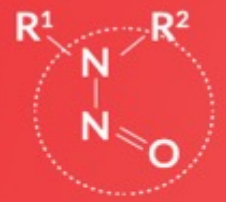
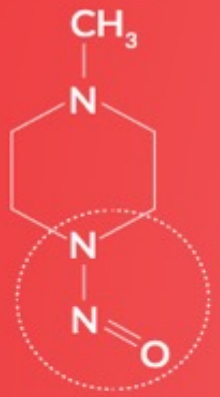
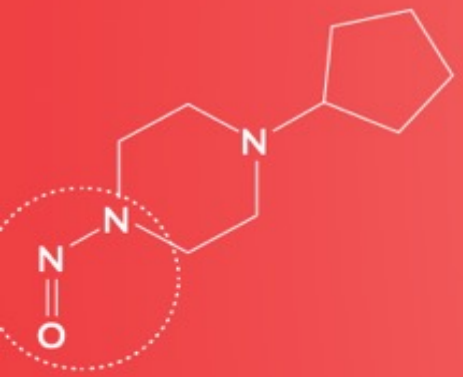


General N-nitrosamine chemical structure



MNP (found in rifampicin)



CPNP (found in rifapentine)

Nitrosamines and Rifampicin and Rifapentine

Mike Frick, MSc

TB project co-director

Treatment Action Group

TAG

Treatment Action Group

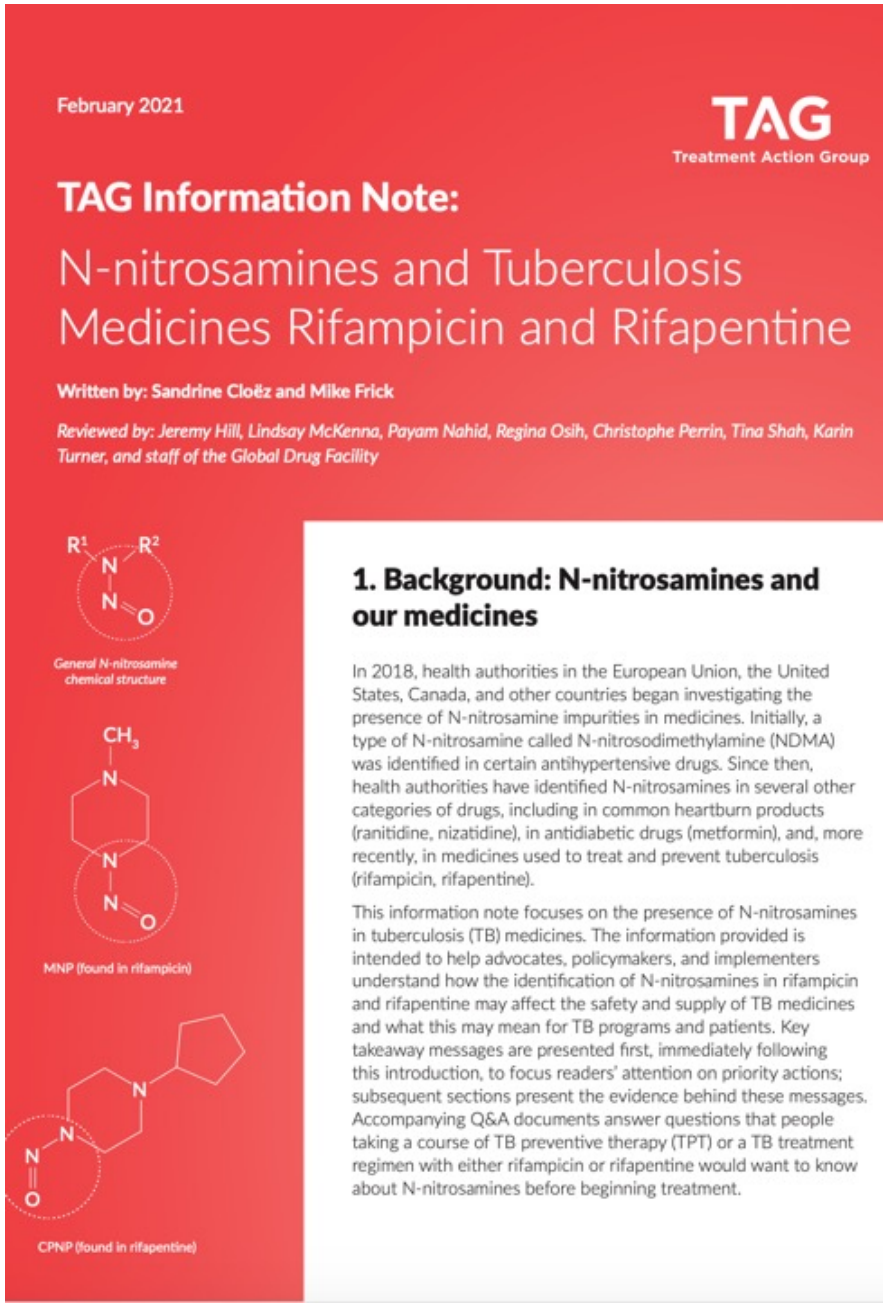
TAG
Treatment Action Group

Who we are

- Treatment Action Group (TAG) is an independent, activist, and community-based research and policy think tank fighting to end HIV, tuberculosis (TB), and hepatitis C virus (HCV) and committed to racial, gender, and LGBTQ+ equity.
- We are science-based activists working to expand and accelerate vital research and effective community engagement with research and policy institutions for an end to the HIV, TB, and HCV pandemics.
- TAG's TB Project strengthens evidence-driven and human rights-based advocacy both for better TB research, and for high-quality programs and policies worldwide, that meet the needs of affected communities.

TAG's work on nitrosamines

https://www.treatmentactiongroup.org/resources/ and search "nitrosamines"



February 2021

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TAG Information Note:

N-nitrosamines and Tuberculosis Medicines Rifampicin and Rifapentine

Written by: Sandrine Cloëz and Mike Frick

Reviewed by: Jeremy Hill, Lindsay McKenna, Payam Nahid, Regina Osih, Christophe Perrin, Tina Shah, Karin Turner, and staff of the Global Drug Facility

General N-nitrosamine chemical structure

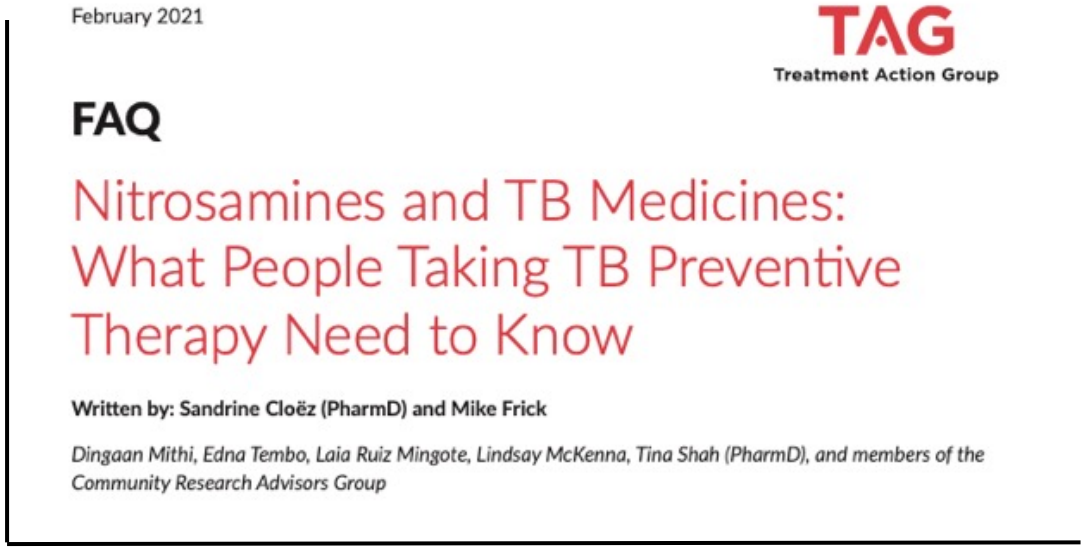
MNP (found in rifampicin)

CPNP (found in rifapentine)

1. Background: N-nitrosamines and our medicines

In 2018, health authorities in the European Union, the United States, Canada, and other countries began investigating the presence of N-nitrosamine impurities in medicines. Initially, a type of N-nitrosamine called N-nitrosodimethylamine (NDMA) was identified in certain antihypertensive drugs. Since then, health authorities have identified N-nitrosamines in several other categories of drugs, including in common heartburn products (ranitidine, nizatidine), in antidiabetic drugs (metformin), and, more recently, in medicines used to treat and prevent tuberculosis (rifampicin, rifapentine).

This information note focuses on the presence of N-nitrosamines in tuberculosis (TB) medicines. The information provided is intended to help advocates, policymakers, and implementers understand how the identification of N-nitrosamines in rifampicin and rifapentine may affect the safety and supply of TB medicines and what this may mean for TB programs and patients. Key takeaway messages are presented first, immediately following this introduction, to focus readers' attention on priority actions; subsequent sections present the evidence behind these messages. Accompanying Q&A documents answer questions that people taking a course of TB preventive therapy (TPT) or a TB treatment regimen with either rifampicin or rifapentine would want to know about N-nitrosamines before beginning treatment.



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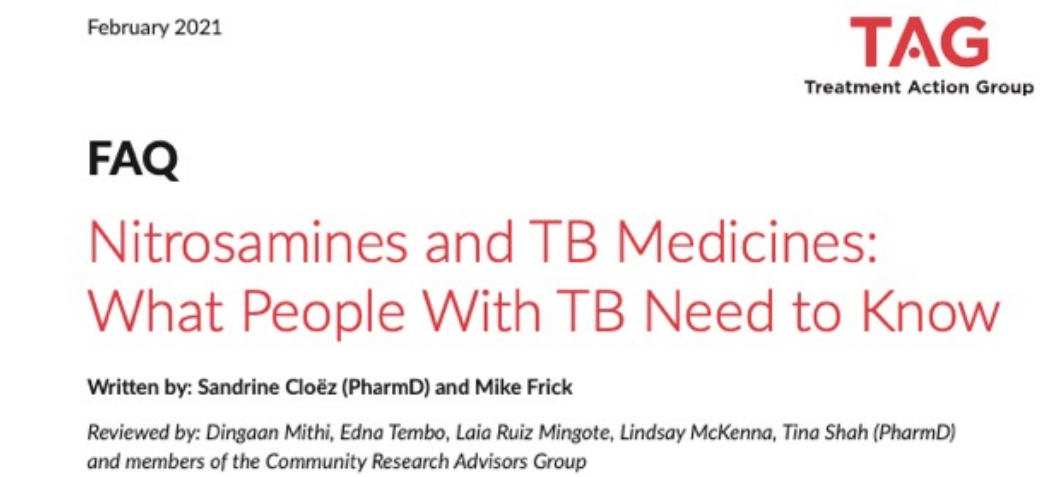
FAQ

Nitrosamines and TB Medicines: What People Taking TB Preventive Therapy Need to Know

Written by: Sandrine Cloëz (PharmD) and Mike Frick

Dingaan Mithi, Edna Tembo, Laia Ruiz Mingote, Lindsay McKenna, Tina Shah (PharmD), and members of the Community Research Advisors Group



February 2021

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Treatment Action Group

FAQ

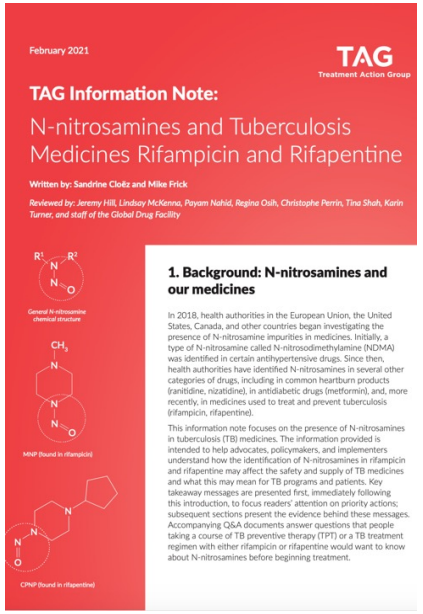
Nitrosamines and TB Medicines: What People With TB Need to Know

Written by: Sandrine Cloëz (PharmD) and Mike Frick

Reviewed by: Dingaan Mithi, Edna Tembo, Laia Ruiz Mingote, Lindsay McKenna, Tina Shah (PharmD) and members of the Community Research Advisors Group

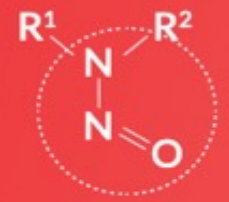
Today's talk:

- What do we know about nitrosamines and rifampicin and rifapentine?
- What information do we still need to gather?
- What is being done to address the problem?

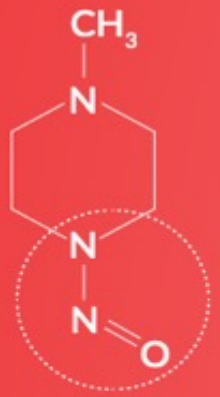


https://www.treatmentactiongroup.org/publication/nitrosamines-and-tb-medicines-information-note-and-patient-faqs/

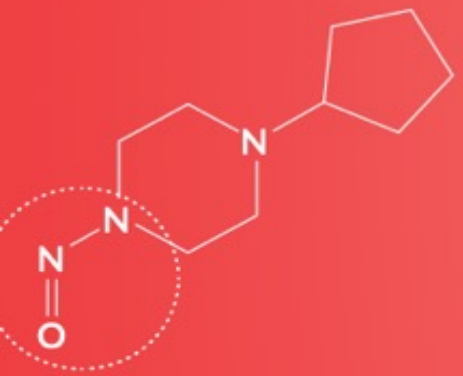
or: https://www.treatmentactiongroup.org/resources/ and search "nitrosamines"



General N-nitrosamine chemical structure



MNP (found in rifampicin)



CPNP (found in rifapentine)

What do we know about nitrosamines and rifampicin and rifapentine?

Nitrosamines | What are they?

General N-nitrosamine chemical structure

- Nitrosamines are chemical compounds classified as probable human carcinogens.
- Carcinogens are substances capable of causing cancer.
- Nitrosamines are **genotoxic**, meaning they can damage the genetic information inside cells. This leads to mutations which could cause cancer.
- Some nitrosamines may be **mutagenic** (able to cause a permanent change in a person's genes).
- There are different types of nitrosamines (NDMA, NDEA, CPNP, MNP etc.); some are more potent and carcinogenic than others.

Nitrosamines are **common**

- **Everyone is exposed to some level of nitrosamines in daily life**.
- Nitrosamines are present in:
  - drinking water,
  - foods (including processed foods, cured/grilled meats, dairy products, and vegetables),
  - tobacco,
  - cosmetics,
  - and rubber products.

Nitrosamines are also found **in medicines**

- Nitrosamine impurities in medicines are not new.
- Not all medicines contain nitrosamines.
- Only recently have regulatory agencies required drug makers to analyze their products for nitrosamines.
- In 2018, health authorities in the EU, USA, and Canada began investigating nitrosamine impurities in human medicines.
- Nitrosamines can be created during drug synthesis, result from cross-contamination during production (e.g., from using already contaminated equipment or reagents), or occur from degradation (e.g., during drug product storage).

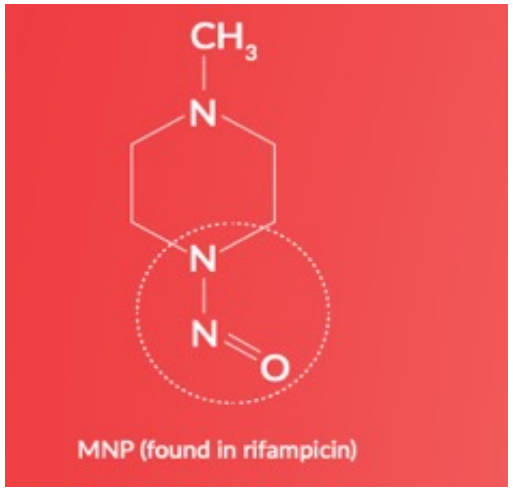
If nitrosamines are common in daily life, why is their presence in some medicines a problem?

"These molecules are of concern because nitrosamine impurities are probable human carcinogens. Although they are also present in some foods and drinking water supplies, their presence in medicines is nonetheless considered unacceptable."

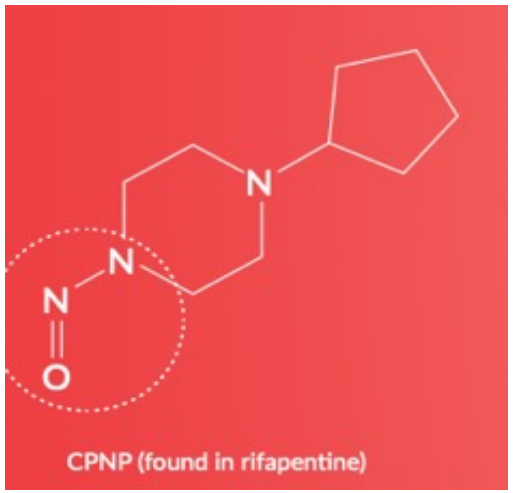
— *WHO Info Note on Nitrosamine Impurities*

WHO and regulatory authorities such as FDA and EMA are working with manufacturers to **identify** and **reduce** nitrosamines in medicines.

Nitrosamines | How do they affect our medicines?



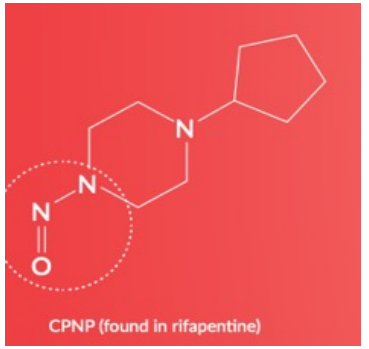
MNP (found in rifampicin)



CPNP (found in rifapentine)

- Nitrosamines were first identified in antihypertensive drugs (ARBs), in heart burn medication (ranitidine), and in antidiabetic drugs (metformin).
- In 2020, nitrosamine impurities were identified in samples of **rifampicin** and **rifapentine**.
  - The impurity found in rifampicin in MNP.
  - The impurity found in rifapentine is CPNP.
- There is little direct toxicity data on MNP and CPNP in humans or animals. In the absence of direct data, health authorities are using a different nitrosamine (NDMA) as a stand-in for MNP and CPNP.

CPNP | What do we know?



CPNP (found in rifapentine)

- CPNP is a nitrosamine found in rifapentine.
- CPNP originates from the synthesis of rifapentine active pharmaceutical ingredient (**API**).

  (CPNP arises from an intermediate step in the production of one of the starting materials of rifapentine API and is present in the final API as an impurity.)
- CPNP is present in rifapentine finished pharmaceutical product (**FPP**). The level of CPNP in rifapentine FPP has been observed to be higher than the level in rifapentine API.

  (This may be due to certain steps in drug processing).

The bottom line: CPNP is found in both rifapentine API and FPP. CPNP is not a problem specific to any one rifapentine manufacturer. All rifapentine manufacturers will need to address this impurity.

MNP | What do we know?

MNP (found in rifampicin)

- MNP is a nitrosamine found in rifampicin. (MNP is sometimes written as MeNP.)
- Like CPNP in rifapentine, MNP is present in both rifampicin API and FPP and likely arises initially from the synthesis of rifampicin API.

In September 2020, WHO requested that all prequalified manufacturers of rifampicin API and medicines undertake a risk evaluation by testing for MNP impurity in a representative number of product batches.

The report was issued in October 2021. It found that all prequalified manufacturers of rifampicin API and FPP reported MNP in batches tested.

So, like for rifapentine, the presence of nitrosamines in rifampicin is not particular to any one manufacturer.

Which TB products are affected by nitrosamines?

Anything with rifapentine or rifampicin.*

TPT	TB Treatment
3HP	HRZE (6-month DS-TB regimen)
1HP	HPZM (4-month Study 31 regimen)
3HR	
4R	

Other drugs used to treat TB (e.g. bedaquiline, delamanid, etc.) and prevent TB (isoniazid in 9H) are not affected.

* Another rifamycin, rifabutin, is not thought to be at risk of nitrosamine contamination.

What is the risk of nitrosamines to people taking TPT or TB treatment?

- There are no direct data on the carcinogenic potential of CPNP and MNP in humans.
- Health authorities use a metric called **acceptable intake (AI)** to set an acceptable level of risk.
  - Most simply, AI is the intake level that poses a negligible cancer risk.
  - More precisely, the AI is a daily exposure to a compound that approximates a 1:100,000 cancer risk after 70 years.
  - The method for determining AI is set by the ICH M7 (R1) guideline.

AI for MNP in rifampicin = 0.16 ppm

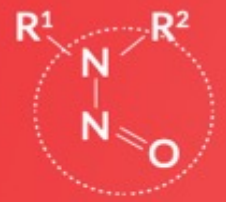
AI for CPNP in rifapentine = 0.1 ppm

- FDA has said that the AI of CPNP in rifapentine is 0.1 ppm and of MNP in rifampicin 0.16 ppm.
- *Temporarily*, in order to maintain access to these essential drugs for TB, FDA will allow manufacturers to distribute rifapentine with nitrosamines at/below 20 ppm and rifampicin at/below 5 ppm.

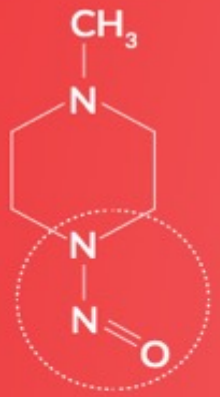
Temporary interim limits for CPNP in rifapentine:

- CPNP should be at/below **20 ppm** at drug product batch release
- CPNP should be at/below **25 ppm** at end of shelf life of drug product

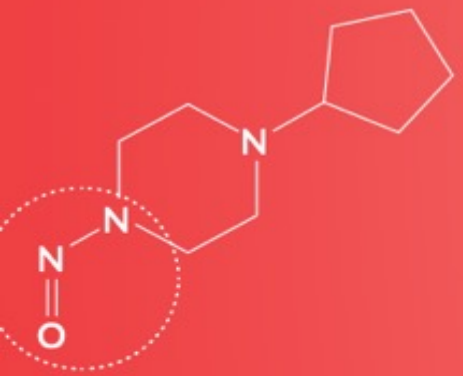
Bottom line: manufacturers can temporarily distribute rifapentine and rifampicin above the AI limits in accordance with higher interim limits. **Batches of drug substance and drug product should be systematically tested before release** to ensure nitrosamine content falls below the interim acceptable limits set by health authorities. Batches above the limit should not be released.



General N-nitrosamine chemical structure



MNP (found in rifampicin)



CPNP (found in rifapentine)

What information do we still need to gather?

Table 5: CPNP Exposure from Rifapentine-containing Regimens Compared to NDMA Background Exposure

Regimen (indication)	Dose and duration of treatment	AI-LTL (in ppm)	Exposure with batch at AI-LTL[α] AI-LTL (ppm) * MDD * treatment days	Exposure with batches at FDA interim limit (20 ppm) 20 ppm * MDD * treatment days	Approximation to NDMA background exposure[β] equivalent with batches at 20 ppm
3HP (TB infection)	900 mg weekly for 12 weeks = 12 days of treatment (24 days if twice) (<1 month of exposure)	8.5 ppm	8.5*900*12= 91.8 µg	20*900*12 =216 µg	~7 months of total background exposure
1HP (TB infection)	600 mg daily for 4 weeks = 28 days of treatment (<1 month of exposure)	12.8 ppm	12.8*600*28= 215 µg	20*600*28= 336 µg	~11 months of total background exposure
Rifaquin regimen (TB disease)	600 mg twice weekly for 2 months, then 600 mg weekly for 4 months = 32 days of treatment (<1 month of exposure)	12.8 ppm	12.8*600*32= 246 µg	20*600*32= 384 µg	~1 year of total background exposure
H/P/Z/M Study 31 regimen (TB disease)	1200 mg daily for 4 months (>1–12 months of exposure)	1.1 ppm	1.1*1200*119= 157 µg	20*1200*119= 2856 µg	~8 years of total background exposure
6P (TB infection)	600 mg daily for 6 weeks then (>1–12 months of exposure)	2.1 ppm	2.1*600*42=53 µg	20*600*42=504 µg	~1 year and 4 months of total background exposure

α. For calculation of AI-LTL values, see table 2.

β NDMA background exposures calculated at 365 µg (see table 4).

1 We need to better understand how nitrosamine exposures from CPNP in rifapentine compare to background exposures from other sources.

Source for background exposure valuation:

Table 4: Estimated Food and Total Background Exposure to NDMA

Source of NDMA exposure	Estimated exposure in ng/day	Estimated annual exposure in µg[α]
Processed meats in adults in EU[β] (lifetime daily)	25 to 85 X365 days	*9 to 31*
Total mean background exposure[χ] (lifetime daily)	100 to 1000 X365 days	*36.5 to 365*

α. 1000 ng (nanograms) = 1µ g (microgram).

β. Source: EFSA Panel on Food Additives and Nutrient Sources added to Food. Re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) as food additives. EFSA Journal. 2017;15(6):e04786. doi: 10.2903/j.efsa.2017.4786.

χ. Total background from contaminated beverages and food, air and water pollution. Source: Keszei A, et al. Dietary N-nitroso compounds, endogenous nitrosation, and the risk of esophageal and gastric cancer subtypes in the Netherlands Cohort Study. Am J Clin Nutr. 2013;97(1):135–46. doi: 10.13945/ajcn.112.043885.

Table 6: MNP Exposure from Rifampicin-containing Regimens Comparison to NDMA Background Exposure

Regimen (indication)	Current dose and duration of treatment	AI-LTL (in ppm)	Exposure with batch at AI-LTL[α] AI-LTL (ppm) * MDD * number of treatment days	Exposure with batch at FDA-agreed limit (5 ppm) 5 ppm * MDD * number of treatment days	Approximation to NDMA background exposure[β] equivalent with batches at 5 ppm
2(HRZE)/4(HR) (TB disease)	600 mg daily for 6 months (>1¬–12 months of exposure)	2.1 ppm	2.1*600*182= 229 µg	5*600*182= 546 µg	~1 year and 6 months of total background exposure
4R (TB infection)	600 mg daily for 4 months (>1–12 months of exposure)	2.1 ppm	2.1*600*119= 148 µg	5*600*119= 357 µg	~1 year of total background exposure
3HR (TB infection) [calculated at pediatric doses]	75 mg daily for 3 months 300 mg daily for 3 months (>1–12 months of exposure)	17.1 ppm 4.3 ppm	17.1*75*91= 117 µg 4.3*300*91= 117 µg	5*75*91= 34 µg 5*300*91= 136 µg	~1 month ~4 months of total background exposure

α. For calculation of AI-LTL values, see table 2.

β NDMA background exposures calculated at 365 µg (see table 4).

2 We need to better understand how nitrosamine exposures from MNP in rifampicin compare to background exposures from other sources.

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3 We need to better define risk/benefit for specific groups of people.

This includes understanding nitrosamine exposures in:

- Children.
  - *Note: The FDA has said that the same AI and interim limits for CPNP and MNP apply to children as to adults.*
- Pregnant women.
  - *Note: Some nitrosamines are known to be teratogenic. It is not known whether CPNP and MNP increase the risk of birth defects or adverse pregnancy outcomes.*
- People taking rifampicin or rifapentine alongside non-TB medications affected by nitrosamines.

4 We need better define potential toxicities and their consequences

- Are **overlapping exposures** to nitrosamines additive?
- Are there **compensatory actions** people taking rifampicin or rifapentine can take to reduce other nitrosamine exposures?
- Is **risk reversal** a possibility?
- Are CPNP and MNP more or less potent than NDMA?
- What is a clinically meaningful exposure of CPNP and MNP?
- Is it appropriate to set “less-than-lifetime” (**LTL**) acceptable limits for CPNP and MNP to account for the fact that TPT and TB treatment are not taken for long periods of time?

5 We need to develop simple + intuitive messages for providers and people taking TB treatment or TPT.

Right now, we think we can say:

Exposure to nitrosamines from taking a TPT regimen containing either rifapentine or rifampicin is approximately a year or less of usual background exposure in daily life.

* Assuming CPNP at 20 ppm and MNP at 5 ppm (current interim limits set by FDA).
** These exposures were calculated assuming that CPNP and MNP are as carcinogenic as NDMA.

Can we evolve the messaging to be even simpler? For example:

- 1 course of 3HP = the nitrosamine equivalent of eating X number of of Shake Shack cheeseburgers?
- Or, one 4th of July BBQ = the nitrosamine equivalent of a TB treatment course with HRZE?

6 We need to train our intuitive toxicology

- Everyone has an intuitive sense of toxicology, or instinctual ideas about what is safe versus dangerous. These ideas shape how we perceive risks and judge risk vs. benefit or one risk vs. another risk.
- We are all **intuitive toxicologists**, but we need to pair our intuition about what's toxic with evidence that helps us understand risk.

Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks*[1]

NANCY NEIL,[2] TORBJÖRN MALMFORS,[3] AND PAUL SLOVIC[4]

- Public less sensitive to considerations of dose and exposure than experts (tendency to view chemicals as either "safe" or "dangerous").
- Tendency among public to equate small exposures with certain harm.
- The public, unlike experts, tends to use a contagion/contamination model to understand exposures.
- 30% of the public respondents did not agree that a 1 in 10,000,000 lifetime risk of cancer from chemical exposure was too small to worry about.

Flags up! Sharks have been spotted nearby. (Hazard)

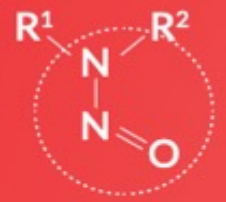
Shark sightings are more common during some months than others.

(Hazard + exposure information = more informed decision making)

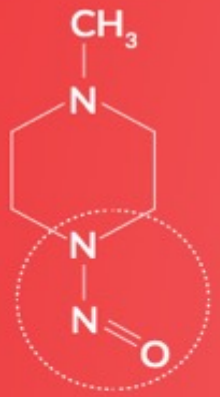
Even with hazard + exposure both present, actual risk can be low.

In the USA, risk of shark attack =

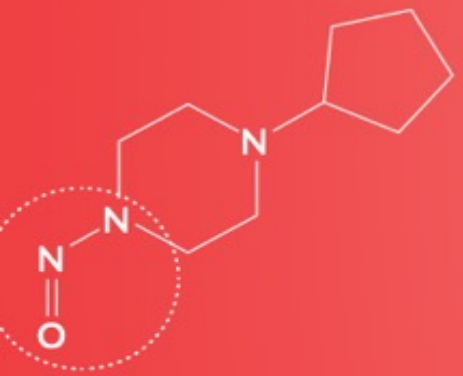
1 in 11.5 million.



General N-nitrosamine chemical structure



MNP (found in rifampicin)



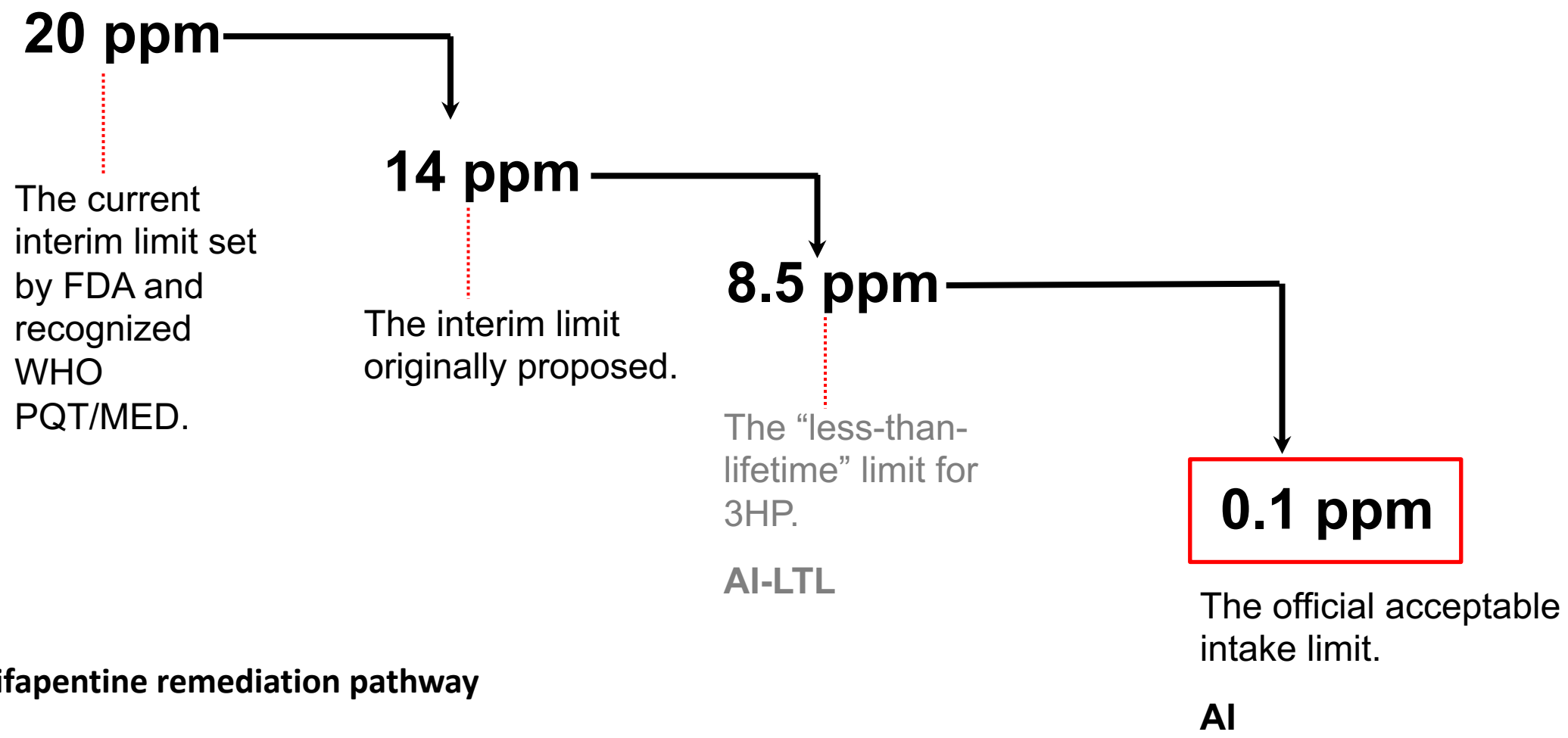
CPNP (found in rifapentine)

What is being done to address the problem?

Q: What should manufacturers do?

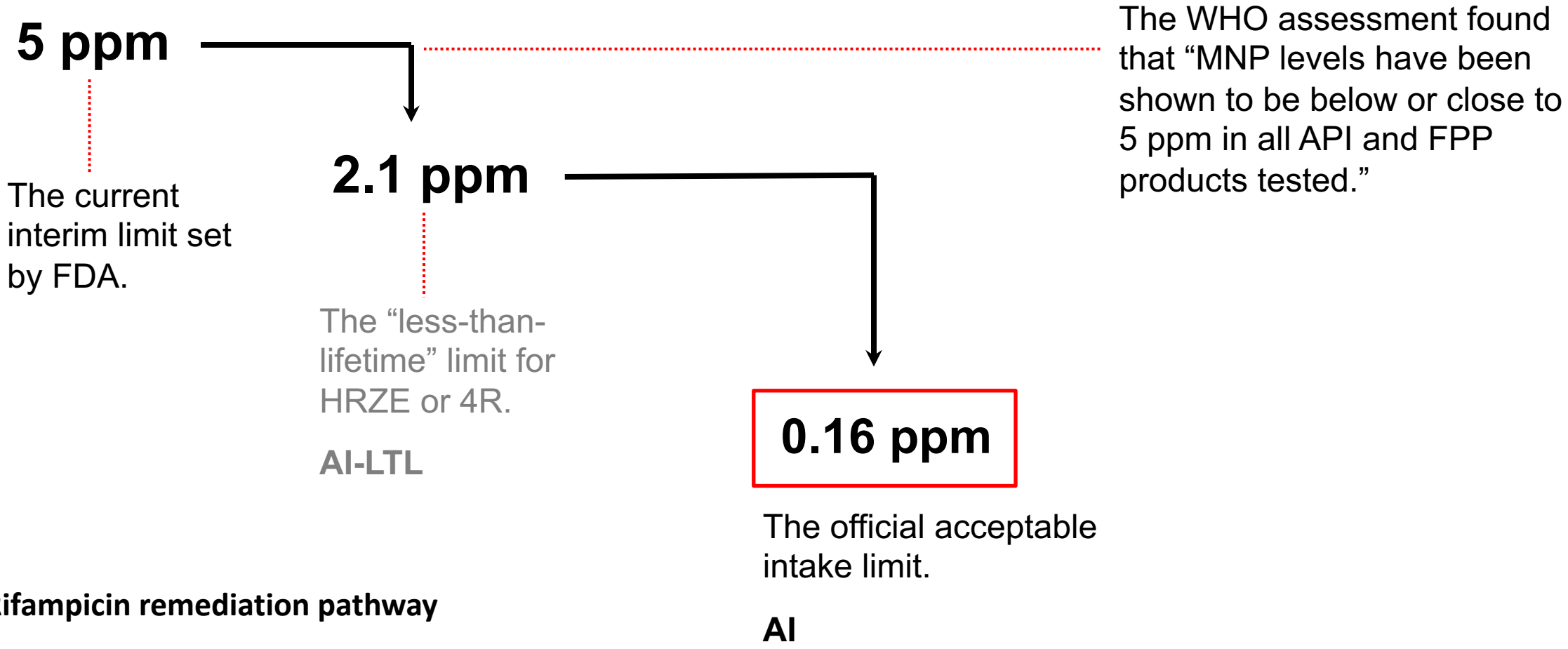
- **Remediate:** Manufacturers of rifapentine should expeditiously implement remediation plans to reduce the presence of CPNP N-nitrosamine impurity toward the target acceptable intake of 0.1 ppm.
- **Monitor:** In the interim, manufacturers should test all batches before drug release to ensure the interim limit of 20 ppm is met.
- Batches over this limit should be held back and not given to patients.
- **Verify:** Ministries of health and national TB programs should verify that any deliveries of rifapentine come with a certificate of analysis testifying that the associated product batch tested at or below the interim limits set by health authorities.

How do we track progress for lowering nitrosamines concentrations in **rifapentine?**



Rifapentine remediation pathway

How do we track progress for lowering nitrosamines concentrations in **rifampicin?**



Rifampicin remediation pathway

Q: Are manufacturers close to reaching AI?

0.1 ppm for CPNP in rifapentine
0.16 ppm for MNP in rifampicin

FDA Laboratory analysis of rifampicin/rifapentine products – Jan 2021

rifampicin

Company (Manufacturer)	Product	Lots Tested	MNP* level (micrograms-mcg/tablet or injection)	MNP* level (ppm)
Akorn	Rx Rifampin 300 mg	3185938, 3185931, 3184496, 3174136, 3191250	0.45-0.96	1.49-3.20
Akorn	Rx Rifampin 150 mg	3178340, 3174138, 3186047	0.44-0.52	2.95-3.47

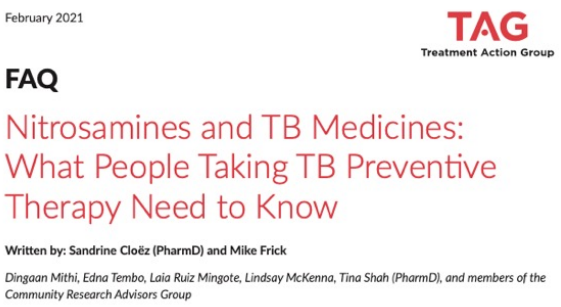
rifapentine

Company (Manufacturer)	Product/API	Lots Tested	CPNP level (microgram-mcg/tablet)	CPNP** level (ppm)
Sanofi	Rx Rifapentine 150 mg	9J2361, 0J0191, 0J1981	1.22-2.13	8.10-14.18

Q: What should **governments** do?

- **Verify**: Ministries of health should verify that deliveries of rifampicin and rifapentine come with a certificate of analysis that the product batch tested at or below the interim limits. (FDA)
- **Inform**: National TB programs should educate healthcare workers about nitrosamines and provide information to people taking TPT and TB treatment. (NTCA, CDC)
- **Prevent**: Ministries of health should strengthen supply chains in order to 1) ensure quality of final product delivered to patients and 2) avoid drug shortages and stockouts. (FDA)
- **Regulate**: Regulators should continue guide industry on nitrosamine remediation. When revising interim limits, regulators should grant manufacturers sufficient time to meet new standards to avoid drug shortages. (FDA)

Q: What should **people taking TPT** do?


February 2021

TAG
Treatment Action Group

FAQ

Nitrosamines and TB Medicines: What People Taking TB Preventive Therapy Need to Know

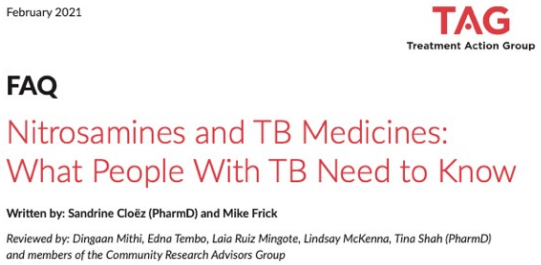
Written by: Sandrine Cloëz (PharmD) and Mike Frick

Dingaan Mithi, Edna Tembo, Laia Ruiz Mingote, Lindsay McKenna, Tina Shah (PharmD), and members of the Community Research Advisors Group

Should I stop taking my TB preventive treatment (TPT) if it contains rifapentine or rifampicin?

- **No**, do not stop taking your TPT (unless advised to by a healthcare worker.)
- The risks of developing TB far outweigh the theoretical risks of cancer associated with nitrosamines.
- Your TPT regimen contains nitrosamines at or below the established intake limits set by health authorities and therefore poses only a negligible risk of cancer.
- If you feel uncomfortable taking a TPT regimen containing rifampicin or rifapentine, you may choose to take IPT(6H, 9H) instead (but remember IPT has its own side effects, including risk of liver toxicity).
- TPT remains one of the best ways to keep yourself and your family safe from TB.

Q: What should **people taking TB treatment** do?



Should I stop taking my TB treatment if it contains rifapentine or rifampicin?

- **No,** do not stop taking your TB treatment.
- TB is a life-threatening disease but is curable when treatment is taken as prescribed.
- The risks of untreated TB disease far outweigh the theoretical risks of cancer associated with nitrosamines.
- Your TB treatment regimen contains nitrosamines at or below the established intake limits set by health authorities and therefore pose only a negligible risk of cancer.

Are there ways I can reduce my intake of other nitrosamines when taking TB treatment?

- **Yes.** You can take action to reduce the level of nitrosamines you are exposed to in daily life. Two of the most powerful actions are 1) avoiding tobacco products and 2) eating fewer grilled or preserved meats.

What does **WHO** say?

"[WHO] has concluded that the risk to the patient associated with interruption of treatment far outweighs any potential future cancer risk associated with MNP impurity present in the products at this level. Therefore, the PQT/MED's recommendation *not to interrupt* any rifampicin treatment remains."

"[WHO] keeps closely monitoring the responses related to rifampicin products and the ongoing work by manufacturers. A field sampling and testing study is also planned."

https://extranet.who.int/pqweb/news/nitrosamine-concerns-rifampicin-products-update

What does **FDA** say?

“Patients taking rifampin or rifapentine should continue taking their current medicine and consult with their health care professional about any concerns.”

“Tuberculosis is a potentially deadly disease that affects the lungs and sometimes other parts of the body, and the risk of not taking the medicine outweighs any potential risk from CPNP [in rifapentine].”

“FDA continues its ongoing review, surveillance, compliance and pharmaceutical quality efforts across every product area and will continue to work with drug manufacturers to ensure safe, effective and high-quality drugs for the American public.”

Take-home messages:

- Rifapentine and rifampicin are essential medicines for preventing and treating TB.
- The known risks of not treating or preventing TB outweigh the theoretical risk of cancer associated with N-nitrosamine exposures from rifampicin and rifapentine.
- People with TB should continue to take TB treatment with rifampicin.
- People at risk of TB should have the option to take preventive treatment based on either rifapentine (3HP, 1HP) or rifampicin (4R, 3HR).
  - If people feel uncomfortable about nitrosamines, 9H, 6H are alternatives. But 9H, 6H are longer, have more liver toxicity, and carry some other side effect risks.
  - People should know the pros/cons of different regimens in order to decide what is best for them.

Acknowledgments

- Sandrine Cloëz
- IMPAACT4TB partners

Questions?

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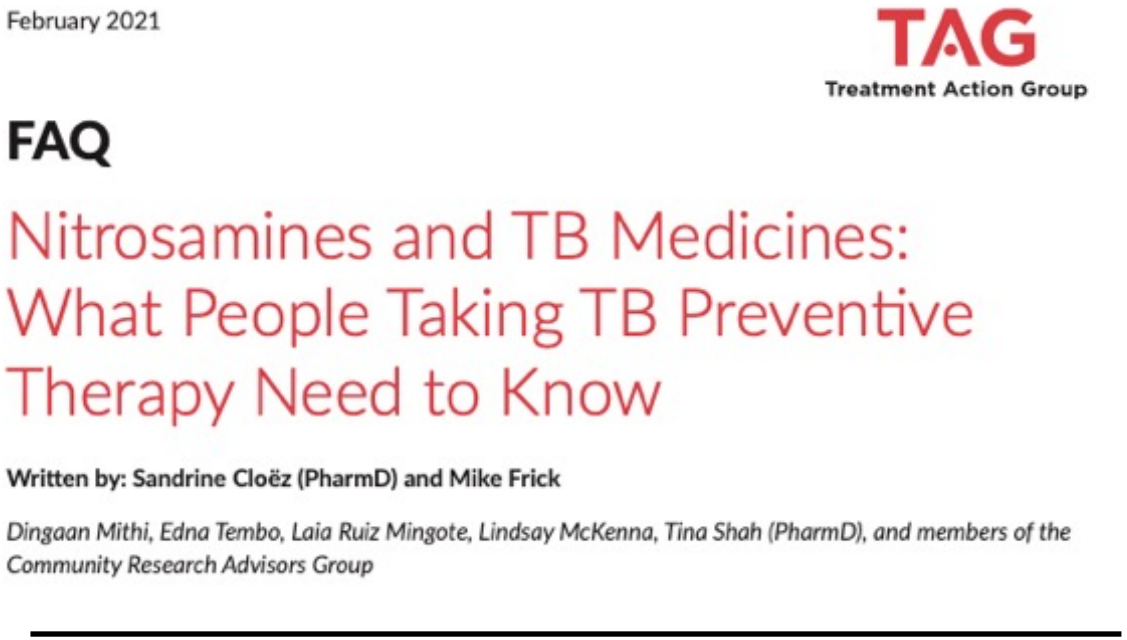

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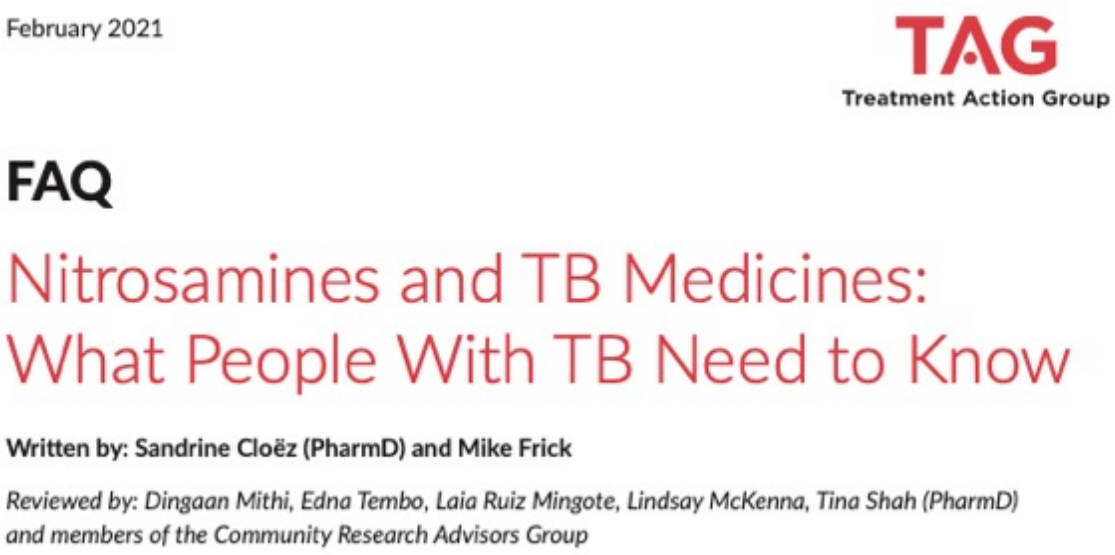

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