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Tylenol® Extra Strength Maximum Daily Dose Reduced

NOTICE

On July 28, 2011, McNeil Consumer Healthcare Division of McNeil-PPC, Inc. announced that it would be lowering the maximum recommended total daily dose for Tylenol (acetaminophen) Extra Strength products to 3000 mg from the current maximum recommended dose of 4000 mg.

BACKGROUND

Tylenol Extra Strength is an over-the-counter (OTC) pain reliever used in the treatment of mild pain and fever, as well as various symptoms associated with the typical cold and flu. Found in numerous over-the-counter products as a stand-alone analgesic and in combination with other agents, the active ingredient in Tylenol, acetaminophen, can also be found in various prescription medications. McNeil indicates that its decision to lower the maximum daily dose for Tylenol Extra Strength is a result of recent concerns over liver damage caused by the over-utilization of acetaminophen containing products. While McNeil has informed the FDA of its decision to modify the product labeling for Tylenol Extra Strength to indicate a maximum daily dose of 3000 mg, the company indicates that only this product's label will be modified at this time. The manufacturer states that the proposed changes to Tylenol Extra Strength will not take place until fall 2011 while other over-the-counter Tylenol products will see similar changes beginning in 2012. At this time, there is no indication that the maximum daily dose of 4000 mg is being changed for any prescription medications containing acetaminophen.

RECOMMENDED ACTIONS

Due to the limited nature and over-the-counter status of this labeling change, there is no recommended action necessary at this time. We will continue to monitor communications from the FDA regarding acetaminophen's maximum recommended daily dose and will inform you if any changes are mandated for prescription medications containing this product. PMSI clinical pharmacists will continue to monitor for high dose acetaminophen use through our MedAssess™ Clinical programs.

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