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Pharmacy & Therapeutics Update: Drug Information for Health Care Professionals

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Update

Drug Information for Health Care Professionals

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FDA Issues Advisory on Benzocaine Spray

By
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The Food and Drug Administration (FDA) issued a public health advisory regarding the use of benzocaine spray (Hurricaine®, Topex®, Cetacaine®) on February 10, 2006.[1] Benzocaine spray is a local anesthetic used to numb the mouth and throat during minor surgical procedures such as endoscopy and bronchoscopy.[1,2] When used appropriately, benzocaine may occasionally cause methemoglobinemia.[1,2] Methemoglobinemia has also resulted due to medication errors and using benzocaine for a longer duration or in a higher dose than is recommended.[1]

Methemoglobinemia occurs due to either increased methemoglobin production or decreased methemoglobin reduction.[3,4] Methemoglobin is a form of hemoglobin in which the ferrous irons of heme have been oxidized to the ferric state.[3,4] Methemoglobin is unable to bind oxygen.[3,4] In methemoglobinemia, the oxygen affinity of ferrous heme in the hemoglobin tetramer is increased, resulting in a "left-shifted" oxygen dissociation curve and impaired oxygen delivery to the tissues.[3,4] As a result, patients with increased concentrations of methemoglobin have a functional anemia.[3,4]

The FDA advisory states that practitioners should consider several things when using benzocaine spray during procedures requiring tube placement in the larynx or pharynx. First, benzocaine spray can result in dangerous concentrations of methemoglobin. Up to 35% of benzocaine applied to mucous membranes is absorbed systemically.[1] Absorption is increased when the product is applied to inflamed tissue. Secondly, patients with asthma, bronchitis, chronic obstructive pulmonary disease (COPD), heart disease, or those who smoke have an increased risk of complications if they develop methemoglobinemia and may benefit from alternative therapeutic agents. There are also certain patients who have an increased risk of developing methemoglobinemia.[1,3,4] These patients include infants; patients with hemoglobin M disease; and patients with deficiencies in glucose-6-phosphate dehydrogenase (G6PD), NADH-methemoglobin reductase, and pyruvate kinase.[1,3,4]

Lidocaine is a reasonable alternative for both patient groups.

FDA recommends that practitioners use the minimum amount of benzocaine needed to reduce the risk of methemoglobinemia. According to the product labeling, the recommended dose of Hurricaine® spray is 1 spray in a less-than-1-second burst. For Cetacaine®, sprays in excess of 2 seconds are contraindicated. Topex® is typically administered in 2 to 3 metered sprays, and the maximum dose is 5 sprays.

Patients who receive benzocaine spray should be carefully monitored for signs of methemoglobinemia including pale gray- or blue-colored skin, headache, lightheadedness, shortness of breath, anxiety, fatigue, and/or tachycardia. FDA cautions practitioners that methemoglobinemia makes pulse oximetry unreliable. Methemoglobin concentrations should be measured using a co-oximeter.[1,3] Patients who are thought to have high concentrations of methemoglobin should be treated promptly.

Additional information may be found at: www.fda.gov/cder/ drug/ advisory/benzocaine.htm.

Automatic Therapeutic Substitution: Angiotensin Converting Enzyme Inhibitors

By
Krystal Moorman, PharmD

Effective March 15, 2006, angiotensin converting enzyme inhibitors (ACEIs) will be included in the automatic therapeutic substitution (ATS) program. The protocol specifies that orders written for benazepril, enalapril, fosinopril, moexipril, perindopril, quinapril, ramipril, and trandolapril will be converted to lisinopril (Table 1). Captopril and enalaprilat are excluded from this ATS. This ATS is applicable to adult inpatients. If a physician does not want a patient to receive lisinopril, he/she must write the order for the desired ACEI, include "dispense as written" in the order, and provide appropriate clinical justification.

Table 1: Oral ACE-inhibitor Dosing Conversion

Order Written As	Converted To
Benazepril 5 mg, Daily	Lisinopril 5 mg, Daily
Benazepril 10 mg, Daily	Lisinopril 10 mg, Daily
Benazepril 20 mg, Daily	Lisinopril 20 mg, Daily
Benazepril 40 mg, Daily	Lisinopril 40 mg, Daily
Enalapril 5 mg, Daily	Lisinopril 5 mg, Daily
Enalapril 10 mg, Daily	Lisinopril 10 mg, Daily
Enalapril 20 mg, Daily	Lisinopril 20 mg, Daily
Enalapril 40 mg, Daily	Lisinopril 40 mg, Daily
Fosinopril 5 mg, Daily	Lisinopril 5 mg, Daily
Fosinopril 10 mg, Daily	Lisinopril 10 mg, Daily
Fosinopril 20 mg, Daily	Lisinopril 20 mg, Daily
Fosinopril 40 mg, Daily	Lisinopril 40 mg, Daily
Moexipril 3.75 mg, Daily	Lisinopril 5 mg, Daily
Moexipril 7.5 mg, Daily	Lisinopril 10 mg, Daily
Moexipril 15 mg, Daily	Lisinopril 20 mg, Daily
Moexipril 30 mg, Daily	Lisinopril 40 mg, Daily
Perindopril 2 mg, Daily	Lisinopril 5 mg, Daily
Perindopril 4 mg, Daily	Lisinopril 10 mg, Daily
Perindopril 8 mg, Daily	Lisinopril 20 mg, Daily
Perindopril 16 mg, Daily	Lisinopril 40 mg, Daily
Quinapril 5 mg, Daily	Lisinopril 5 mg, Daily
Quinapril 10 mg, Daily	Lisinopril 10 mg, Daily
Quinapril 20 mg, Daily	Lisinopril 20 mg, Daily
Quinapril 40 mg, Daily	Lisinopril 40 mg, Daily
Ramipril 1.25 mg, Daily	Lisinopril 5 mg, Daily
Ramipril 2.5 mg, Daily	Lisinopril 10 mg, Daily
Ramipril 5 mg, Daily	Lisinopril 20 mg, Daily
Ramipril 10 mg, Daily	Lisinopril 40 mg, Daily
Ramipril 20 mg, Daily	Lisinopril 40 mg, Daily
Trandolapril 1 mg, Daily	Lisinopril 5 mg, Daily
Trandolapril 2 mg, Daily	Lisinopril 10 mg, Daily
Trandolapril 4 mg, Daily	Lisinopril 20 mg, Daily
Trandolapril 8 mg, Daily	Lisinopril 40 mg, Daily

Therapeutic Alternative to Cefotetan

AstraZeneca announced that it would discontinue production of cefotetan in February 2005. Therefore, the Anti-infective Subcommittee has made the following recommendation regarding alternative therapy for patients undergoing abdominal surgery: cefazolin 1 to 2 g in combination with metronidazole 500 mg, administered intravenously. If you need additional information, please contact the Drug Information Center at 2-3896.

Gatifloxacin is Contraindicated in Patients with Diabetes

By
Krystal Moorman, PharmD

Bristol-Myers Squibb (BMS) announced changes to the prescribing information for gatifloxacin (Tequin®). The changes include an updating of the existing warning on hypo- and hyperglycemia and a contraindication for use in patients with diabetes. The changes also include information identifying other risk factors for developing hypo- or hyperglycemia including advanced age, renal insufficiency, and concomitant use of glucose-altering medications. Additional information is posted at www.fda.gov/medwatch/safety/2006/tequin_DHCP.pdf.

Listed below are formulary alternatives to gatifloxacin for patients with diabetes. Clinicians should consider patient- and pathogen characteristics when choosing an alternative. These recommendations apply to situations in which gatifloxacin would be an appropriate therapeutic choice—not necessarily first-line treatment for a particular disease state.

Acute bacterial exacerbation of chronic bronchitis: Augmentin® 875 mg, administered orally, twice daily; Unasyn® 1.5 to 3 g, administered intravenously, every 6 hours; cefuroxime 750 mg to 1.5 g, administered intravenously, every 8 hours; cefotaxime 1 g, administered intravenously, every 8 to 12 hours; ceftriaxone 1 g, administered intravenously, daily.

Acute sinusitis: Augmentin® 875 mg, administered orally, twice daily.

Community acquired pneumonia:
Previously healthy patients being treated as outpatients– azithromycin 500 mg, administered orally, once, then 250 mg, administered orally, daily in combination with amoxicillin 1 g, administered orally, 3 times daily.

Patients with comorbidities who have not recently received antibiotics and are being treated as outpatients – azithromycin 500 mg, administered orally, once, then 250 mg, administered orally, daily.

Patients with comorbidities who have recently received antibiotics – cefpodoxime 200 mg, administered orally, every 12 hours or amoxicillin 1 g, administered orally, 3 times daily.

Non-ICU patients — ceftriaxone 1 g, administered intravenously, daily with azithromycin 500 mg, administered intravenously, daily.

ICU patients – ceftriaxone 2 g, administered intravenously, daily with azithromycin 500 mg, administered intravenously, daily.

Uncomplicated cystitis: Fluoroquinolones are only recommended if the local *E. coli* resistance to Septra® is at least 20%. In these cases, it is necessary to substitute a nonformulary fluoroquinolone (FQ). Moxifloxacin should not be used to treat urinary tract infections due to inadequate urine concentration.

Complicated urinary tract infections: Zosyn® 3.375 g, administered intravenously, every 6 hours; ampicillin 500 mg, administered intravenously, every 6 hours in combination with gentamicin.

Pyelonephritis:
Outpatient treatment— Augmentin® 875 mg, administered orally, twice daily; Septra® DS, administered orally, twice daily.

Hospital treatment — ampicillin 500 mg, administered intravenously, every 6 hours in combination with gentamicin; ceftazidime 2 g, administered intravenously, every 8 hours; Zosyn® 3.375 g administered intravenously, every 6 hours; Unasyn® 3 g, administered intravenously, every 6 hours. Patients should be treated for 14 days.

Uncomplicated urethral and cervical gonorrhea or acute, uncomplicated rectal infection in women due to *Neisseria gonorrheae*: ceftriaxone 125 mg, administered intramuscularly, once or cefpodoxime 400 mg, administered orally, once in combination with azithromycin 1 g, administered orally, once or doxycycline 100 mg, administered orally, twice daily, for 7 days.

Patients who require FQ therapy may be treated with levofloxacin or moxifloxacin. For further assistance selecting an antibiotic regimen, please contact the pharmacist in your area or the Drug Information Center at 2-3896.

MED•U•WAY Conference to Focus on the Role of Percent Carbohydrate-deficient Transferrin Screening for Heavy Alcohol Use

The next MED•U•WAY will focus on percent carbohydrate-deficient transferrin (CDT) screening for heavy alcohol use. The program will be held on Thursday, April 20, 2006, at 12:00 PM, in 2 West Amphitheater.

The featured speakers will be Karen Stanley, APRN, BC, Psychiatric Consultation Liaison Nurse; Raymond Anton, MD, Distinguished University Professor of Psychiatry and Director for the Center of Drug and Alcohol Programs; Peter Miller, PhD, Professor of Psychiatry; and Cynthia Dominick, MHA, Manager of the Clinical Neurobiology Laboratory.

Attendees will receive 1 credit hour of continuing education.

Formulary Update

The Pharmacy and Therapeutics Committee recently approved the following formulary changes, effective March 15, 2006:

Additions with Restrictions:
Palonosetron (Aloxi®)
Prescribing will be restricted to physicians on the hematology/oncology services for patients who have failed therapy with ondansetron.

Dexmedetomidine (Precedex®)
Prescribing will be restricted for use during awake craniotomies.

Changes in Restrictions:
Bevacizumab (Avastin®)
The restriction for bevacizumab was revised to allow intravitreal administration by an ophthalmologist on an individual basis for patients experiencing treatment failure with photodynamic therapy and pegaptanib. Patients will be required to sign an informed consent prior to receiving this therapy. The formulary effective date will be assigned once the institutional review board has approved the informed consent and a mechanism for reimbursement has been established.

Automatic Therapeutic Substitution:
Orders written for benazepril, enalapril, fosinopril, moexipril, perindopril, quinapril, ramipril, and trandolapril will be converted to lisinopril. This ATS will be applicable to adult patients. Captopril and enalaprilat are excluded from this ATS.

Line Extensions:
Nifedipine (various)
4-mg/mL extemporaneous oral solution

Morphine (various)
0.2- and 1-mg/mL extemporaneous intravenous dilution

Lorazepam (various)
0.2-mg/mL extemporaneous intravenous dilution

Aripiprazole (Abilify®)
5-mg tablets

Deletions:
Salicylic acid (Keralyt®)
6% gel [30 grams]

0.9% sodium chloride with benzyl alcohol injection
2.5-mL syringe

Lidocaine (various)
2.5% ointment

Metyrapone (various)
250-mg capsule

Prednisolone phosphate (various)
0.125% ES solution

Neomycin (various)
0.5% ointment [15 grams]

Barium sulfate (EZPaque®)
96% w/w suspension

Methybenzethonium (Diaparene®)
ointment [60 grams]

Masse Breast Cream®
cream [60 grams]

Humulin ultralente insulin (Humulin® U)
100 units/mL

Iothalamate meglumine (Cysto-CONRAY® II)
500-mL bottle

Gadodiamide injection (Omniscan®)
5-mL vial

Iodixanol (Visipaque®)
270-mg/mL [100- and 150-mL vial]; 320-mg/mL [100-mL vial]

Iohexol (Omnipaque®)
180-, 240-, 300-, and 350-mg vials

Iopamidol (Isovue®)
370-mg vial

Didanosine (Videx®)
25-, 50-, 100-, 150-, and 200-mg chewable tablets

Ramipril (Altace®)
1.25-, 2.5-, 5-, and 10-mg tablets