Alembic Pharma announces USFDA final approval for Icatibant injection, 30 mg/3 mL (10 mg/mL) single-dose prefilled syringe

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Firazyr Injection, 30 mg/3 mL (10 mg/mL)

Alembic Pharmaceuticals (Alembic) has announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Icatibant injection, 30 mg/3 mL (10 mg/mL) single-dose prefilled syringe.

The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Firazyr Injection, 30 mg/3 mL (10 mg/mL), of Takeda Pharmaceuticals U.S.A., Icatibant injection is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

“This is the first peptide product approval from the USFDA received by the Company,” the statement informs.

“Icatibant Injection has an estimated market size of US$ 112 million for 12 months ending Mar 2024 according to IQVIA. Alembic has a cumulative total of 205 ANDA approvals (177 final approvals and 28 tentative approvals) from USFDA,” the statement further informs.

News Source:

https://www.expresspharma.in/alembic-pharma-announces-usfda-final-approval-for-icatibant-injection-30-mg-3-ml-10-mg-ml-single-dose-prefilled-syringe/