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DUR DIGEST

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FDA Safety Alerts/Communications

High Dose Loperamide

The FDA released a Drug Safety Communication in June 2016 regarding serious heart problems with high doses of loperamide, including abuse or misuse of the drug. The risk of serious heart problems, such as QT interval prolongation, Torsades de Pointes, other ventricular arrhythmias, cardiac arrest, syncope, and death has been observed. The risk of serious heart problems is also increased when high doses of loperamide are taken with several kinds of drugs that interact with loperamide. Drugs that can potentially interact with loperamide include cimetidine, clarithromycin, erythromycin, gemfibrozil, itraconazole, ketoconazole, quinidine, quinine, ranitidine, and ritonavir.

At approved doses, loperamide has a relatively long half-life of 9 to 13 hours. At doses of 16mg and higher, the half-life has been found to be as high as 41 hours. In most cases, individuals intentionally abused loperamide by taking large doses to achieve a feeling of euphoria or prevent opioid withdrawal. Some patients also misused loperamide by taking higher than recommended doses to treat diarrhea. Individuals self-treated with doses ranging from 70mg to 1600mg daily in the most severe cases.

http://www.fda.gov/Drugs/DrugSafety/ucm504617.htm

Serious Bleeding Risk with OTC Antacid Products Containing Aspirin

The FDA is warning of the risk of serious bleeding when using over-the-counter (OTC), aspirin-containing antacid products to treat heartburn, sour stomach, acid indigestion, or upset stomach. The following risk factors can put a patient at an increased risk of serious bleeding when taking aspirin-containing antacid products:

- 60 years or older
- History of stomach ulcers or bleeding problems
- Currently taking anticoagulants
- Currently taking oral steroids
- Currently taking NSAIDs
- Consumption of three or more alcoholic drinks per day

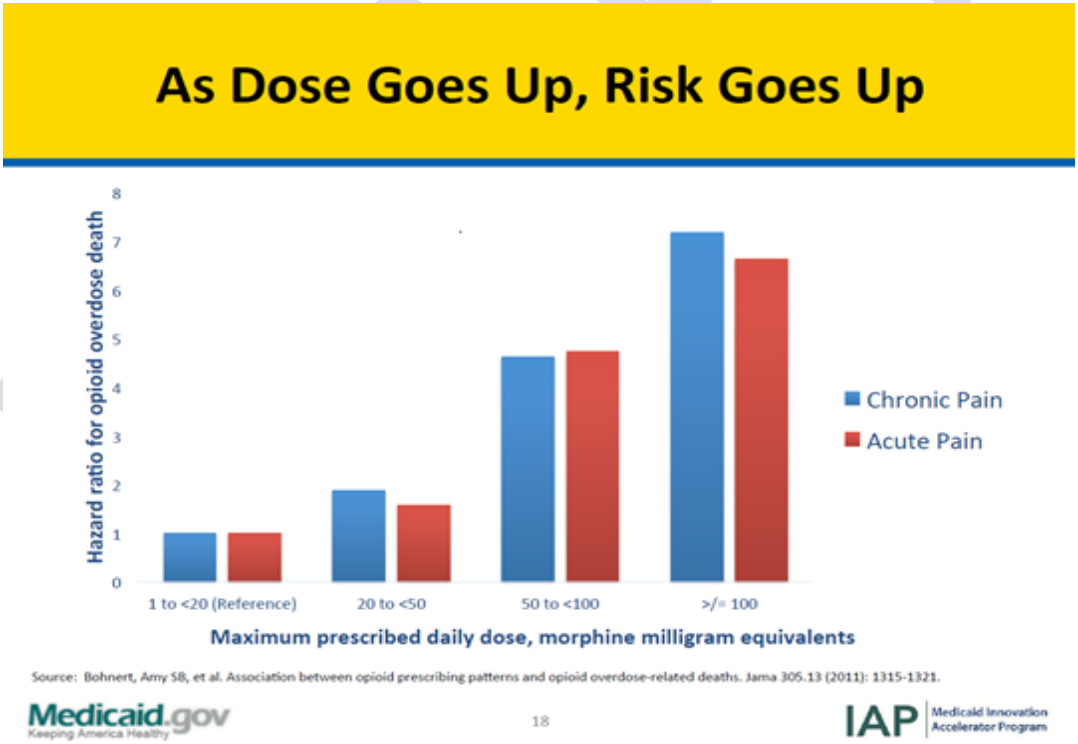
Although these products currently contain warnings about the risk of bleeding on their labels, the FDA continues to receive reports of this safety issue. The FDA will continue to evaluate this safety concern. An advisory committee of external experts will be convened to determine whether additional FDA actions are needed.

http://www.fda.gov/Drugs/DrugSafety/ucm504328.htm

CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016

In March 2016, the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain was released. The guideline provides recommendations about opioid prescribing for primary care clinicians treating adult patients with chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The twelve (12) recommendations are grouped into three conceptual areas:

- Determining when to initiate or continue opioids for chronic pain.
  - Non-pharmacologic and non-opioid therapies are preferred.
  - Establish treatment goals before starting opioid therapy.
  - Discuss risks and realistic benefits before starting opioid therapy.
- Opioid selection, dosage, duration, follow-up, and discontinuation.
  - When starting opioid therapy, prescribe immediate-release opioids
  - Start opioid therapy with lowest effective dose.
  - Prescribe lowest effective dose for acute pain treatment.
  - Evaluate benefits and harms of opioid therapy within 1 to 4 weeks of starting treatment.
- Assessing risk and addressing harms of opioid use.
  - Evaluate risk factors for opioid-related harms before and during opioid therapy.
  - Review patient history using state PDMP.
  - Use drug testing before starting opioid therapy.
  - Avoid prescribing opioid therapy and benzodiazepines concurrently.
  - Offer a range of evidence-based treatments with patients with opioid use disorder.



Complete guideline can be found at the following link:
http://www.cdc.gov/drugoverdose/prescribing/providers.html including guideline resources for providers.

American Medical Association Drops Pain as Vital Sign

The American Medical Association (AMA) has recommended that pain be removed as a "fifth vital sign". Delegates at their annual meeting passed several resolutions aimed at reducing opioid prescribing and increasing access to addiction treatment. The complete story can be found at the following link:
http://www.painnewsnetwork.org/stories/2016/6/16/ama-drops-pain-as-vital-sign

Medicaid Statistics for Prescription Claims

from January 1, 2016 to March 31, 2016*

Number of claims paid: 1,892,447

Total dollars paid: $130,333,386

Percent generic prescriptions: 87.2%

Average amount paid per claim: $68.87

Average amount paid per claim, brand: $394.92

Average Amount paid per claim, generic: $21.21

Top Drugs by Number of Prescriptions	Top Drugs by Dollars Spent	Top Therapeutic Class by Dollars Spent
Hydrocodone/APAP 5-325mg 31,879 prescriptions	*Lantus* Injection 100/ml $2,906,507	Antipsychotics – Atypicals $11.1 million
Amoxicillin Susp. 400mg/5ml 21,949 prescriptions	*Harvoni* 90-400mg $2,797,521	Stimulants – Amphetamines – Long Acting $6.5 million
Tramadol 50mg 21,926 prescriptions	*Humalog* Injection 100/ml $2,778,838	Anticonvulsants $6.6 million
Omeprazole 20mg 19,435 prescriptions	*Humira Pen* 40mg/0.8ml $2,048,588	Diabetic – Insulin $6.4 million
Omeprazole 40mg 19,335 prescriptions	*Spiriva HandiHaler* $1,721,773	Anti-Inflammatories, Non-NSAID $4.9 million

*All dollars reported are pre-rebate