FDA approves first nasal spray diuretic for heart, liver and kidney disease

The US FDA has approved the first-ever nasal spray diuretic for heart, liver, and kidney disease patients for the treatment of edema, one of the most common complications of the chronic diseases. This can reduce hospitalisations and save cost.

A Nevada-based biopharmaceutical company Corstasis Therapeutics has received approval from the US Food and Drug Administration for the bumetanide nasal spray, which could be useful in the treatment of edema associated with heart, liver, and kidney diseases.

In a breakthrough, The <u>US FDA</u> has approved the first-ever nasal spray diuretic for heart, liver, and kidney disease patients for the treatment of edema associated with several health conditions, according to a release posted on Corstasis Therapeutics website via Business Wire.

A Nevada-based biopharmaceutical company Corstasis Therapeutics has received approval from the US Food and Drug Administration for Enbumyst, the bumetanide nasal spray, which could be useful in the treatment of <u>edema</u> associated with <u>congestive heart failure</u> (CHF), kidney disease and <u>liver disease</u>, marking the first time an intranasal loop diuretic has been approved by the FDA.

Edema and fluid overload are among the most common complications of these chronic diseases, which lead to more than one million hospital admissions every year in the US. The nasal spray is aimed at cutting costs and the hospitalisations that reach more than a million every year.

The role of diuretics

Diuretics, often referred to as water pills, are a class of medicines that help reduce fluid buildup in the body. They help the kidneys remove salt and water through the urine, lowering the amount of fluid flowing through the veins and arteries, which can help bring down the blood pressure.

While oral diuretics are commonly prescribed to many, but there may be challenges of poor absorption and delayed onset. On the other hand, intravenous (IV) diuretics require hospital or infusion center administration, which can raise costs and lead to inconvenience.

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What the new nasal spray promises

The new nasal spray Enbumyst helps patient avoid hospitalisations and clinical studies demonstrate its effectiveness.

In studies conducted between December 2023 and April 2024, where around 68 adults aged 18 to 55 years participated, the spray demonstrated rapid absorption and a predictable diuretic effect comparable to IV bumetanide.

"The FDA approval of Enbumyst represents a meaningful advancement in the treatment of edema for patients and providers," said Ben Esque, Chief Executive Officer of Corstasis Therapeutics.

The new nasal spray can greatly ease the burden for heart failure patients. The drug's most common side effects reported being hypovolemia, headache, muscle cramps, dizziness and nausea.

"[Bumetanide nasal spray] offers the potential to change the standard of care by enabling earlier, outpatient intervention," said Anuradha Lala-Trindade, MD, the director of heart failure research at the Mount Sinai Fuster Hospital in New York. "This innovation may meaningfully improve outcomes while potentially easing the economic burden on the healthcare system."

Enbumyst's expected launch date would be around late 2025.

News Source:

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