Ruconest approved for rare genetic disease

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(HealthDay)—Ruconest has been approved by the U.S. Food and Drug Administration to treat hereditary angioedema, a genetic disease that leads to sudden and potentially fatal swelling of the hands, feet, limbs, face, intestinal tract or airways.

The disease, affecting as many as 10,000 people in the United States, is caused by the body's inability to produce enough of a plasma protein called C1-esterase inhibitor. The remedy is produced from the milk of genetically-modified rabbits, the FDA said Thursday in a news release.

Ruconest was evaluated in a clinical study of 44 adults and adolescents with hereditary angioedema. The most common side effects recorded were headache, nausea and diarrhea.

Ruconest is manufactured by the Netherlands-based Pharming Group NV, and will be distributed by a subsidiary of Salix Pharmaceuticals, based in Raleigh, NC.

More information: The FDA has more about this approval.