

ORKAMBI - (125MG;200MG, 125MG;100MG ; Tablet)

Generic Name	IVACAFTOR; LUMACAFTOR	Innovator	Vertex pharma
Dosage	125MG;200MG, 125MG;100MG ; Tablet	Branded US Sales	Less Than \$1000 mn
Probable FTF	None	Known Para IV Filers	None
Other ANDA developers	Less Than 5	Tentative Approvals	None
Final Approvals	None	Generic Launches	None
Indication	ORKAMBI is a combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.		
Complexities	Yes		

Chronology Of Events

Please Contact contact@researchdelta.com to get Detailed Information.

Executive Summary

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Patent Status

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Launch Timelines and Competition

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Chronology Of Events

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ORKAMBI - (125MG/PACKET;100MG/PACKET, 188MG/PACKET;150MG/PACKET, 94MG/PACKET;75MG/PACKET ; Granules)

Generic Name	IVACAFTOR; LUMACAFTOR	Innovator	Vertex pharma
Dosage	125MG/PACKET;100MG/PACKET, 188MG/PACKET;150MG/PACKET, 94MG/PACKET;75MG/PACKET ; Granules	Branded US Sales	Less Than \$1000 mn
Probable FTF	None	Known Para IV Filers	None
Other ANDA developers	Less Than 5	Tentative Approvals	None
Final Approvals	None	Generic Launches	None
Indication	ORKAMBI is a combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.		
Complexities	Yes		

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