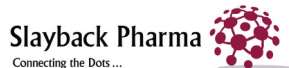


Slayback Pharma announces approval of Icatibant Injection 30 mg/3 ml (10 mg/ ml), generic equivalent of Firazyr®.



NEWS PROVIDED BY
Slayback Pharma LLC →
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PRINCETON, N.J., Sept. 2, 2020 /PRNewswire/ -- Slayback Pharma, LLC announced today that it has received final approval for its ANDA for Icatibant Injection 30 mg/3 ml (10 mg/ml) in a Prefilled Syringe - a generic equivalent of Firazyr®.

Ajay Singh, CEO of Slayback Pharma, said: "We are pleased to announce the approval of our ANDA for Icatibant - another complex generic injectable of a difficult-to-characterize peptide and a drug-device combination. We are particularly excited at the opportunity to enhance the affordability of yet another expensive orphan drug."

See the following important safety information and refer to the package insert for full prescribing information.

Indication

Icatibant injection is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

Important Safety Information for Icatibant

Angioedema (which can include swelling of the throat or larynx) can be life-threatening. Inject Icatibant and go to the nearest hospital emergency room immediately if you have a laryngeal attack.

- Do not take Icatibant if you are allergic to it or any other ingredient in the formulation.
- Do not administer if the product contains visible particulate material or is discolored.
- Do not take more than 3 doses in 24 hours.
- Do not drive or use machinery if you feel dizzy, drowsy, or tired.
- Use only the needle that is provided with the syringe.
- Please discuss with your doctor if you:
 - are taking any blood pressure medications
 - have hepatic or renal disease
 - are pregnant, nursing, or planning on being pregnant or nursing
 - are under the age of 18
 - recently experienced a heart attack, unstable angina, or a stroke
 - have any other medical conditions

- Some known side effects are:
 - redness, bruising, swelling, warmth, burning, itching, irritation, hives, numbness, pressure, or pain at the injection site
 - dizziness
 - drowsiness
 - fever
 - headache
 - increase in transaminase (liver enzyme) levels
 - nausea
 - rash
 - tiredness

These are not all the possible side effects of Icatibant. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Tell your healthcare provider if you have any other medical conditions. You and your healthcare provider will decide if Icatibant is right for you.

For more information, please see full Prescribing Information.

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You are encouraged to report any side effects or adverse event by calling 1-844-566-2505 or emailing medical@slayback-pharma.com. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly at fda.gov/medwatch or call 1-800-FDA-1088.

Slayback Pharma is a New Jersey-based pharmaceutical company focused on the development of complex and specialty generic products.

Intended only for residents of the United States of America.

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References:

Icatibant Injection prescribing information. Slayback Pharma, 6/2020

Firazyr® is a registered trademark of Shire, a Takeda company.

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Related Links

<http://www.slayback-pharma.com>