Brilinta® Use in Acute Coronary Syndrome

Brilinta (ticagrelor) is used to reduce the rate of thrombotic cardiovascular events in patients with unstable angina, non-ST elevation myocardial infarction, or ST elevation myocardial infarction. Ticagrelor, a cyclo-pentyl-triazolo-pyrimidine, is orally active, selective and reversible inhibitor of platelet activation and aggregation mediated by the P2Y(12) ADP-receptor. Ticagrelor is known as a P2Y(12) platelet inhibitor. Ticagrelor also blocks ADP-mediated vasoconstriction of vascular smooth muscle and enhances the adenosine-induced coronary blood flow through inhibition of adenosine uptake by erythrocytes. Ticagrelor is given with aspirin to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome.

In the PLATO study, over 18,000 patients with Acute Coronary Syndrome (ACS) as well as symptom onset within the previous 24 hours were randomized to ticagrelor or clopidogrel. The results showed, compared to clopidogrel, ticagrelor was more effective in reducing the risk of cardiovascular death, heart attack, or stroke in patients with ACS. In PLATO, the use of ticagrelor with aspirin showed decreased effectiveness if the dose of aspirin was greater than 100 mg, therefore it is recommended that the patient is dosed with aspirin 75 -100 mg.

Recommended dosing in the management of ACS is to initiate Brilinta treatment with 180 mg loading dose, then administer 90 mg twice daily for the first year after an ACS event. After one year of therapy, recommended dosage was 60 mg twice daily. Brilinta can be crushed and mixed with water to drink. Brilinta comes in 90 mg and 60 mg tablets.

The most common adverse events reported with Brilinta therapeutic use are bleeding and dyspnea. In clinical trials, about 14% of patients treated with Brilinta developed dyspnea. Dyspnea was usually mild to moderate in intensity and often resolved during continued treatment. Other events may include: chest pain, alterations in blood pressure, nausea, diarrhea, headache, dizziness, muscle pain and fatigue. In a Holter substudy of PLATO, more patients had ventricular pauses than with clopidogrel in the acute phase, therefore patients with an overdose should be on a cardiac monitor and electrocardiograms should be monitored closely. Other recommendations should include, monitoring hematocrit, hemoglobin, partial thromboplastin time (PTT), platelet count, INR and fibrinogen in severe bleeding. In addition, it is recommended to monitor vital signs, respiratory rate and effort due to increase risk of dyspnea.

Discontinuation of Brilinta will increase the risk of myocardial infarction, stroke, and death. If Brilinta must be temporarily discontinued (e.g., to treat bleeding or for significant surgery), restart it as soon as possible. When possible, interrupt therapy with Brilinta for five days prior to surgery that has a major risk of bleeding. Resume Brilinta as soon as hemostasis is achieved.

References
Children’s Acetaminophen Chewable Strength Change

In 2011, an FDA Advisory Committee recommended that the FDA consider a single strength for solid pediatric acetaminophen products. The recommendation was intended to minimize potential for medication errors due to confusion between multiple strengths. Many manufacturers and retailers of pediatric acetaminophen solid dose medicines including the makers of Children’s Tylenol®, are changing to a single strength of 160 mg in the United States. The manufacturers are phasing out the 80 mg chewable tablets and will only manufacture 160 mg tablets. For Tylenol products, the change will involve the name change from Jr. Tylenol to Children’s Tylenol and there will only be one strength. Acetaminophen 80 mg products will still be available in pharmacies until the supplies run out. Health care professionals have been informed to always verify the product strength when providing dosing directions. Parents and caregivers should also be reminded to follow the Drug Facts label dosing directions of the specific medication that they are using. In-store transition to single strength 160 mg acetaminophen began in early 2017 but the transition within the caregivers’ medicine cabinet may take considerably longer.

FDA Approves Bunavail® for Opioid Addiction Treatment

The FDA approved a supplemental new drug application (sNDA) for Bunavail, a partial opioid agonist. The sNDA allows for use of Bunavail at the start of buprenorphine treatment for opioid dependence. Previously, the indication for Bunavail only covered the maintenance phase of treatment for opioid dependence. Bunavail is a buccal film that comes in three strengths - 2.1 buprenorphine/0.3 mg naloxone; 4.2 mg buprenorphine/0.7 mg naloxone and 6.3 mg buprenorphine/1 mg naloxone.

Bunavail is the most recent opioid dependence therapy. It is the first and only bi-layer buccal film. The manufacturer, BioDelivery Sciences, states that it sticks to the inside of the patient’s cheek to deliver the medicine more discreetly than other treatments. The top layer contains the active drug and the backing layer acts as a barrier to help facilitate the unidirectional flow of medication to the bloodstream. This reduces the flow of buprenorphine back into the mouth, so less is swallowed. The company also claims other advantages of this medicine are that the patient can talk while the medicine is in the mouth and has a pleasant citrus taste.

References

References