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New Warning for Anemia Drug Aranesp.

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FDA Urges Doctors Not to Exceed Approved Doses of Drug That Treats Side Effect of Chemotherapy

WebMD Medical News

Jan. 14, 2005 -- Doctors are being urged not to use more than the recommended dose of Aranesp, a drug used to treat chemotherapy-induced anemia.

Together with the FDA, the drug's maker, Amgen, has sent a letter to doctors advising them of a revision to the warning label for Aranesp.

Two recent studies with other drugs in the same class of Aranesp, known as erythropoietic drugs, have shown that using the drugs at higher-than-recommended doses increases the risk of adverse effects including blood clots and death.

Although the studies were conducted with other drugs (Eprex and NeoRecormon), Amgen has incorporated this information into the prescribing information for Aranesp to alert doctors to these potential risks.

Aranesp is approved to treat anemia caused by chemotherapy. Anemia is a common side effect of chemotherapy, which can damage the production of red blood cells. In anemia, the blood is lacking in healthy red blood cells, which transport oxygen to organs.

Doctors often use hemoglobin levels to help determine how much of the drug is needed to treat the anemia. Hemoglobin is the oxygen-carrying protein in red blood cells. The prescribing information for Aranesp indicates that the target hemoglobin level should not exceed 12 g/dL.

In these studies, doctors used higher doses of the drug to achieve hemoglobin levels of greater than 12 g/dL, which subsequently increased the risk of blood clots and death.

SOURCES: FDA. Amgen.

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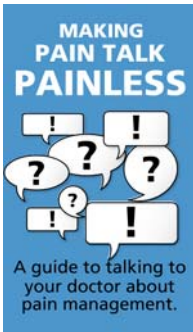
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