# 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

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

## Patent Status

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

## Launch Timelines and Competition

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

## 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 | | |

## Chronology Of Events

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