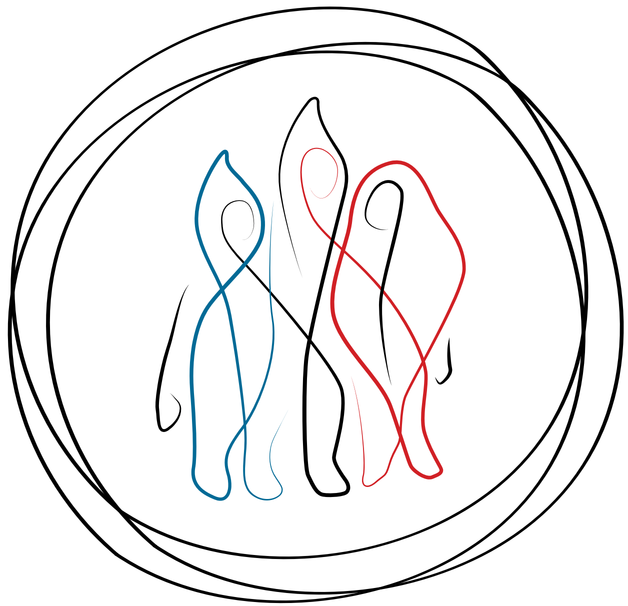

Guide for TB infection treatment with 3HP in Nunavik

Authors: Jessica Trahan, Valérie Messier, Geneviève Auclair and Julie Desjardins

April 18, 2024

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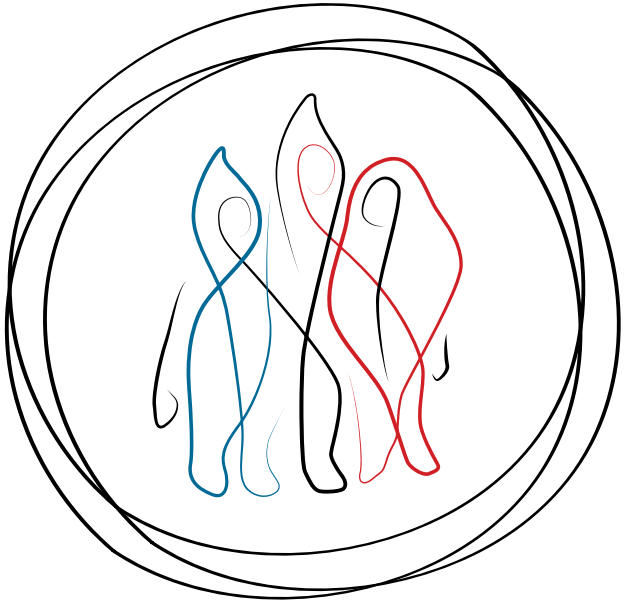
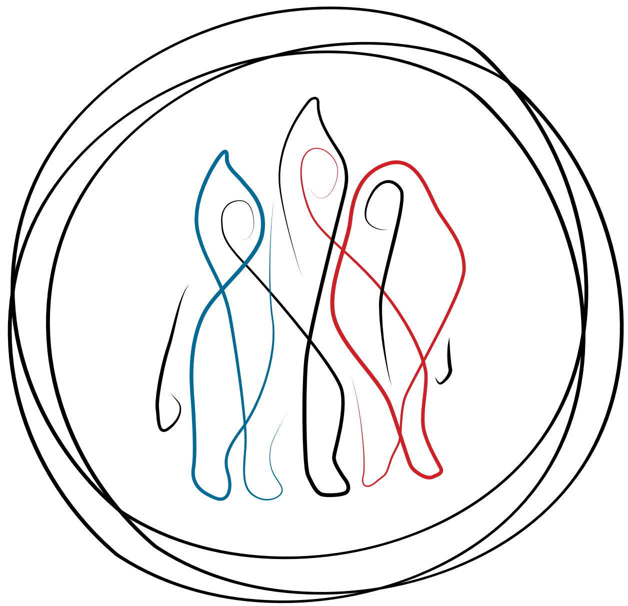
RÉGIE RÉGIONALE DE LA SANTÉ ET DES SERVICES SOCIAUX DU NUNAVIK
NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES



No conflict of interest to declare



Acknowledgements

We would like to thank the Nunavut Department of Health and the North Shore Public Health Department for sharing their 3HP protocols, from which the following content is inspired

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Training objectives

After this training session, participants will be able to:

- ✓ Provide a clear definition of the 3HP treatment;
- ✓ Explain the indications and contraindications associated with the 3HP treatment;
- ✓ Identify the side effects and potential interactions;
- ✓ Provide appropriate follow-up to patients on treatment.

A few basic concepts

Definition

TB infection (**TBI or LTBI**) refers to "the presence of *Mycobacterium tuberculosis* (MTB) bacilli inside the body without signs of the disease"

Persons with TBI:

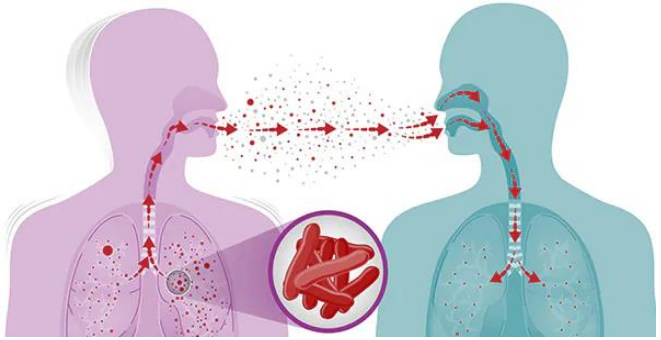
- exhibit no clinical signs or symptoms of the disease;
- are not contagious, hence do not present a risk for the people around them;
- show no signs of active TB disease on the chest X-ray (CXR);
- obtain negative microbiological test results (GeneXpert, smears, cultures);
- are not subject to mandatory treatment.

Source: MSSS – *Guide d'intervention - La tuberculose*, 2017

TBI treatment

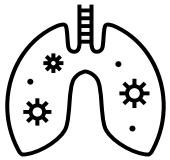
- ✓ Only approach to prevent active TB disease.
- ✓ Clinical and radiological follow-up ≠ prevention:
  - ➢ can only detect active TB once it has manifested itself, but it does not prevent the disease!

Risks of not treating TBI



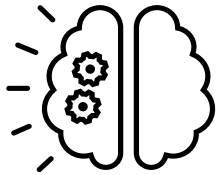
Source: CDC, 2023

- ✓ TBI can evolve into active TB disease (up to 10%)



- ✓ ↑ active TB = ↑ community transmission

- ✓ <u>Children < 5 years of age</u>: high risk of developing severe forms of TB (e.g., disseminated TB, TB meningitis)



Risk of active TB disease and manifestations according to age

Table 2. **Average age-specific risk for disease development after untreated primary infection.**

Age at primary infection	Manifestations of disease	Risk of disease (%)
<12 months	No disease	50
	Pulmonary disease	30-40
	TB meningitis or miliary disease	10-20
12-23 months	No disease	70-80
	Pulmonary disease	10-20
	TB meningitis or miliary disease	2-5
2-4 years	No disease	95
	Pulmonary disease	5
	TB meningitis or miliary disease	0.5
5-10 years	No disease	98
	Pulmonary disease	2
	TB meningitis or miliary disease	<0.5
>10 years	No disease	80-90
	Pulmonary disease	10-20
	TB meningitis or miliary disease	<0.5

Source: Adapted from Marais et al.[9]

Source: CTS, 2022

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	Pulmonary disease	10-20
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Source: Adapted from Marais et al.[9]

Source: CTS, 2022

3 → 3 months of weekly Tx

H → IN**H** (Isoniazid)

P → **P**riftin (Rifapentine)

TBI treatments offered in Nunavik

	Molecules	Duration	Frequency	Administration
First line	Rifapentine (RPT) and Isoniazid (INH) – 3HP	3 months	Once weekly	DOT
	Rifampicin (RIF)	4 months	Daily	SA (self-administration)
Second line	Isoniazid (INH)	9 months	Daily	SA (self-administration)
Third line	Isoniazid (INH)	9 months	Twice weekly	DOT

Source: CTS, 2022 and TB toolbox - NRBHSS

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New!

Source: CTS, 2022 and TB toolbox - NRBHSS

3HP:
First line therapy in Canada

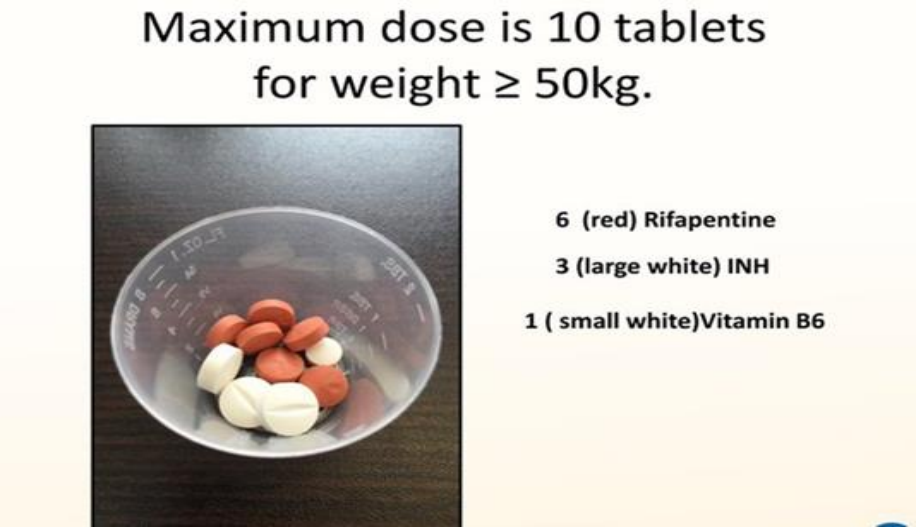
Source: https://bhekisisa.org/resources/general-resource/2020-04-01-world-health-organisation-guidelines-for-managing-and-treating-latent-tb/

- ✓ As effective as Rifampicin (RIF)
- ✓ Standard of care in the United States
- ✓ Used in Nunavut and other regions of Québec (e.g. North Shore)
- ✓ Priftin = not registered in Canada*

*Available through Health Canada's access program for urgent public health needs and through Indigenous Services Canada (ISC).

Sources: NCS, 8 ed., 2022 ; Alvarez et al., 2020

3HP



Source: Nunavut Department of Health

- ✓ Shortest treatment available : 12 weeks
- ✓ Dose taken once a week
- ✓ Lower hepatotoxicity than with INH alone
- ✓ Addition of vitamin B6 (↓ neurotoxicity)

Better completion rates

Sources: INESSS, 2019; CTS, 2022; Alvarez et al., 2020; CTS, 2022

Who can be treated with 3HP?

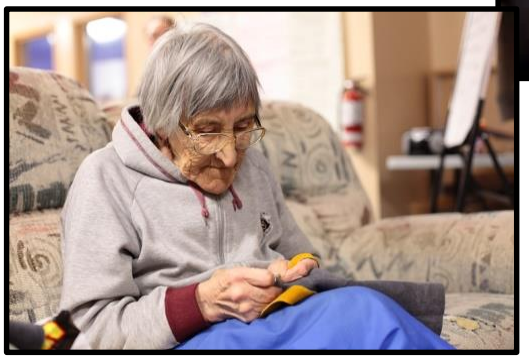
- **Children and adults between 2 and 65 years of age** (on a case by case basis if 65+ yo)

Treatment indications

- Recently diagnosed TBI
- Untreated or inadequately treated old TBI
- Window period prophylaxis (WPP) for vulnerable contacts (young children between 2 and 4 years of age)

Exclusions

- Pregnancy, breastfeeding or < 3 mo postpartum
- Children < 2 yrs old
- Adults > 65 yrs old (on a case by case basis)
- Persons with risk factors for <u>hepatotoxicity</u>



Source: Nunavut Department of Health, 2019

DOT – Directly Observed Therapy

Objectives

- ✓ ↑ treatment compliance and success rate
- ✓ ↑ early detection of adverse reactions, difficulties associated with treatment and other potential issues
- ✓ ↑ individual support throughout the treatment

↓ risk of active TB in the future

Nitrosamine contamination

- Since 2020, small quantities of contaminants called nitrosamines have been detected in rifapentine.
- Nitrosamines are potential carcinogenic compounds also found in certain food products and drugs, as well as in the environment.
- 3 months exposure with 3HP ≈ «normal» daily exposure x 1 year

Health Canada and CDC conclusions

- Risk of not treating TBI **>>>** Limited risk of exposure to nitrosamines due to 3HP.

Source: Kim, Thal et Szkwarko, 2023; TAG, 2021

Adverse reactions

3HP is a safe treatment that is usually well-tolerated

However, can be associated with:

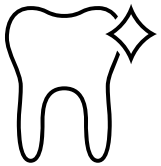
- Mild or moderate reactions mostly → usually no need to stop the treatment
- Rare severe adverse reactions → stop treatment and reassess the situation

Common reactions

Orange coloration of body fluids
(tears, urine, sweat)

- Disappear on cessation of treatment

Caution: may stain contact lenses and dentures.



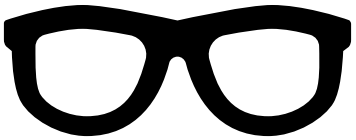
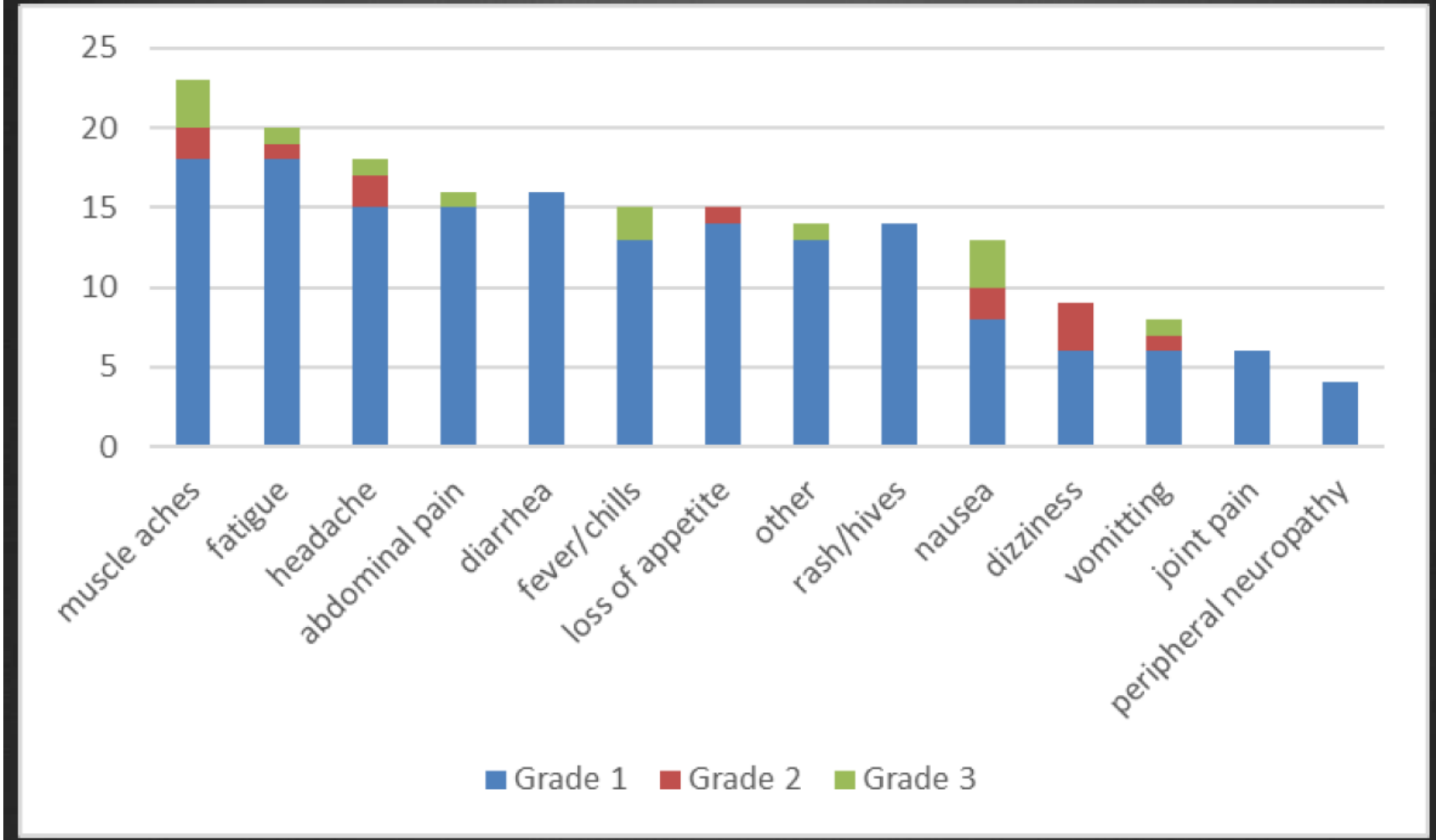


Figure 3 – Frequency of possibly related or related adverse events stratified by grade*



* Includes all adverse events reported by participants deemed as 'related' or 'possibly related' to 3HP by the investigators. Number of participants experiencing an adverse event with one or more doses where each participant is counted only once at the highest level of severity (Grade) for that symptom. Grade 1=Mild - discomfort noticed but no disruption of normal daily activity, Grade 2=Moderate - discomfort sufficient to reduce or affect daily activity, Grade 3=Severe - inability to work or perform normal daily activity, Grade 4=Life Threatening or Disabling - represents an immediate threat to life, Grade 5=Death related to adverse event.

Sources: Nunavut Department of Health, 2019 ; Alvarez, G. (2020)

Management of adverse reactions

	Definition	Recommended steps to take
Grade 1	Temporary reaction, no impact on daily routine (short-lived and not disabling).	• Notify the treating physician PRN • Ensure appropriate monitoring • Continue treatment
Grade 2	Reaction with an impact on daily routine and which limits usual functioning or persisting over 12-24 hours.	• Notify the treating physician • Ensure appropriate monitoring • Treat symptoms PRN • May require laboratory tests and temporary suspension of treatment
Grade 3	Reaction with a significant impact on daily routine and which is disabling in terms of work or usual tasks and activities.	• Notify the treating physician • Stop treatment • Ensure appropriate monitoring • Treat symptoms or provide support (PRN). • Laboratory tests (as per the clinic) • Report the situation as per the institution's procedure

Adverse reactions

Flu-like symptoms = frequent and generally benign (grade 1)

E.g.: nausea/vomiting, fatigue, aching muscles, fever, headaches, dizziness, abdominal pain

- ✓ Short-lived (usually < 12 hours)
- ✓ Usually present after the 3rd or 4th dose
- ✓ Onset within a few hours after taking the medication
- ✓ Not necessary to stop treatment, but follow-up required until symptoms resolve

Note:
Avoid administering 3HP on the same day as a vaccine

Adverse reactions

Hepatotoxicity*

Jaundice
Abdominal pain/discomfort
Anorexia
Nausea/vomiting
Dark (tea-coloured) urine
Pale (whitish) stool
Rash
Pruritus

*In the presence of jaundice or if suspicion of hepatotoxicity, do a liver function workup and suspend treatment.

Adverse reactions

Hepatotoxicity

If concentration of transaminases (AST/ALT) is **5X** the upper limit of normal range <u>without symptoms</u>

OR

If concentration of transaminases (AST/ALT) is **3X** the upper limit of normal range <u>in the presence of symptoms</u>

Notify the treating physician and **Stop treatment**

Adverse reactions

Hypersensitivity = severe reaction

Presence of ONE of the following Sx:

- Hypotension (systolic BP < 90 mm Hg)
- Hives (urticaria)
- Angiodema (swelling of lips and eyelids)
- Acute bronschospasm
- Conjunctivitis (red eyes)

<u>And</u> ≥ 4 of the following symptoms:

- Weakness, fatigue, nausea, vomiting, headache, fever, chills, sore muscles, dizziness, shortness of breath, hot flashes, profuse sweating (diaphoresis)

Cessation of treatment and urgent medical assessment

REMINDER

Particular conditions and moderate or severe adverse reactions must be documented and reported to the treating physician:

- ✓ abnormal laboratory results;
- ✓ potential adverse drug reactions;
- ✓ active TB symptoms;
- ✓ possible pregnancy;
- ✓ change in a pre-existing medical condition;
- ✓ visit to the ER or clinic;
- ✓ other special conditions presenting during treatment.

REMINDER

Any severe or unforeseen adverse reaction due to treatment/medication needs to be declared by the pharmacist to Health Canada as stipulated by the health centre's internal procedure.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html

Drug interactions*

Before starting any treatment, important to check:

- ✓ Medication taken on a regular or occasional basis
- ✓ Natural products used
- ✓ Substance use/abuse
- ✓ Potential interactions (confirm with pharmacist)

*Certain severe reactions can occur as a result of undocumented interactions.

Some interactions will require modifying the treatment while others may call for dosage adjustments or serum levels

Below is a partial list of molecules that can interact with 3HP:

- Certain antibiotics (clarithromycin, doxycycline, fluoroquinolones such as ciproflocaxin, levofloxacin, etc.)
- Warfarin
- Methadone
- Cyclosporin, tacrolimus
- Antihypertensive drugs (propranolol)
- Prednisone
- Digoxin
- Sulfonylureas
- Levothyroxine
- Fibrates and antilipemic agents
- Phosphodiesterase-5 inhibitors (sildenafil)
- Ticagrelor
- Anticonvulsants (phenytoin, valproic acid)
- Tricyclic antidepressants (amitryptiline, nortriptyline)
- Antifungals (fluconazole, itraconazole, ketoconazole)

Source: Nunavut Department of Health, 2019

Drug interactions

Examples

Antiretroviral substances

Combination not recommended

Combined Oral Contraceptives (COC) and other hormonal contraceptives

Decreases effectiveness:
add a barrier method

TB Toolbox

Professionals

- Professionals
- Nunavik DPH Publications
- Info-Vaccin
- Infectious Diseases
- Sexual-health
- Ece and schools
- Environmental Health
- Overdose
- Training
- Vaccination

Tuberculosis (TB) Toolbox

Introduction

Under the coordination of the Nunavik Public Health Department, this TB toolbox brings together all the tuberculosis assessment and follow-up protocols and documents used at regional level in Nunavik's two health centers.

Its objectives are to :

- standardize tuberculosis clinical and public health practice guidelines at regional level;
- support and guide the interventions of the various professionals involved in tuberculosis control.

It is the fruit of consultation and consensus-building between all institutional and professional partners involved in the regional fight against tuberculosis.

This TB toolbox is regularly updated and improved with the gradual addition of new tools.

Priority villages

Guides for practice

Diagnostic investigations

Latent tuberculosis infection (LTBI)

Active tuberculosis (TB)

Teaching materials

Mass screening

Capsules de formation avancée en tuberculose pour le Nunavik

S'abonner

Latent tuberculosis infection (LTBI)

	1ère diffusion	Mise à jour
Prescription of LTBI medication		
Prescription of LTBI medication - RIF	2023-10-02	2024-03-14
Prescription of LTBI medication – INH DOT	2023-10-02	2024-03-14
Prescription of LTBI medication – INH daily	2023-10-02	2024-03-14
Prescription of LTBI medication - RIF window-period	2023-10-02	2024-03-14
LTBI follow-up protocols		
Follow-up protocol - RIF	2023-10-02	2023-10-01
Follow-up protocol – INH Daily and DOT	2023-10-02	2023-10-01
Follow-up protocol – RIF window-period	2023-10-02	2023-10-01
Registration of the LTBI medication		
Registration of the medication - RIF	2023-10-02	2023-10-01
Registration of the medication – INH DOT	2023-10-02	2023-10-01
Registration of the medication – INH daily	2023-10-02	2023-10-01
Compliance curve		
Compliance curve – RIF	2023-10-02	2023-10-01
Compliance curve – INH daily	2023-10-02	2023-10-01
Monthly clinical assessment		
Adverse reactions of the main TB treatments	2023-10-02	2023-10-01
Monthly clinical assessment	2020-03-25	2023-10-02
Clinical and radiological follow-up		
Clinical and radiological follow-up guide	2023-10-02	2023-10-01
STANDARD clinical and radiological follow-up - Clinical evaluation and medical action	2023-10-02	2023-10-01
ADDITIONAL clinical and radiological follow-up - Clinical evaluation and medical action	2023-10-02	2023-10-01

Prescription – TBI (LTBI)

TB Program
Medical prescription

TREATMENT FOR LATENT TUBERCULOSIS INFECTION – 3HP (Rifapentine and Isoniazid) DOT

Allergies: ☐ Nil or Specify: _____

Attention: Pregnancy and breastfeeding are contraindications.

EMBOSSER ICI LA CARTE DU CSI OU CSTU, SI NON DISPONIBLE, INSCRIRE LES NOM, PRÉNOM, DATE DE NAISSANCE ET NUMÉRO DE DOSSIER

EMBOSS THE CARD OF THE IHC OR UTHC HERE, IF NOT AVAILABLE, WRITE THE NAME, SURNAME, DATE OF BIRTH AND FILE NUMBER

℞

CHILD OR ADULT (2 to 65 years)

Date of the prescription: _____ /_____ /_____
YYYY-MM-DD

Weight: _____kg

3HP – Rifapentine (RPT) and Isoniazid (INH)
1 dose/week PO administered under directly observed therapy (DOT) x 12 weeks (maximum of 16 weeks)

Rifapentine (RPT) – Child or adult (2 to 65 years) (max.: 900 mg), thus:

- ☐ 10.0 - 14.0 kg: 300 mg
- ☐ 14.1 - 25.0 kg: 450 mg
- ☐ 25.1 - 32.0 kg: 600 mg
- ☐ 32.1 - 49.9 kg: 750 mg
- ☐ ≥ 50.0 kg: 900 mg

Isoniazid (INH) (max.: 900 mg), thus:
(Round up to the next 50 mg dose)

- ☐ Child (2 to 11 years): 25 mg/kg
- ☐ Adolescent or adult (12 to 65 years): 15 mg/kg

Pyridoxine (vitamin B6) - Child or adult (2 to 65 years):

- ☐ 2 mg/kg (max.: 50 mg)

TO BE COMPLETED BY THE PHARMACY:

RPT: _____ *mg PO 1x/week X 12 doses*

INH: _____ *mg PO 1x/week X 12 doses*

Vit. B6: _____ *mg PO 1x/week X 12 doses*

Signature : _____

Name: _____ License #: _____

RÉGIE RÉGIONALE DE LA SANTÉ ET DES SERVICES SOCIAUX DU NUNAVIK
NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES

Protocol – TBI (LTBI)

Time	F-up	Interventions and investigations	Date and Signature
Prior to treatment / / YY/ MM/ DD	**MD**	**Before prescribing 3HP, ensure that:** ☐ Patient is between the ages of 2 and 65 (If > 65, assess on a case by case basis). ☐ Patient has no known allergies or severe side effects (hepatotoxicity, hypersensitivity, thrombocytopenia) to Isoniazid (INH), Rifapentine (RPT) or Rifampicin (RIF). ☐ A chest X-ray was done recently (< 8 weeks if LTBI diagnosis over the past 24 months or < 12 weeks in all other instances). ☐ If bacteriological specimens were requested, all results (smears/cultures) were negative (unless otherwise indicated by the treating pneumologist). ☐ If patient is a female of child-bearing age: negative results from a urine β-hCG test and not planning to get pregnant in the near future (12 to 16 weeks). ☐ If patient gave birth recently, ensure ≥ 3 months postpartum and not breastfeeding. **Also check for:** 1. Prior active TB: ☐ Yes ☐ No 2. History of abnormal liver function (AST-ALT ≥ 3 times normal) or porphyria: ☐ Yes ☐ No 3. Index case resistant to RIF or INH[2]: ☐ Yes ☐ No **Note:** If **YES** to 1, 2 or 3, consult the pediatric or adult pneumologist. If **NO** to 1, 2 and 3, initiate the LTBI treatment *(ITL_PRESC-MED-3HP_EN)*. **Prescribe:** ☐ Initial blood tests: ☐ Liver function, creat., CBC. ☐ Syphilis[3], HIV[3] ☐ For patients ≥ 12 years: follow-up blood tests of liver function after 1st month of treatment. ☐ Follow-up blood tests every month PRN[4]: liver function, creat., CBC. ☐ Initial and monthly β-hCG urine[5] test. **Other:** ☐ Check with pharmacist for potential interactions with other drugs (e.g., Dilantin) *(DSPu-TB_INTERACTIONS_MED_EN)*. ☐ Plan medication dosage or adjustment (e.g., Dilantin levels) during treatment if required. ☐ Counselling with regard to contraceptive use: if hormonal contraceptives are being used, promote adding another method (barrier contraception, such as condom).	Signatur / / YY/ MM/ D

- Symptomatic
- Abnormal initial workup results
- 50 years+ of age
- Hx of cirrhosis or hepatitis
- Rx at risk for hepatotoxicity
- Alcohol consumption

Protocol – TBI (LTBI)

Time*	F-up	Interventions and investigations	Date and Signature

1st day/date of the onset of treatment
__/__/__
YY/ MM/ DD
	Nurse	**Before initiating 3HP:**
		☐ Make sure there are no active TB symptoms. In case of symptoms, request a medical opinion STAT.
		☐ Take the patient's blood pressure and weight *(ITL_EVAL-CLIN-HEBDO-3HP_EN)*.
		☐ Initiate 3HP according to the medical order.
		☐ Inform the patient (treatment, compliance, side effects).
		☐ Prepare to complete follow-up forms:
		  ☐ Registration of the medication *(ITL-ENREG-MED-INH-DIE_EN)*.
		  ☐ Weekly clinical evaluation *(ITL_EVAL-CLIN-HEBDO-3HP_EN)*
		As per the medical order:
		  ☐ Do initial blood tests: liver function, creat., CBC, Syphilis[3], HIV infection[3].
		  ☐ Have a urine β-hCG test done[6].
			Signature
			__/__/__
			YY/ MM/ DD

End of the 4th week of treatment
__/__/__
YY/ MM/ DD
	Nurse	☐ **<u>Regular monthly follow-up</u>**: Notify the physician if abnormal.
		  ☐ Medication follow-up and provide support to the patient (*ITL_ENREG-MED-3HP_EN*)
		  ☐ Complete clinical evaluation for each dose administered *(ITL_EVAL-CLIN-HEBDO-3HP_EN)*
		As per the medical order:
		  ☐ Do follow-up blood tests PRN: liver function, creat., CBC.
		  ☐ Have a urine β-hCG test done[6].
			Signature
			__/__/__
			YY/ MM/ DD

End of the 8th week of treatment
__/__/__
YY/ MM/ DD
	Nurse	☐ **<u>Regular monthly follow-up</u>**: Notify the physician if abnormal.
		  ☐ Medication follow-up and provide support to the patient (*ITL_ENREG-MED-3HP_EN*)
		  ☐ Complete clinical evaluation for each dose administered *(ITL_EVAL-CLIN-HEBDO-3HP_EN)*
		As per the medical order:
		  ☐ Do follow-up blood tests PRN: liver function, creat., CBC.
		  ☐ Have a urine β-hCG test done[6].
			Signature
			__/__/__
			YY/ MM/ DD

Protocol – TBI (LTBI)

Time	F-up	Interventions and investigations	Date and Signature
End of Treatment (12th week) __/__/__ YY/ MM/ DD	**MD**	☐ Document compliance and treatment outcome. ☐ Complete and sign the *Clinical and radiological follow-up guide* during the post-treatment phase (*TB-ACT-ITL_GUIDE-SCR_EN)* once the treatment has ended. ☐ Update the list of problems (prior history) in the patient's chart.	Signature __/__/__ YY/ MM/ DD
	Nurse	☐ **Regular monthly follow-up**: Notify the physician if abnormal. ☐ Medication follow-up and provide support to the patient (*ITL_ENREG-MED-3HP_EN)*. ☐ Complete clinical evaluation for each dose administered *(ITL_EVAL-CLIN-HEBDO-3HP_EN)*. As per the medical order: ☐ Do follow-up blood tests PRN: liver function, creat., CBC. ☐ Have a urine β-hCG test done[6]. ☐ Plan for clinical and radiological follow-up as required, *Clinical and radiological follow-up guide (TB-ACT-ITL_GUIDE-SCR_EN)*. ☐ Send all completed documents to Public Health team.	Signature __/__/__ YY/ MM/ DD

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RÉGIE RÉGIONALE DE LA SANTÉ ET DES SERVICES SOCIAUX DU NUNAVIK
NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES

Protocol – TBI (LTBI)

FOLLOW-UP GUIDE FOR ADDITIONAL WEEKS

Extension of the planned duration of the treatment

To be followed if the treatment is extended beyond the 12-week period. Apply the interventions in the End of treatment line if one or more additional weeks are needed to complete the treatment. Beyond 16 weeks, the prophylaxis is considered inadequate if fewer than 11 doses were administered.

Time	Follow-up	Interventions and investigations	Date and Signature
End of treatment (12 to 16 weeks) __/__/__ YY/ MM/ DD	**MD**	☐ Document compliance and treatment outcome. ☐Complete and sign the *Clinical and radiological follow-up guide* once the treatment has ended (*TB-ACT-ITL_GUIDE-SCR_EN*). ☐ Update the list of problems (prior history) in the patient's chart.	_____ Signature __/__/__ YY/ MM/ DD
	Nurse	☐ **Regular monthly follow-up**: Notify the physician if abnormal. ☐ Medication follow-up and provide support to the patient (*ITL_ENREG-MED-3HP_EN*). ☐ Complete clinical evaluation for each dose administered *(ITL_EVAL-CLIN-HEBDO-3HP_EN)*. As per the medical order: ☐ Do follow-up blood tests PRN: liver function, creat., CBC ☐ Have a urine β-hCG test done[6]. ☐ Plan for clinical and radiological follow-up as required, *Clinical and radiological follow-up guide* (*TB-ACT-ITL_GUIDE-SCR_EN*). ☐ Send all completed documents to Public Health team.	_____ Signature __/__/__ YY/ MM/ DD

Prescription - WPP

Tuberculosis Program Medical Prescription
WINDOW-PERIOD PROPHYLAXIS – CHILD AGED 2 to 4 years 3HP – RIFAPENTINE and ISONIAZID DOT
Allergies: ☐ Nil or specify: ____________________

EMBOSSER ICI LA CARTE DU CSI OU CSTU,
SI NON DISPONIBLE, INSCRIRE LES NOM, PRÉNOM,
DATE DE NAISSANCE ET NUMÉRO DOSSIER

EMBOSS HERE THE CARD OF IHC OR UTHC,
IF NOT AVAILABLE, WRITE THE NAME, SURNAME,
DATE OF BIRTH AND FILE NUMBER

℞

CHILD AGED 2 to 4 years

Date of prescription: _____ /_____ /_____
YYYY MM DD

Weight : ____kg

3HP – rifapentine (RPT) and isoniazid (INH) administered once a week under DOT for the duration of the window-period or up to the equivalent of 12 doses/12 weeks

☐ WINDOW-PERIOD* – Child aged 2 to 4 years

Rifapentine (RPT) (max.: 900 mg), as follows:

- ☐ 10-14.0 kg: 300 mg
- ☐ 14.1-25.0 kg: 450 mg
- ☐ 25.1-32.0 kg: 600 mg
- ☐ 32.1-49.9 kg: 750 mg
- ☐ ≥50.0 kg: 900 mg

Isoniazid (INH) (max.: 900 mg), as follows:

(Round up to the next 50 mg dose)

- ☐ 25 mg/kg

Pyridoxine (vit. B6) (max.: 50 mg):

- ☐ 2 mg/kg

TO BE COMPLETED BY THE PHARMACY:
RPT: _____ mg PO 1x/week x 12 doses (maximum)
INH: ______ mg PO 1x/ week x 12 doses (maximum)
Vit. B6: ____ mg PO 1x/ week x 12 doses (maximum)

* If POST-WINDOW PERIOD TST not significant, end 3HP window-period prophylaxis on medical prescription.
If POST-WINDOW PERIOD TST significant and active TB excluded, continue LTBI treatment with 3HP up to equivalent of 12 doses/12 weeks (including window-period) by completing 3HP prescription (*DSPu-TB_ITL_PRESC-MED-3HP_EN*) and 3HP monitoring protocol (*DSPu-TB_ITL_PROT-SUIVI-3HP_EN*).

Signature: ______________________________ Licence #: ______________

Name : ____________________________________

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NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES

Protocol - WPP

When	Moni-toring	Interventions and investigations	Date and signature
Pre-treatment __/__/__ YY/MM/DD	**MD**	**Before prescribing 3HP for window-period:** ☐ Confirm that child's age is between 2 and 4 years old and consult growth chart (minimum 10 Kg) ☐ Make sure there are no known allergies or serious side effects (hepatoxicity, hypersensitivity, thrombocytopenia) with isoniazid (INH), rifapentine (RPT) or rifampicin (RIF) ☐ Eliminate an active TB diagnosis (normal chest X-ray (CXR) and clinical examination) ☐ If treatment longer than 12 weeks is expected due to an extended window-period (e.g., domestic contact of an active case isolated at home), prophylaxis with rifampicin is recommended **Check for:** 1. Previous active TB: ☐ Yes ☐ No 2. History of hepatic disorders (AST-ALT ≥ 3 times normal) or porphyria: ☐ Yes ☐ No 3. Index case resistant to RIF or INH[1]: ☐ Yes ☐ No **Note: If YES** to 1, 2 or 3: consult pediatric pneumologist. **If NO** to 1, 2 and 3, begin 3HP treatment for window-period *(DSPu-TB_ITL_PRESC-MED-3HP-FENETRE)*. ☐ Prescribe initial blood tests: liver function, creat., CBC ☐ Prescribe follow-up blood tests PRN[2]: liver function, creat., CBC ☐ Check with pharmacist for possible interactions with other drugs (e.g., Dilantin) *(DSPu-TB_INTERACTIONS_MED)* ☐ Plan medication dosage (e.g., Dilantin) during treatment if required	Signature YY/MM/DD
1st day/start date of Tx __/__/__ YY/MM/DD	**Nurse**	**Before beginning 3HP:** ☐ Make sure there are no active TB symptoms. In case of symptoms, request a medical opinion STAT ☐ Weigh patient and record weight on growth chart ☐ Provide instructions for parent/guardian (treatment, observance, side effects) **According to medical prescription:** ☐ Test liver function, creatinine, CBC ☐ Begin 3HP and fill out monitoring forms: - Registration of the medication *DSPu-TB_ITL_ENREG-MED-ITL-3HP-TOD* - Clinical evaluation *DPu-TB_ITL_EVAL-CLIN-HEBDO-3HP*	Signature YY/MM/DD

Protocol - WPP

When	Moni-toring	Interventions and investigations	Date and signature
Pre-treatment __/__/__ YY/MM/DD	**MD**	**Before prescribing 3HP for window-period:** ☐ Confirm that child's age is between 2 and 4 years old and consult growth chart (minimum 10 Kg) ☐ Make sure there are no known allergies or serious side effects (hepatoxicity, hypersensitivity, thrombocytopenia) with isoniazid (INH), rifapentine (RPT) or rifampicin (RIF) ☐ Eliminate an active TB diagnosis (normal chest X-ray (CXR) and clinical examination) ☐ If treatment longer than 12 weeks is expected due to an extended window-period (e.g., domestic contact of an active case isolated at home), prophylaxis with rifampicin is recommended **Check for:** 1. Previous active TB: ☐ Yes ☐ No 2. History of hepatic disorders (AST-ALT ≥ 3 times normal) or porphyria: ☐ Yes ☐ No 3. Index case resistant to RIF or INH[1]: ☐ Yes ☐ No **Note: If YES** to 1, 2 or 3: consult pediatric pneumologist. **If NO** to 1, 2 and 3, begin 3HP treatment for window-period *(DSPu-TB_ITL_PRESC-MED-3HP-FENETRE)*. ☐ Prescribe initial blood tests: liver function, creat., CBC ☐ Prescribe follow-up blood tests PRN[2]: liver function, creat., CBC ☐ Check with pharmacist for possible interactions with other drugs (e.g., Dilantin) *(DSPu-TB_INTERACTIONS_MED)* ☐ Plan medication dosage (e.g., Dilantin) during treatment if required	Signature YY/MM/DD
1st day/start date of Tx __/__/__ YY/MM/DD	**Nurse**	**Before beginning 3HP:** ☐ Make sure there are no active TB symptoms. In case of symptoms, request a medical opinion STAT ☐ Weigh patient and record weight on growth chart ☐ Provide instructions for parent/guardian (treatment, observance, side effects) **According to medical prescription:** ☐ Test liver function, creatinine, CBC ☐ Begin 3HP and fill out monitoring forms: - Registration of the medication *DSPu-TB_ITL_ENREG-MED-ITL-3HP-TOD* - Clinical evaluation *DPu-TB_ITL_EVAL-CLIN-HEBDO-3HP*	Signa YY/MM/DD

- Symptomatic
- Abnormal initial workup
- Risk factors or Rx at risk for hepatotoxicity

Protocol - WPP

When	Moni-toring	Interventions and investigations	Date and signature
End of 1st month of Tx __/__/__ YY/MM/DD	**Nurse**	**Regular monthly follow-up**: If abnormal, notify physician ☐ Complete Registration of medication form *DSPu-TB_ITL_ENREG-MED-ITL-3HP-TOD* ☐ Provide support to the patient ☐ Complete clinical evaluation before each dose *DPu-TB_ITL_EVAL-CLIN-HEBDO-3HP* ☐ As per medical prescription, test liver function, creat., CBC PRN[2]	_____ Signature YY/MM/DD
End of 2nd month of Tx OR End of window period[4] __/__/__ YY/MM/DD	**Nurse**	**Perform post-window-period TST[3]:** See section 4 of clinical evaluation of a contact of a case of active TB *DSPu-TB_DETECT-EVAL-CLIN* ☐ **If TST < 5 mm** and **asymptomatic:** Notify physician and stop window-period prophylaxis as per medical prescription _____ ☐ **If TST ≥ 5 mm** or **conversion[4]** or **symptomatic patient**: Notify physician If active TB is excluded: ☐ Continue LTBI treatment with 3HP according to medical prescription and 3HP monitoring protocol: *DSPu-TB_ITL_PRESC-MED-3HP* et *DSPu-TB_ITL_PROT-SUIVI-3HP* ☐ As per medical prescription, test liver function, creat., CBC PRN[2] ☐ Send all completed documents concerning window-period to Public Health TB team tuberculose-santepublique.nrbhss@ssss.gouv.qc.ca	_____ Signature YY/MM/DD
	MD	☐ **If post-window period TST ≥ 5 mm** or **conversion[5]** or **symptomatic patient**: medical evaluation ☐ If medical evaluation is abnormal, consult mchtb@muhc.mcgill.ca ☐ If active TB excluded: ☐ Prescribe LTBI treatment with 3HP *DSPu-TB_ITL_PRESC-MED-3HP* ☐ Sign 3HP LTBI protocol *DSPu-TB_ITL_PROT-SUIVI-3HP*	_____ Signature YY/MM/DD

Weekly clinical evaluation

Inuulitsivik

WEEKLY CLINICAL ASSESSMENT- LTBI TREATMENT
3HP (Isoniazid and Rifapentine) DOT (2 to 65 years)

Starting weight: _____ kg on (date): ____ /____ /____

EMBOSSER ICI LA CARTE DU CSI OU CSTU,
SI NON DISPONIBLE, INSCRIRE LES NOM, PRÉNOM,
DATE DE NAISSANCE ET NUMÉRO DE DOSSIER

EMBOSS THE CARD OF THE IHC OR UTHC HERE,
IF NOT AVAILABLE, WRITE THE NAME, SURNAME,
DATE OF BIRTH AND FILE NUMBER

	Presence of signs/symptoms[1,2] Enter N for No or Y for Yes If Yes, advise the physician	1 yy /mm/dd	2 yy /mm/dd	3 yy /mm/dd	4 yy /mm/dd	5 yy /mm/dd	6 yy /mm/dd	7 yy /mm/dd	8 yy /mm/dd	9 yy /mm/dd	10 yy /mm/dd	11 yy /mm/dd	12 yy /mm/dd
Hepatotoxicity	Deterioration of general condition												
	Abdominal pain/discomfort												
	Anorexia												
	Nausea/vomiting												
	Fatigue/drowsiness												
	Dark urine (tea-coloured)[3]												
	Pale stool (whitish)												
	Jaundice/ rash / pruritis												
Hypersensitivity	**ONE of the following symptoms:** Hypotension (systolic blood pressure < 90 mm Hg)[4]	mm Hg											
	Hives												
	Swelling around the lips and eyes (angioedema)												
	Acute bronchospasm												
	Conjunctivitis (red eyes)												
	And ≥ 4 of the following symptoms: Weakness, fatigue, nausea, vomiting, headaches, fever, chills, sore muscles, dizziness, shortness of breath, hot flashes, sweating												
	Flu-like symptoms (nausea, fatigue, aching muscles, fever, headaches, dizziness, abdominal pain)												
	Referred to physician												
	Nurse's initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials

[1] Simultaneously refer to the tool *Adverse reactions of the main TB treatments*.
[2] **In the absence of signs/symptoms**, enter N for No. **In the presence of signs/symptoms,** enter Y for Yes, include a note in the chart and advise the physician.
[3] Not to be confused with orange urine, which is a common side effect of taking Rifapentine
[4] Take blood pressure during the first dose and in the presence of symptoms compatible with hypersensitivity.
(DSPu-TB_ITL_EVAL-CLIN-HEBDO-3HP_EN, V2024-03-28)

RÉGIE RÉGIONALE DE LA SANTÉ ET DES SERVICES SOCIAUX DU NUNAVIK
NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES

Weekly clinical evaluation

Inuulitsivik

EMBOSSER ICI LA CARTE DU CSI OU CSTU,
SI NON DISPONIBLE, INSCRIRE LES NOM, PRÉNOM,
DATE DE NAISSANCE ET NUMÉRO DE DOSSIER

EMBOSS THE CARD OF THE IHC OR UTHC HERE,
IF NOT AVAILABLE, WRITE THE NAME, SURNAME,
DATE OF BIRTH AND FILE NUMBER

WEEKLY CLINICAL ASSESSMENT- LTBI TREATMENT
3HP (Isoniazid and Rifapentine) DOT (2 to 65 years)

	Presence of signs/symptoms[1, 2] Enter N for No or Y for Yes If Yes, advise the physician	1 yy/mm/dd	2 yy/mm/dd	3 yy/mm/dd	4 yy/mm/dd	5 yy/mm/dd	6 yy/mm/dd	7 yy/mm/dd	8 yy/mm/dd	9 yy/mm/dd	10 yy/mm/dd	11 yy/mm/dd	12 yy/mm/dd
Active TB symptoms[5]	New or unusual cough, wheezing (child)												
	Fever												
	Persistent night sweats												
	Hemoptysis												
	Weight loss or failure to thrive (child) - Record the weight every 4 weeks[6] (kg)	kg				kg				kg			
Other	Risk of pregnancy[7]												
	Referred to physician												
	Nurse's initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials	Initials

Signature and permit no.	Initials	Signature and permit no.	Initials	Signature and permit no.	Initials

[5] New or ongoing active TB symptoms can mean that the treatment is not working.
[6] **If body weight changes,** have the medication adjusted.
[7] Should there be a risk or signs of pregnancy while treatment is underway (unprotected sexual relations, late period, pregnancy symptoms, etc.), have a urine β-hCG test done and advise the physician.

(DSPu-TB_ITL_EVAL-CLIN-HEBDO-3HP_EN, V2024-03-28)

RÉGIE RÉGIONALE DE LA SANTÉ ET DES SERVICES SOCIAUX DU NUNAVIK
NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES

Registration of medication

RÉGIE RÉGIONALE DE LA SANTÉ ET DES SERVICES SOCIAUX DU NUNAVIK / NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES

Inuulitsivik

Centre de Santé et Services Sociaux Inuulitsivik
Inuulitsivik Health & Social Services Centre
Puvirnituq, Québec J0M 1P0
T 819 988-2957 / F 819 988-2796

UNGAVA TULATTAVIK HEALTH CENTER
CENTRE DE SANTÉ TULATTAVIK DE L'UNGAVA

EMBOSSER ICI LA CARTE DU CSI OU CSTU,
SI NON DISPONIBLE, INSCRIRE LES NOM, PRÉNOM,
DATE DE NAISSANCE ET NUMÉRO DE DOSSIER

EMBOSS THE CARD OF THE IHC OR UTHC HERE,
IF NOT AVAILABLE, WRITE THE NAME, SURNAME,
DATE OF BIRTH AND FILE NUMBER

REGISTRATION OF THE MEDICATION – Latent TB infection (LTBI)

3HP DOT (Directly Observed Therapy) (Rifapentine and Isoniazid) – Adult AND child (2 to 65 years)

Treatment start date[1]: ____/_____/____ Treatment end date[2]:____/_____/____

Duration of the treatment and number of doses to give: 12 doses over 12 weeks, maximum of 16 weeks

Enter the dosage prescribed by the physician:	▸▸ Notify the treating physician and Public Health team if:	▸▸ Discontinue treatment on medical order if :
Rifapentine (RPT) ______ mg po DOT 1 X week Isoniazid (INH) _______ mg po DOT 1 X week Vitamin B6 _________ mg po DOT 1 X week } = 1 dose	a) 2 consecutive doses are missed over a period of 2 weeks b) 3 doses are missed over a period of 6 weeks c) Only 6 doses have been taken at week 11	Less than 6 doses taken at week 12

IMPORTANT: A missed dose can be administered on the next acceptable day during the same week, AS LONG AS THE MINIMUM TIMEFRAME OF 72 HOURS BETWEEN THE DOSES IS COMPLIED WITH AND THAT NO MORE THAN 5 DOSES ARE ADMINISTERED OVER A PERIOD OF 28 DAYS.

Week	Monday[3,4]	Tuesday[3,4]	Wednesday[3,4]	Thursday[3,4]	Friday[3,4]	Saturday[3,4]	Sunday[3,4]	Total[5]
Week 1	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 2	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 3	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 4	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 5	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 6	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 7	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 8	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 9	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 10	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 11	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 12	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Fill in the lines below if the treatment extends beyond 12 weeks.								
Week 13	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 14	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 15	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	
Week 16	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	YY/MM/DD ___	

Degree of compliance at the end of the treatment[6]: □ Inadequate (< 11 doses over 16 weeks) □ Acceptable (≥ 11 doses over the max. of 16 weeks) □ Optimal (12 doses/12 weeks)

[1]Enter the date on which the first dose was taken.
[2]Enter the date on which the last dose was taken.
[3]Enter the date and the nurse's initials once the dose has been administered; enter X if the patient did not show up for his dose.
[4]Before each dose is administered, fill in the tool *Weekly clinical evaluation* for the 3HP and advise the physician of the presence of any symptoms.
[5] Calculate the cumulative (total) number of doses given.
[6] Once the treatment has ended, check the total number of doses taken, determine the degree of compliance and based on the latter, prepare a follow-up plan as indicated in the *Clinical and radiological follow-up guide*.

Signature and permit no.	Initials	Signature and permit no.	Initials	Signature and permit no.	Initials

(DSPu-TB_ITL_ENREG-MED-ITL-3HP-TOD_EN, V2024-04-04)

CLSC FILE

RÉGIE RÉGIONALE DE LA SANTÉ ET DES SERVICES SOCIAUX DU NUNAVIK / NUNAVIK REGIONAL BOARD OF HEALTH AND SOCIAL SERVICES

Registration of medication

A missed dose can be taken in the next few days if the following criteria are met:

- **At least 72 hours** between the doses

AND

- **No more than 5 doses** in a 28-day period

Notify the treating physician if:

- **2 consecutive missed doses** over a period of **2 weeks**
- **3 missed doses** over a period of **6 weeks**
- **At week 11,** only **6 doses** have been taken
- Discontinue Tx **if less than 6 doses** taken at **week 12**

Clinical and radiological follow-up

TUBERCULOSIS

CLINICAL AND RADIOLOGICAL FOLLOW-UP GUIDE

EMBOSSER ICI LA CARTE DU CSI OU CSTU,
SI NON DISPONIBLE, INSCRIRE LES NOM, PRÉNOM,
DATE DE NAISSANCE ET NUMÉRO DOSSIER

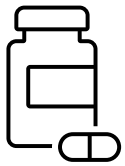
EMBOSS HERE THE CARD OF IHC OR UTHC,
IF NOT AVAILABLE, WRITE THE NAME, SURNAME,
DATE OF BIRTH AND FILE NUMBER

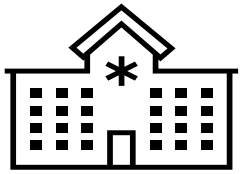
CHECK THE APPLICABLE CATEGORY (BELOW)			FOLLOW-UP PLAN: ENTER SCHEDULED DATE(S)						
Untreated or inadequately treated LTBI	**Clinical and radiological F/up**	**To schedule as of**	**6**	**12**	**18**	**24**	**36**	**48**	**60**
☐ LTBI acquired over the past 2 years (recent)	q 6 months X 2 years, then q 12 months X 3 years	Date of significant TST yyyy/ mm/ dd							
☐ LTBI at an unknown date AND resident of a priority village	q 12 months X 5 years	Date of significant TST yyyy/ mm/ dd	X		X				
☐ LTBI at an unknown date AND resident of a non-priority village	At 12 months	Date of significant TST yyyy/ mm/ dd	X		X	X	X	X	X
☐ LTBI acquired between 3-5 years ago (prior)	q 12 months, ad 5 years after significant TST	Date of Tx cessation/refusal yyyy/ mm/ dd	X		X		X	X	X
☐ LTBI acquired more than 5 years ago (prior)	No follow-up required	X	X	X	X	X	X	X	X
Treated LTBI									
☐ Prophylaxis deemed acceptable	6 months after end of prophylaxis	End date of prophylaxis yyyy/ mm/ dd		X	X	X	X	X	X
☐ Optimal prophylaxis	No follow-up required	X	X	X	X	X	X	X	X
Re-exposure to a case of smear-positive pulmonary TB (high-priority contacts according to Public Health)									
☐ Prior active TB OR LTBI (already known)[1]	q 6 months X 2 years, then q 12 months X 3 years	Date of re-exposure yyyy /mm /dd							
Follow-up after end of active TB treatment									
☐ Active TB <u>confirmed</u> (cavitary) OR smear-positive	q 6 months X 2 years, then q 12 months X 3 years	End date of treatment yyyy/ mm/ dd							
☐ Active TB (non-cavitary) AND negative smear (confirmed or probable)	q 6 months X 2 years	End date of treatment yyyy/ mm/ dd					X	X	X

Signature of the physician: ______________________ **License no.:** ______________ **Date:** yyyy/ mm /dd

Program	Inadequate prophylaxis	Prophylaxis deemed acceptable	Optimal prophylaxis
3HP	• < 11 doses within 16 weeks	• ≥ 11 doses within a maximum of 16 weeks	• 12 doses in 12 weeks
Rifampicin	• < 90 doses or > 4.5 months for 90 doses or > 6 months for 120 doses	• Between 90 and 120 doses – Consult RIF compliance curve *(ITL_COURBE-RIF)*	• 120 doses taken over 120 consecutive days
Isoniazid (INH)	• < 180 doses – die self-administered (SA) • < 62 doses of INH (DOT)	• Program die 6 months = 180 doses SA over 9 months (270 days) • Program die 9 months = 270 doses SA over 13.5 months (405 days) • INH (DOT): ≥ 62 doses 2 times a week over 9 months (270 days) max.	• 270 doses die SA over 9 months • 78 doses INH (DOT) 2 times a week

Rifapentine: supply





- Follow regular procedure with health centre (either UTHC for Ungava communities or IHC for Puvirnituq) or Pharmacie Voyer (for other communities served by IHC).
- Products available in Kuujjuaq and Puvirnituq if needed.
- Medication available in communities where there are outbreaks or where there is a screening initiative (e.g. to replace a lost or spoiled dose).
- Make sure that all 12 doses have been received before starting treatment.

Rifapentine: storage and transportation

- Store at room temperature (between 20° and 25°)

- Store away from direct light

- Do not freeze

Rifapentine: administration

- Administer with food if possible
- If medication is crushed, administer immediately after crushing
- Fill out the clinical evaluation form prior to each dose:

  In the presence of symptoms, do not give the dose and notify the treating physician.

Recommendations for patients

Prior to beginning and throughout the treatment:

- Encourage alcohol consumption reduction/cessation
- Ask for consumption of medication or substances that could potentially be hepatotoxic (e.g., acetaminophen)
- Check for risk or Sx of pregnancy
- Verify whether the patient has travel plans
- Ask for active TB symptoms
- Check for the presence of adverse reactions

TRAITEMENT AU 3HP POUR L'INFECTION TUBERCULEUSE LATENTE

Tant que nos poumons respirent,
notre histoire se poursuit.

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3HP treatment for latent tuberculosis infection

Contact at the clinic

Phone number: _____

What is latent tuberculosis (LTBI) infection?

Latent TB infection (also known as sleeping TB) means that the TB germs are in the body, but they are NOT active and NOT causing the disease. The person does not have any symptoms and is not contagious.

Why is it important to treat latent TB?

Latent TB treatment, with medication such as 3HP, can prevent you from getting sick and developing active TB disease.

What is 3HP?

3HP is a combination of two medications, rifapentine and isoniazid, and vitamin B6.

This treatment is the shortest available in Nunavik. It is offered once a week for 12 weeks under Directly Observed Therapy (DOT). Under DOT, you take your medication in the presence of a healthcare professional to help detect any side effects and to help you complete your treatment.

Who can take 3HP?

This treatment is offered to people from 2 to 65 years old. It is not recommended for pregnant or breast-feeding women, or women who expect to become pregnant. This treatment is also not recommended for people with some health conditions. Talk to your healthcare professional to find out if it is right for you.

What side effects can you expect?

3HP is a safe treatment and most people taking it do not have any side effects. You might see a red or orange discoloration of urine and other body fluids, like tears. This is normal. It will go away when you stop taking the medication. However, it can permanently stain dentures and contact lenses. Use glasses if possible.

This medication can make most contraceptive methods less effective. It is important to use condoms as an additional precaution. If you think you are pregnant, tell your healthcare professional.

In some rare situations, 3HP can be associated with liver toxicity. Avoiding or reducing alcohol intake will minimize the risks of developing adverse effects on the liver during treatment. If you do drink alcohol, blood tests will be done to check your liver function. Other drugs and medication can cause side effects if taken with 3HP (e.g. acetaminophen). Ask your healthcare professional if you have any questions about drug interactions.

Other rare side effects can occur. Make sure to mention them rapidly to your healthcare professional. They include:

- Flu-like symptoms: fever, headache, fatigue or weakness, muscle pain;

- Rash or hives, swelling of eyelids, lips, tongue or throat, hot flashes, ch[illegible]s or unusual sweats, dizziness, fa[illegible]ti[illegible] shortness of breath, wheezing;

- Numbness or tingling in you[illegible] hands, arms, legs or feet;

- Nausea, vomiting, diarrhea, loss of appetite, stomach upset or pain, yellow skin, dark urine, pale stools.

You also need to mention any of the following symptoms to your healthcare professional:

- Cough that lasts more than three weeks;

- Blood in your sputum;

- Night sweats;

- Fever;

- Unusual weight loss or fatigue.

Since these symptoms can be suggestive of active TB dise[illegible], mo[illegible]e tests can be necessary if t[illegible]ey occur.

Nitrosami[illegible] i[illegible]

Nitro[illegible]mines are potential carcinogens (could increase risk of cancer in a long time period) that were detected in very low quantity in rifapentine. They are common in some foods, drugs and in the environment. It is estimated that a three-month treatment with 3HP corresponds to about 1 year of "normal" exposure to nitrosamines in daily life. Levels found in rifapentine are safe and it is considered better to treat latent TB with 3HP than not to treat it.

What follow-up will be done during the treatment?

At the beginning of the treatment, and after the first month, a blood test will be done. If it is normal, most people will not need additional blood tests. If it is abnor[illegible]al, further tests will be done.

[illegible]very week, your healthcare professional will monitor your symptoms and possible side effects of the treatment.

For women of child-bearing age, a urine test will be performed every month to make sure they are not pregnant.

What should you mention to your healthcare professional?

- Any new symptoms
- Pregnancy, or plan to get pregnant
- Drug or alcohol use
- Any new medication
- Vaccination received or planned
- Travel outside the community

***Please mention that you are on 3HP treatment if you see another healthcare professional.

Calendar

You are scheduled to take your 3HP dose every _____ for 12 weeks.

Dose	Date	Comments
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		

If you forget your dose, visit the clinic as soon as possible.

Acknowledgements

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Questions

Thank you!
Nakurmiik!

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