April 2012

# ICP ConsultantConnection

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## New Once Weekly Treatment Option For Type 2 Diabetes

The FDA has approved an extended release form of Byetta, under the brand name Bydureon. It is the first ever once weekly treatment for type 2 diabetes. It works in the same manner as Byetta and Victoza but is only given on a once a week basis.

Research indicates that Bydureon produced better glycemic control and less nausea than Byetta. Weight loss with all three agents was similar with average loss being about 6-8 pounds over 6 months. The cost of all three agents is similar.

Bydureon 2 mg is given once per week (every 7 days) at the same time of day. It can be given with or without meals. While Victoza and Byetta are available in prefilled syringes, Bydureon is not, due to its extended release formulation. It is provided as a powder in single dose vials with diluent provided in pre-filled syringes. The medication should be given immediately after mixing. If a patient forgets a dose it should be given as soon as it is remembered provided the next dose is scheduled at least 3 days away.

Side effects associated with use include nausea, diarrhea, headache, vomiting, constipation, pain and itching at injection site, and dyspepsia. Some patients may notice a bump at the injection site that goes away as the drug is absorbed.

Bydureon does carry a black box warning about the possibility of thyroid tumors similar to the warning on Victoza. All the agents in this class also carry a warning in relation to the possibility of rare fatal and nonfatal pancreatitis. Patients with a history of pancreatitis should consider other therapies.

The approval of a once weekly medication for the treatment of diabetes is truly a milestone. However, this medication is not appropriate for every patient. Patients should work closely with their Physician to determine what is the best treatment option to manage their disease.

Kathleen A Duncan RPh. Consultant Pharmacist ICP Inc.

Works Cited: Rx Consultant March 2012; Pharmacists Letter March 2012; Vol: 28 No. 3

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***Mission Statement:***
*ICP is committed to exceeding our customers' and employees' expectations through quality health-care service, continuous education, and effective communication.*

# Nursing Consideration for the Patient Taking Anxiolytics

Some patients suffer from anxiety, an unpleasant experience. This is an emotional state defined by psychological and physiological responses to the anticipation of real or imagined danger. Physical signs and symptoms can include increased heart rate, altered respiration, sweating, trembling and fatigue. Psychological factors include feelings of powerlessness, apprehension, and potential danger. As clinicians, we are trained to assess and implement interventions to decrease the stress and anxiety of our patients to enhance their quality of life.

The list of interventions utilized for success with our patients is endless. Comfort measures, conversation, 1:1, group activities, personal care needs, removal from stimulation or noise, exercise, food, and even medications are used to help decrease anxiety.

Medications are not our first line of treatment. These medications may help the current situation but have the potential to cause adverse effects in the elderly such as somnulence, unsteady gait, confusion and altered cognition. These side effects can further put our patients in danger of falls, broken bones and accidents.

Implementation of non-pharmalogical interventions happens throughout the day from many different staff members. Care plans reflect how we manage our patients' needs and deliver care in an holistic individualized manner Documentation is required to paint an accurate picture of what is truly occurring, what has been implemented, what didn't work, and what alternatives are available.

Without proper documentation of all our efforts to decrease stress and anxiety for our patients, it looks as if nothing is done to enhance their quality of life. Rather a picture of giving a pill is clearly recorded on the MAR as if it was the first intervention for treatment. In many situations this is not the case.

## Remember, next time you go to give that PRN anxiolytic, ask yourself:

- Have we tried other alternative?
- What else can I try?
- Is there a care plan in place?
- Am I following the care plan?
- Have attempts at non-pharmacological interventions been documented?
- These simple questions may help to provide documentation and interventions that are successful for our patients. Remember, if it isn't charted, it didn't happen!

Josephine Notter RN

# Multi-dose vials

By: Mary Burkart, RN

Administering parenteral medications has become routine for nurses across the healthcare spectrum. Subcutaneous, intramuscular, intravenous, or intradermal routes all provide medications in a specific manner. These medications are dispensed in vials, some of which are single use, others multi-dose.

Single dose vials are just that-medication for one-time-use on one patient. Use the medication; then appropriately discard the vial.

Multi-dose vials are different; they contain several doses of medication. The manufacturer's label indicates the amount of medication in the vial and the expiration date. Anti-microbial preservatives are added to prevent the growth of bacteria (but not viruses), which allows the medication to remain safe for several days.

Multi-dose vials are designed for the administration of several doses for one patient. If a multi-dose vial is used on more than one patient (for example: TB skin test solution and influenza vaccine), the vial should not be kept or accessed in the immediate patient area, such as patient rooms or treatment rooms. If a multi-dose vial does enter a patient treatment area, it should be designated for that patient only or discarded.

## Maintaining aseptic technique is extremely important when handling multi-dose vials:

- Proper hand hygiene prior to handling the multi-dose, wear appropriate personal protective equipment
- Cleanse the rubber septum or needleless device thoroughly with alcohol
- Use a sterile syringe/needle to draw up the solution in a specified clean area. Using the same syringe or needle to draw up more than one dose greatly increases the potential spread of infection

Once a needle and/or syringe have been used, they are considered contaminated and must be disposed of in appropriate puncture-resistant waste receptacles

## United States Pharmacopeia (USP) General Chapter 797 (16) and the Centers for Disease Control (CDC) recommend:

- If a multi-dose vial has been opened or accessed, the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (longer or shorter) date for that specific medication
- If a multi-dose vial has NOT been opened or accessed, it should be discarded according to the manufacturer's expiration date

Check with your consultant pharmacist or technician for a list of expiration dates for commonly used multi-dose vials. For more information, visit the CDC at www.cdc.gov.

# FDA NEWS RELEASE

## FDA Announces Safety Changes In Labeling For Some Cholesterol-Lowering Drugs

Important safety changes to the labeling for some widely used cholesterol-lowering drugs known as statins are being announced today by the U.S. Food and Drug Administration.

These products, when used with diet and exercise, help to lower a person's "bad" cholesterol (low-density lipoprotein cholesterol). The products include: Lipitor (atorvastatin), Lescol (fluvastatin), Mevacor (lovastatin), Altoprev (lovastatin extended-release), Livalo (pitavastatin), Pravachol (pravastatin), Crestor (rosuvastatin), and Zocor (simvastatin). Combination products include: Advicor (lovastatin/niacin extended-release), Simcor (simvastatin/niacin extended-release), and Vytorin (simvastatin/ezetimibe).

"We want health care professionals and patients to have the most current information on the risks of statins, but also to assure them that these medications continue to provide an important health benefit of lowering cholesterol," said Mary Parks, M.D., director for the Division of Metabolism and Endocrinology Products in the Office of Drug Evaluation II in FDA's Center for Drug Evaluation and Research.

### The changes to the statin labels are:

- The drug labels have been revised to remove the need for routine periodic monitoring of liver enzymes in patients taking statins. FDA now recommends that liver enzyme tests should be performed before starting statin therapy, and as clinically indicated thereafter. FDA has concluded that serious liver injury with statins is rare and unpredictable in individual patients, and that routine periodic monitoring of liver enzymes does not appear to be effective in detecting or preventing this rare side effect. Patients should notify their health care professional immediately if they have the following symptoms of liver problems: unusual fatigue or weakness; loss of appetite; upper belly pain; dark-colored urine; yellowing of the skin or the whites of the eyes.
- Certain cognitive (brain-related) effects have been reported with statin use. Statin labels will now include information about some patients experiencing memory loss and confusion. These reports generally have not been serious and the patients' symptoms were reversed by stopping the statin. However, patients should still alert their health care professional if these symptoms occur.
- Increases in blood sugar levels (hyperglycemia) have been reported with statin use. The FDA is also aware of studies showing that patients being treated with statins may have a small increased risk of increased blood sugar levels and of being diagnosed with type 2 diabetes mellitus. The labels will now warn healthcare professionals and patients of this potential risk.
- Health care professionals should take note of the new recommendations in the lovastatin label. Some medicines may interact with lovastatin, increasing the risk for muscle injury (myopathy/rhabdomyolysis). For example, certain medicines should never be taken (are contraindicated) with Mevacor (lovastatin) including drugs used to treat HIV (protease inhibitors) and drugs used to treat certain bacterial and fungal infections.

Reporting side effects to the FDA is important. Health care professionals and patients should report any side effects associated with statin use to FDA MedWatch program.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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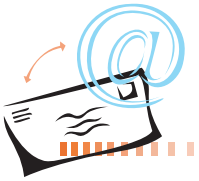

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