

"Giving Voice to Those Seldom Heard"

November 2018

Dear Colleague:

Greetings from the Office of Ombudsman for Mental Health and Developmental Disabilities (OMHDD). This cover letter is to announce the Winter Alerts for 2018/2019 from the Medical Review Subcommittee:

Winter Alert 2017-2018 - Hypothermia Alert - Frostbite Alert - NWS Wind Chill Chart

If you haven't already, please visit the OMHDD website to [subscribe to receive the Medical Alerts via E-mail](https://public.govdelivery.com/accounts/MNOMHDD/subscriber/new?qsp=CODE_RED).
(https://public.govdelivery.com/accounts/MNOMHDD/subscriber/new?qsp=CODE_RED)

Death and Serious Injury Reporting Update

Reports of deaths and serious injuries can be faxed to the OMHDD at the following number:

Fax: 651-797-1950

It has come to our attention that this fax number only can receive faxes from digital (not analog) fax machines. If you are using an older (analog) fax machine and have difficulty faxing reports to the office, please use this number: 651-296-1021.

If you have questions about reporting or need to contact our office, please call either of the following numbers:
Voice: 651-757-1800 or Toll Free: 1-800-657-3506

The "Next of Kin" Letter, which can be used to notify a client's next of kin of a death report to the Office of Ombudsman for Mental Health and Developmental Disabilities, has been updated and posted on the website. You can access the [Next of Kin Letter](https://mn.gov/omhdd/assets/Next-of-Kin-Letter_tcm23-357046.pdf) at: (https://mn.gov/omhdd/assets/Next-of-Kin-Letter_tcm23-357046.pdf)

MedWatch Updates:

This office continues to recommend that providers, families and clients be aware of the FDA's MedWatch website, which provides updated and on-going information about warnings and alerts for medications and medical devices. The FDA has released MedWatch Safety Alerts for many medications, many of which are prescribed for clients of this Office. These medications include:

[Fluoroquinolone Antibiotics: FDA Requires Labeling Changes Due to Low Blood Sugar Levels and Mental Health Side Effects](https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm612979.htm) (<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm612979.htm>)
[Posted 07/10/2018]

AUDIENCE: Patient, Health Professional, Pharmacy

ISSUE: FDA is strengthening the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects.

BACKGROUND: Fluoroquinolone antibiotics are approved to treat certain serious bacterial infections, and have been used for more than 30 years. They work by killing or stopping the growth of bacteria that can cause illness. Without treatment, some infections can spread and lead to serious health problems. Most fluoroquinolone antibiotic drug labels include a warning that blood sugar disturbances, including high blood sugar and low blood sugar and depending on the fluoroquinolone antibiotic class, a range of mental health side effects are already described under Central Nervous System Effects in the Warnings and Precautions section of the drug label, which differed by individual drug.

RECOMMENDATION: The new label changes will add that low blood sugar levels, also called hypoglycemia, can lead to coma and the new label will also make the mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are: disturbances in attention, disorientation, agitation, nervousness, memory impairment, serious disturbances in mental abilities called delirium.

FDA continues to monitor and evaluate the safety and effectiveness of medicines after we approve them and they go on the market. In the case of fluoroquinolones, we reviewed reports of cases submitted to FDA and the published medical literature of apparently healthy patients who experienced serious changes in mood, behavior, and blood sugar levels while being treated with systemic fluoroquinolones.

Patients should tell your health care professionals if you are taking a diabetes medicine when your health care professional is considering prescribing an antibiotic, and also if you have low blood sugar or symptoms of it while taking a fluoroquinolone. For patients with diabetes, your health care professional may ask you to check your blood sugar more often while taking a fluoroquinolone. Early signs and symptoms of low blood sugar include: confusion, pounding heart or very fast pulse, dizziness, pale skin, feeling shaky, sweating, unusual hunger, trembling, headaches, weakness, irritability, unusual anxiety.

Health care professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin.

- Alert patients of the symptoms of hypoglycemia and carefully monitor blood glucose levels in these patients, and discuss with them how to treat themselves if they have symptoms of hypoglycemia.
- Inform patients about the risk of psychiatric adverse reactions that can occur after just one dose.
- Stop fluoroquinolone treatment immediately if a patient reports any central nervous system side effects, including psychiatric adverse reactions, or blood glucose disturbances and switch to a non-fluoroquinolone antibiotic if possible.
- Stop fluoroquinolone treatment immediately if a patient reports serious side effects involving the tendons, muscles, joints, or nerves, and switch to a non-fluoroquinolone antibiotic to complete the patient's treatment course.

Health care professionals should not prescribe fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections because the risks outweigh the benefits in these patients.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the [FDA's MedWatch Safety Information and Adverse Event Reporting Program](#):

- Complete and submit the report online OR
- **Download form** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[Valsartan-Containing Products: Update Health Professional and Consumer on Recent Recalled Products](https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm614030.htm)

(<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm614030.htm>)
[Posted 07/19/2018]

AUDIENCE: Consumer, Health Professional, Pharmacy

ISSUE: The investigation into valsartan-containing products is ongoing and the following list may change. We will update this statement as we have more information. There are currently three voluntary recalls related to the NDMA impurity detected in the valsartan API:

- **Teva Pharmaceuticals USA labeled as Major Pharmaceuticals** — recall is at the retail level because these products are only used in facilities where they are directly administered to patients by health care professionals: Valsartan 80 mg and 160 mg products
- **Prinston Pharmaceuticals Inc. labeled as Solco Healthcare LLC** — recall is at the consumer/user level: Valsartan 40 mg, 80 mg, 160 mg, and 320 mg; and valsartan/HCTZ 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg products
- **Teva Pharmaceuticals labeled as Actavis LLC** — recall is at the consumer/user level: Valsartan 40 mg, 80 mg, 160 mg, and 320 mg; and valsartan/HCTZ 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg products.

BACKGROUND: Valsartan is used to treat high blood pressure and heart failure. Not all products containing valsartan are being recalled. This update will clarify which valsartan-containing products are being recalled.

The recalled products contain an impurity, N-nitrosodimethylamine (NDMA), in the API manufactured by Zhejiang Huahai Pharmaceuticals, Linhai, China. The presence of the potentially cancer-causing NDMA was unexpected, and the agency believes the NDMA is related to changes in the way the active substance was manufactured. Some levels of the impurity may have been in the valsartan-containing products for as long as four years.

RECOMMENDATION: Patients should be aware that not all valsartan-containing medications are affected and being recalled and if you have questions, you should ask your pharmacist or health care provider. Patients should:

- Compare the information on your prescription bottle with the information in this list (company, National Drug Code, lot number) to determine if your current medicine has been recalled.
- Continue taking your current medicine until your health care provider or pharmacist gives you a replacement or a different treatment option.

Health professionals should know:

- FDA has determined the recalled valsartan products pose an unnecessary risk to patients. Therefore, FDA recommends patients use valsartan-containing medicines made by other companies or consider other available treatment options for the patient's medical condition.
- If you have medication samples from these companies, quarantine the products and do not provide them to patients.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the [FDA's MedWatch Safety Information and Adverse Event Reporting Program](#):

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[SGLT2\(sodium-glucose cotransporter-2\) Inhibitors for Diabetes: Drug Safety Communication - Regarding Rare Occurrences of a Serious Infection of the Genital Area](https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm618908.htm)

(<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm618908.htm>)

[Posted 08/29/2018]

AUDIENCE: Patient, Endocrinology, Health Professional, Pharmacy

ISSUE: FDA is warning that cases of a rare but serious infection of the genitals and area around the genitals have been reported with the class of type 2 diabetes medicines called sodium-glucose cotransporter-2 (SGLT2) inhibitors. This serious rare infection, called necrotizing fasciitis of the perineum, is also referred to as Fournier's gangrene. We are requiring a new warning about this risk to be added to the prescribing information of all SGLT2 inhibitors and to the patient Medication Guide.

BACKGROUND: SGLT2 inhibitors are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine. First approved in 2013, medicines in the SGLT2 inhibitor class include canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin (see FDA-Approved SGLT2 Inhibitors). In addition, empagliflozin is approved to lower the risk of death from heart attack and stroke in adults with type 2 diabetes and heart disease. Untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease.

RECOMMENDATION: To read all of the recommendations see the [Drug Safety Communication](#).

Patients should:

- Seek medical attention immediately if you experience any symptoms of tenderness, redness, or swelling of the genitals or the area from the genitals back to the rectum, and have a fever above 100.4 F or a general feeling of being unwell. These symptoms can worsen quickly, so it is important to seek treatment right away.
- Read the patient Medication Guide every time you receive a prescription for an SGLT2 inhibitor because there may be new or important additional information about your drug. The Medication Guide explains the benefits and risks associated with the medicine

Health care professionals should:

- Assess patients for Fournier's gangrene if they present with the symptoms described above. If suspected, start treatment immediately with broad-spectrum antibiotics and surgical debridement if necessary.
- Discontinue the SGLT2 inhibitor, closely monitor blood glucose levels, and provide appropriate alternative therapy for glycemic control.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the [FDA's MedWatch Safety Information and Adverse Event Reporting Program](#):

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[Caution When Using Pen Needles to Inject Medicines: FDA Safety Communication](#)

(https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm621788.htm?utm_campaign=FDA%20MedWatch%20-%20Caution%20When%20Using%20Pen%20Needles%20to%20Inject%20Medicines&utm_medium=email&utm_source=Eloqua&elqTrackId=2d83cbd4e74646dc96732415b8906345&elq=6fafac4105854cc3a90d90e8e969b7af&elqaid=5313&elqat=1&elqCampaignId=4241)

Date Issued: September 27, 2018]

Audience - Patients and caregivers who use or are considering using pen injectors with pen needles to inject prescription medicines and Health care providers who treat patients, or who train users on pen needles and pen injectors.

Specialties: Health care providers including Nurses, Nurse Practitioners, Physician Assistants, Health Educators, Pharmacists, and Physicians

Device - Pen needles are used to inject medicine with pen injectors. For example, when insulin is packaged in a multi-dose pen injector, a new pen needle is used each time to inject the insulin. Common types of pen needles include standard pen needles and safety pen needles. **Standard pen needles** often have an outer cover and a removable inner needle cover, which are both removed before an injection. **Safety pen needles** are different. They have an outer cover that is removed, and a fixed inner needle shield that is not removed before an injection. Standard pen needles often have an outer cover and a removable inner needle cover. Both the outer cover and the inner needle cover must be removed before an injection. Safety pen needles have an outer cover and a fixed inner needle shield (sharps injury prevention feature). The outer cover is removed before an injection, but the fixed inner needle shield is NOT removed before an injection.

Purpose

The FDA is providing recommendations to patients, caregivers, and health care providers to promote the safe use of pen needles used to inject medicines from pen injectors.

Summary of Problem and Scope

Pen needles are used with pen injectors to inject different types of medicines. The same pen injector can be used with both standard and safety pen needles. It is possible that patients could be taught using one type of pen needle, then receive the other type later. This could cause confusion about how to use the pen needle correctly, and may prevent the patient from getting the medicine they need.

The FDA has received reports of patients using standard pen needles to inject insulin without removing the inner needle cover. In these cases, the inner cover stopped the needle from entering the skin and the patients did not get the insulin. Some patients developed high blood sugar (hyperglycemia) because the inner needle cover stopped them from getting insulin. One patient was hospitalized and died because of having blood sugar that was too high for too long.

To help people use pen needles safely, the FDA recommends these actions:

Recommendations for Patients and Caregivers

- Each time you get a new box of pen needles, check to see if they are the same type as the ones you were trained to use. If not, ask your health care provider to show you how to use this new type properly.
- If you use a standard pen needle with an outer cover and an inner needle cover, be sure to remove both covers before use.
- If you feel like your medicine from the pen injector is not working, talk to your health care provider.
 - For example, if you have diabetes and your blood sugar levels are high after insulin injections, contact your health care provider to talk about your injection technique, insulin dosage, and other things that can affect your blood sugar levels.
- If you have any questions about your pen needle, contact your health care provider.

Recommendations for Health Care Providers and Health Care Educators

- Train and educate patients and caregivers:
 - Show them how to use the pen needle for their medication.
 - Ensure they can demonstrate correct technique to verify proper use of their pen needles.
 - Be sure they are aware of the different types of pen needles, and they know which type they use.

- Explain the signs and symptoms of under-dose (and over-dose) of their medication, how to monitor their medical condition (for example, blood glucose levels), and when to contact their health care provider.
- **Prescribers:** Consider whether there could be a problem with an injection or medication administration technique before changing a medication dose.
- **Pharmacists:** When dispensing a new box of pen needles, consider asking the patient if they know how to use the type of pen needles being dispensed.
 - For example, remind patients that:
 - For standard pen needles with an outer cover and an inner needle cover, remove both covers before use.
 - For the safety pen needle, remove only the outer cover, as the fixed inner needle shield remains in place.
 - Be available to answer questions from patients and caregivers or refer them to their applicable health care provider.

FDA Activities - The **FDA asked pen needle manufacturers** to review their most recent labeling (that is Instructions or Directions for Use) and training materials to assess the need for updates to clearly explain how to use the pen needle safely. In addition, the FDA requested that standard pen needle manufacturers consider adding a warning in the labeling regarding the need to remove both the outer cover and the inner needle cover before use....

Other Resources

- [Institute for Safe Medical Practices, Severe Hyperglycemia in Patients Incorrectly Using Insulin Pens at Home](https://www.ismp.org/alerts/severe-hyperglycemia-patients-incorrectly-using-insulin-pens-home) (https://www.ismp.org/alerts/severe-hyperglycemia-patients-incorrectly-using-insulin-pens-home)
- Truong, T. H., Nguyen, T. T., Armor, B. L., & Farley, J. R. (2017). [Errors in the Administration Technique of Insulin Pen Devices: A Result of Insufficient Education](http://doi.org/10.1007/s13300-017-0242-y). *Diabetes Therapy*, 8(2), 221–226. http://doi.org/10.1007/s13300-017-0242-y
- [American Diabetes Association](http://www.diabetes.org) (http://www.diabetes.org)
- [NIH - Diabetes](https://medlineplus.gov/diabetes.html) (https://medlineplus.gov/diabetes.html)

Contact Information

If you have questions about this communication, please contact the [Division of Industry and Consumer Education \(DICE\)](mailto:DICE@FDA.HHS.GOV) at DICE@FDA.HHS.GOV, 800-638-2041 or 301-796-7100.

Additional information about MedWatch Safety Alerts can be obtained at the [FDA website: FDA.Gov/Medical Product Safety Information](http://FDA.Gov/MedicalProductSafetyInformation)

When administering prescription and over-the-counter medications to your clients, please be aware of the potential side effects of the medications. Document any changes in the client's condition that the medications are intended to treat, as well as any side effects observed and/or reported by your clients, so the health care provider/prescriber can be informed.

Thank you for your interest in our Medical Alerts and for your continued cooperation with the Office of Ombudsman for Mental Health and Developmental Disabilities. Please call me, at either the toll free or voice numbers above, with any questions or concerns.

Sincerely,

Jo Zillhardt, BSN, RN-BC, PHN
Medical Review Coordinator

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