



Drug & Poison Information Bulletin

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Tanta University Drug and Poison Information Center (DPIC) Facilities:

Tanta University DPIC is equipped with the updated editions of drug-related compendia, textbooks and references such as:

- ☒ Drug Facts and Comparisons (2014)
- ☒ Drug Information Handbook 22nd Edition (2013-2014)
- ☒ Drug Information Handbook for Oncology 12th Edition (2014)
- ☒ Physicians' Desk Reference (2014)
- ☒ Handbook of Nonprescription Drugs (17th Edition)
- ☒ Trissel'sTM Stability of Compounded Formulations (5th Edition)

Also the DPIC has access to the following online subscription databases:

- ☒ Lexicomp Online access
- ☒ Facts & Comparisons ® eAnswers – Comparative Tables
- ☒ Martindale Online
- ☒ 5-Minute Clinical Consult
- ☒ Drug Facts & Comparisons
- ☒ Trissel's IV- ChekTM
- ☒ King Guide to Parenteral Admixtures
- ☒ Uptodate online databases

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Codeine Cough and Cold Medicines in Children: Potential Risk of Serious Side Effects

The European Medicines Agency (EMA) introduced new measures to minimize the risk of serious adverse effects (e.g. breathing problems), with codeine-containing medicines, when used for cough and cold in children. As a result of these new measures:

- ✚ Use of codeine for cough and cold is now ***contraindicated*** in children < 12 years.
- ✚ Use of codeine for cough and cold is ***not recommended*** in children and adolescents between 12 and 18 years who have breathing problems.



Codeine is an opioid medicine that is converted into morphine in the body. High levels of morphine can lead to serious adverse effects, such as breathing difficulties.

Codeine is converted into morphine in children < 12 years in a more unpredictable manner, making this population at special risk of such adverse effects. Children with existing breathing difficulties are more susceptible to respiratory effects of codeine.

In addition to the new measures for children, codeine must also **not be used in:**

- People of any age who are known to convert codeine into morphine at a faster rate than normal (CYP2D6 ultra-rapid metabolizers).
- Breastfeeding mothers, as codeine can harm the baby because it passes into breast milk.

Source:

- 1. www.fda.gov, [Posted 07/01/2015].***
- 2. WHO Pharmaceuticals Newsletter No. 3, 2015.***

Capecitabine and folic acid Risk of enhancement of toxicity of capecitabine

The Egyptian Pharmaceutical Vigilance Center (EPVC) has publicized a report concerning the risk of enhanced capecitabine toxicity when taken with folic acid.

Capecitabine (Xeloda®) is a fluoropyrimidine carbamate and a pro-drug of 5'-deoxy-5-fluorouridine (5' DFUR). It is administered orally and is converted to 5-fluorouracil. It has antineoplastic activity and is used for colon, colorectal and gastric cancer, either as a single agent (monotherapy) or in combination therapy.

Centrum® is a multivitamin and mineral supplement. It is used to provide extra vitamins and minerals that are not taken in through the diet. Multivitamins and minerals are also used to treat vitamin or mineral deficiencies caused by illness, pregnancy, poor nutrition, digestive disorders, certain medications, and many other conditions. One of its components is folic acid.

According to the capecitabine Summary of Product Characteristics (SmPC): folic acid has no major effect on the pharmacokinetics of capecitabine and its metabolites. However, folic acid has an *effect on the pharmacodynamics of capecitabine*. The toxicity of capecitabine may be enhanced by folic acid.

This may also be relevant with folic acid supplementation for folate deficiency due to the similarity between folinic acid and folic acid. The EPVC has recommended for health-care professionals that:

- ❖ The co-administration of capecitabine with folate therapy may potentiate the pharmacologic effects of 5-fluorouracil (5-FU).
- ❖ A lower dosage of 5-FU or the pro-drug may be required.
- ❖ Patients should be monitored closely for potential toxicities of 5-FU such as neutropenia, thrombocytopenia, stomatitis, gastrointestinal haemorrhage, severe diarrhoea, vomiting, cutaneous reactions, and neuropathy.
- ❖ Patients should be instructed to avoid taking folic acid supplementation or multivitamin preparations containing folic acid without first speaking with their physician.
- ❖ Caution should be taken when receiving tablets containing multivitamins with chemotherapy.

Source:

1. **Egyptian Pharmaceutical Vigilance Center (EPVC) Newsletter, Volume 6, Issue 5, May 2015.**
2. **WHO Pharmaceuticals Newsletter No. 3, 2015.**

First U.S. Guideline for Vertebral Osteomyelitis

Persistent severe back pain may indicate vertebral osteomyelitis, a rare spine infection that must be diagnosed and treated correctly to prevent serious complications, according to a new Infectious Diseases Society of America (IDSA) guideline which was [published online](#) July 30 in *Clinical Infectious Diseases* and on the IDSA website.



Because these complications may include paralysis and death, patients with severe back pain (often wakes the patient at night) unresponsive to rest and analgesics should see an infectious disease physician, particularly if fever develops.

This infection, in which bacteria in the blood enter an intervertebral disc, can affect anyone but is more common in the elderly. Overall incidence is two to six per 100,000 annually. *Staphylococcus aureus* is the most common culprit.

Specific recommendations include the following:

- ☒ Elevated diagnostic markers of inflammation, such as erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) may suggest vertebral osteomyelitis.
- ☒ Plain radiographs of the spine are not sensitive for early diagnosis.
- ☒ Patients with elevated ESR and CRP should undergo magnetic resonance imaging (MRI) to distinguish infection from disc herniation or other structural cause of back pain.
- ☒ Unless patients are septic or have neurologic compromise, empiric antimicrobial therapy should be withheld until the microbiologic diagnosis is confirmed.
- ☒ However, most patients with *Staphylococcus aureus* bloodstream infection within the preceding 3 months and compatible spine MRI changes may be treated empirically without disc space aspiration.
- ☒ Treatment usually includes intravenous antibiotics for 6 weeks, based on the results of culture and in vitro susceptibility testing.
- ☒ Patients whose pain resolves after antibiotic treatment or surgery generally do not require repeat MRI.

Source: www.idsociety.org

FDA
Approval

Novel Antiplatelet Agent Gets FDA Approval

The Food and Drug Administration (FDA) has approved ***Kengreal (cangrelor)*** on June 22, 2015 as an adjunct to percutaneous coronary intervention (PCI) to reduce the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients who have not been treated with a P2Y₁₂ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.

Kengreal is the first and only intravenous, reversible P2Y₁₂ platelet inhibitor with an immediate onset of action. In a clinical trial comparing *Kengreal* to *clopidogrel* in over 10,000 patients, *Kengreal* was shown to significantly reduce the occurrence of heart attack, the need for further procedures to open the artery, and stent thrombosis. While the overall occurrence of serious bleeding was low, it was more common with *Kengreal* compared to *clopidogrel*.

Mechanism of Action: P2Y₁₂ platelet inhibitor that blocks ADP-induced platelet

activation and aggregation; it binds selectively and reversibly to the P2Y₁₂ receptor to prevent further signaling and platelet activation.

Dose: 30 mcg/kg IV bolus infused over 1 minute before PCI, then immediately follow bolus injection with 4 mcg/kg/min IV infusion; continue for at least 2 hr or duration of PCI, whichever is longer

Transition patients to oral P2Y₁₂ platelet inhibitor: Choose from 1 of the loading-dose regimens described below to initiate oral therapy:

- ☒ 180 mg ***Ticagrelor*** PO at any time during *cangrelor* infusion or immediately after discontinuation.
- ☒ 60 mg ***Prasugrel*** 600 mg ***Clopidogrel*** PO immediately after discontinuing *cangrelor*; don't administer *prasugrel* or *clopidogrel* prior to *cangrelor* discontinuation because of drug interaction.

Source: www.empr.com,
www.fda.gov,
www.medscape.com



Heatstroke (Sunstroke)

Heatstroke is the most serious form of heat injury and is considered a medical emergency. It is also known as sunstroke. Heatstroke occurs when your body temperature rises rapidly and you're unable to cool down. It can be life-threatening by causing damage to your brain and other vital organs.

Risk Factors

- ☒ **Age:** Your ability to cope with extreme heat depends on the strength of your central nervous system. Whether it is not fully developed or begins to deteriorate as in children or adults over 65 yr. respectively.
- ☒ **Exertion in hot weather.**
- ☒ **Sudden exposure to hot weather.**
- ☒ **A lack of air conditioning:** Fans may make you feel better, but during sustained hot weather, air conditioning is the most effective way to cool down and lower humidity.
- ☒ **Certain medications:** Some medications affect your body's ability to stay hydrated and respond to heat (vasoconstrictors, beta blockers, diuretics, antidepressants or antipsychotics).
- ☒ **Certain health conditions.** Certain chronic illnesses, such as heart or lung disease, diabetes might increase your risk of heatstroke.

Symptoms

- Fever of 104⁰ F (40⁰ C) or greater
- Changes in mental status or behavior, such as confusion, agitation, slurred speech
- Hot, dry skin or heavy sweating
- Nausea and vomiting
- Flushed skin
- Rapid pulse
- Rapid breathing
- Headache
- Fainting, which may be the first sign in older adults

First Aid for Heatstroke

- Put the person in a cool shower.
- Remove the person's unnecessary clothing, and place the person on his or her side to expose as much skin surface to the air as possible.
- Spray and sponge his body with cool water.
- Fan while misting with cool water.
- Place ice packs or cool wet towels on the neck, armpits and groin.
- Cover with cool damp sheets.
- **Do not give aspirin or acetaminophen** to reduce a high body temperature because antipyretics interrupt the change in the hypothalamic set point caused by pyrogens; they are not expected to work on a healthy hypothalamus that has been overloaded, as in the case of heatstroke
- Let the person drink cool water or other nonalcoholic beverage without caffeine, if he or she is able.
- Begin CPR if the person loses consciousness and shows no signs of circulation, such as breathing, coughing or movement.



How to Prevent Heatstroke

- ✓ Wear lightweight, light-colored, loose-fitting clothing, and a wide-brimmed hat.
- ✓ Use a sunscreen with a sun protection factor (SPF) of 30 or more.
- ✓ Drink extra fluids. Take additional precautions when exercising or working outdoors.
- ✓ Monitoring the color of your urine. Darker urine is a sign of dehydration. Avoid fluids containing caffeine or alcohol,
- ✓ Check with your doctor before increasing liquid intake if you have epilepsy or heart, kidney, or liver disease; are on fluid-restricted diets; or have a problem with fluid retention.

Sources: www.mayoclinic.com, www.webmd.com

About Tanta University DPIC Events

*Drug Information Specialty Isn't
Only a Profession.... It's a Manner
of Thinking*

REGISTER NOW
**“Drug Information
Workshop”**
**Starting on September 2015
at Faculty of Pharmacy
Tanta University**

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