Rifampin and Priftin® (rifapentine) – Safety update

- On August 26, 2020, the FDA announced that there are nitrosamine impurities in certain samples of rifampin and Priftin (rifapentine). Patients taking these medicines should continue taking their current medicine and consult with their health care professional about any concerns.

- Rifampin and rifapentine are antibacterial drugs used to treat tuberculosis. Rifampin is also indicated for the treatment of asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from the nasopharynx.

- To mitigate or avoid shortages and to help ensure patients have access to these necessary medicines, the FDA will not object to certain manufacturers temporarily distributing rifampin containing 1-methyl-4-nitrosopiperazine (MNP) or rifapentine containing 1-cyclopentyl-4-nitrosopiperazine (CPNP) above the acceptable intake limits until they can reduce or eliminate the impurities.

- The acceptable intake limits are 0.16 parts per million (ppm) for MNP in rifampin and 0.1 ppm for CPNP in rifapentine. The agency will not object to certain manufacturers temporarily distributing rifampin containing MNP below 5 ppm. The agency also will not object to certain manufacturers temporarily distributing rifapentine containing CPNP below 14 ppm. The FDA will not object to these higher exposures to maintain patient access to these life-saving medications.

    - MNP and CPNP belong to the nitrosamine class of compounds, some of which are classified as probable or possible human carcinogens, based on laboratory tests such as rodent carcinogenicity studies.
    - Although there are no data available to directly evaluate the carcinogenic potential of MNP and CPNP, information available on closely related nitrosamine compounds was used to calculate lifetime exposure limits for MNP and CPNP.

- 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 MNP or CPNP. Patients taking rifampin for other conditions should discuss with their health care professional whether they can use an alternative medicine.

- Manufacturers should contact the Center for Drug Evaluation and Research's Drug Shortages Staff when their testing of rifampin or rifapentine shows levels of nitrosamines that exceed the acceptable intake limits of 0.16 ppm for MNP and 0.1 ppm for CPNP. The FDA will determine on a case-by-case basis whether those drugs should be released for distribution.

- The FDA and manufacturers are investigating the origin of these impurities in rifampin and rifapentine, and the agency is developing testing methods for regulators and industry to detect MNP and CPNP in these medicines.

- The 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.

Continued . . .

- OptumRx will monitor for any potential shortages and supply issues of rifampin and rifapentine.

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