Safety Warnings Added to Desipramine Label

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Warnings related to the risk of sudden death and cardiac dysrhythmias associated with desipramine have been added to the label of the tricyclic antidepressant, according to the Food and Drug Administration.

A notice posted on the FDA's MedWatch site states that "extreme caution" should be used when desipramine is prescribed to patients who have a family history of sudden death, cardiac dysrhythmias, and cardiac conduction disturbances. This statement has been added to the general warnings section of the label. Also added to this section is the statement that "seizures precede cardiac dysrhythmias and death in some patients."

Desipramine, approved in 1964, is marketed as Norpramin by Sanofi-Aventis, which issued a Dear Healthcare Professional letter summarizing the changes to the label.

The letter lists other related changes to the overdosage section of the label, including the statement that desipramine overdoses have resulted in a higher death rate when compared to overdoses of other tricyclics. The letter also contains descriptions of early EKG changes associated with overdoses, and the recommendation to administer activated charcoal for patients who present early after an overdose. This section also now states that "serum alkalinization with intravenous sodium bicarbonate and hyperventilation [as needed] should be instituted in patients manifesting significant toxicity such as QRS widening," and that "dysrhythmias despite adequate alkalemia may respond to overdrive pacing, beta-agonist infusions, and magnesium therapy." ■