

## VIJOICE - (50MG, 125MG, 200MG ; Tablet)

<b>Generic Name</b>	ALPELISIB	<b>Innovator</b>	Novartis
<b>Dosage</b>	50MG, 125MG, 200MG ; Tablet	<b>Branded US Sales</b>	Less Than \$1000 mn
<b>Probable FTF</b>	None	<b>Known Para IV Filers</b>	None
<b>Other ANDA developers</b>	None	<b>Tentative Approvals</b>	None
<b>Final Approvals</b>	None	<b>Generic Launches</b>	None
<b>Indication</b>	VIJOICE is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CARelated Overgrowth Spectrum (PROS) who require systemic therapy.		
<b>Complexities</b>	Yes		

### Chronology Of Events

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Executive Summary

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Patent Status

Please Contact [contact@researchdelta.com](mailto:contact@researchdelta.com) to get Detailed Information.

### Launch Timelines and Competition

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### Chronology Of Events

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## VIJOICE - (50MG/PACKET ; Granules)

<b>Generic Name</b>	ALPELISIB	<b>Innovator</b>	Novartis
<b>Dosage</b>	50MG/PACKET ; Granules	<b>Branded US Sales</b>	Less Than \$1000 mn
<b>Probable FTF</b>	None	<b>Known Para IV Filers</b>	None
<b>Other ANDA developers</b>	None	<b>Tentative Approvals</b>	None
<b>Final Approvals</b>	None	<b>Generic Launches</b>	None
<b>Indication</b>	VIJOICE is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CARelated Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.		
<b>Complexities</b>	Yes		

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