



Health Alert Network

Tri-County Health Department

Serving Adams, Arapahoe and Douglas Counties

Phone 303/220-9200 • Fax 303/741-4173 • www.tchd.org

Follow us on Twitter @TCHDHealth

John M. Douglas, Jr., M.D. Executive Director

The pages that follow contain information critical to protecting the health of your patients and the citizens of Colorado.

HAN ADVISORY

Number of pages including cover: 4

Subject: **Advisory - Nitrosamine guidance for TB healthcare providers - October 7, 2020**

Message ID: 10/7/2020 3:10:00 PM

Recipients: HAN Community Members.

From: TRI-COUNTY HEALTH DEPARTMENT

Adams, Arapahoe and Douglas County, Colorado

Recipient Instructions: **Tri-County Health Department is forwarding you the attached HAN. You may have already received this broadcast if you are on the CDPHE distribution list, however, we wanted to ensure you did not miss this important information. No response is required.**

You have received this message based upon the information contained within our Health Alert Network Notification System. If you have a different or additional e-mail or fax address that you would like us to use, or if you have additional questions, call 720-200-1477.

Categories of Health Alert Network Messages:

Health Alert: Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation; may not require immediate action.

Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.

Info Service/Public Health Brief: Provides general information that is not necessarily considered to be of an emergent nature.

You may download a copy of this HAN from the TCHD website at
<http://www.tchd.org/259/Health-Alert-Network>



HEALTH ALERT NETWORK BROADCAST

MESSAGE ID: 10072020 12:00

FROM: CO-CDPHE

SUBJECT: HAN Advisory - Nitrosamine guidance for TB healthcare providers

RECIPIENTS: Local Public Health Agencies / IPs / Clinical Labs / EDs / ID Physicians / Coroners

RECIPIENT INSTRUCTIONS: Local Public Health Agencies please forward to healthcare providers

HEALTH ADVISORY | Nitrosamine guidance for TB healthcare providers | October 7, 2020

Health care providers: Please distribute widely in your office

Key points

- The U.S. Food and Drug Administration (FDA) has found nitrosamine impurities, which are known to be carcinogens, in the tuberculosis (TB) drugs rifampin and rifapentine.
- Nitrosamines are a class of compounds that are impurities and refer to any molecule containing a nitroso functional group. These impurities are commonly found in low quantities in foods such as cured and grilled meats, dairy products, and vegetables, but can also be present in medications. More information about nitrosamines can be found at https://www.who.int/medicines/publications/drugalerts/InformationNote_Nitrosamine-impurities/en/
- The FDA is working with manufacturers to identify and address the origin of the impurities.
- The FDA is temporarily allowing the distribution of rifampin and rifapentine to continue while they investigate and until there is a resolution.
- Healthcare providers should consider and educate new and existing TB patients on the risks and benefits when evaluating treatment options for patients in various scenarios, as described below.

Background information

Nitrosamine impurities may increase the risk of cancer if people are exposed to elevated levels over long periods of time. The FDA regulates medications and has set acceptable daily intake limits on the concentrations of these compounds. The FDA estimates that a person taking a drug that contains nitrosamines at-or-below these limits every day for many years is not expected to have an increased risk of cancer. The number of impurities currently identified in rifampin and rifapentine is many times higher than the previously set limits. The true risk is unknown but is thought to be low. More information can be found at

<https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications>

Medication	Normal Acceptable Intake Limit	Temporary Acceptable Intake Limit
Rifampin	0.16 ppm of MNP	5 ppm of MNP
Rifapentine	0.1 ppm of CPNP	14 ppm of CPNP

Recommendations / guidance

Talking points for patient education and discussion can be found at

<https://www.fda.gov/consumers/consumer-updates/what-know-and-do-about-possible-nitrosamines-your-medication>

Tuberculosis is a serious and potentially deadly disease that usually affects the lungs but can cause disease in any part of the body.

If a patient *is sick* with TB disease

The risk of not taking the medicine to treat tuberculosis disease must be balanced against any potential risk from nitrosamine impurities. While other treatments may be available, and as with any medication, these treatment options carry their own set of potential risks, and the course of treatment *will* need to be longer. You will need to discuss these options with your patient.

If the patient *is not sick* with TB disease but has been diagnosed with TB infection and is currently taking one of these medicines to prevent TB disease

Discuss the following with your patient: educate on the recent identification of impurities, discuss risk vs. benefits, answer questions and address concerns, offer alternative treatment options if appropriate, and document discussion and the patient's decision in the patient record.

Another option is to stop treatment now and resume when this issue has been resolved. All options should be discussed with your patient.

If the patient is newly diagnosed with TB infection (*not sick* with TB disease)

Discuss issues of impurities, provide the same education on risk vs. benefits, answer questions, and offer treatment options as appropriate per patient's medical history and medical comorbidities.

Documentation

As a health care provider who is providing this education, you must document the following information in the patient's medical records:

- What information and education you provided to the patient
- The patient's response and level of understanding of the information you provided
- Any follow-up discussion including questions and answers
- The patient's consent or refusal for the medication

More information

Nitrosamine provider education document is available here:

<https://drive.google.com/file/d/1w2cvwtX8f651lgHex6ZK5ievRVHbdn4d/view>

CDPHE TB Nurse Consultant, 720-258-6562 or ann.scarpita@state.co.us

TB program website: <https://www.colorado.gov/pacific/cdphe/tb>