Imodium® (loperamide) – New Boxed Warning

- On November 3, 2016, the FDA approved the addition of a *Boxed Warning* to the Imodium (loperamide) drug label. The information pertains to prolongation of the QT interval, torsades de pointes, other ventricular arrhythmias, cardiac arrest, some resulting in death, that have been reported in adults with use of higher than recommended dosages of loperamide.

- Loperamide is indicated for the control and symptomatic relief of acute nonspecific diarrhea in patients 2 years of age and older, chronic diarrhea in adults associated with inflammatory bowel disease, and for reducing the volume of discharge from ileostomies.

- Loperamide is available generically as prescription capsules. Brand Imodium is no longer available as a prescription product.

    - Loperamide is available over-the-counter (OTC) as capsules, caplets, tablets, chewable tablets and liquid.
    - Loperamide is also available OTC in combination with simethicone as caplets and chewable tablets.

- Cases of cardiac adverse reactions include patients who were abusing (using supratherapeutic doses in place of opioids to induce euphoria) or misusing (taking higher than recommended doses to control diarrhea or to prevent opioid withdrawal) loperamide.

- Cases of syncope and ventricular tachycardia have been reported in adult patients receiving the recommended dosage of loperamide. Some of these patients were taking other drugs or had other risk factors that may have increased their risk of cardiac adverse reactions.

- Post marketing cases of cardiac arrest, syncope, and respiratory depression have been reported in pediatric patients < 2 years of age.

- Loperamide is contraindicated in:

    - Pediatric patients less than 2 years of age due to the risks of respiratory depression and serious cardiac adverse reactions.
    - Patients with a known hypersensitivity to loperamide hydrochloride or to any of the excipients.
    - Patients with abdominal pain in the absence of diarrhea.
    - Patients with acute dysentery, which is characterized by blood in stools and high fever.
    - Patients with acute ulcerative colitis.
    - Patients with bacterial enterocolitis caused by invasive organisms including *Salmonella*, *Shigella*, and *Campylobacter.*
    - Patients with pseudomembranous colitis (eg, *Clostridium difficile*) associated with the use of broad-spectrum antibiotics.

- Other warnings and precautions of loperamide include dehydration, gastrointestinal disorders, and variability in pediatric response.

- Avoid loperamide in:

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- Dosages higher than recommended in adults and pediatric patients 2 years of age and older due to the risk of serious cardiac adverse reactions.
- Combination with others drugs or herbal products that are known to prolong the QT interval, including Class 1A (eg, quinidine, procainamide) or Class III (eg, amiodarone, sotalol) antiarrhythmics, antipsychotics (eg, chlorpromazine, haloperidol, thioridazine, ziprasidone), antibiotics (eg, moxifloxacin), or any other drug known to prolong the QT interval (eg, Nebupent®, Pentam® 300 (pentamidine), methadone).
- Patients with risk factors for QT prolongation, including patients with congenital long QT syndrome, with a history of cardiac arrhythmias or other cardiac conditions, elderly patients and those with electrolyte abnormalities.

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