

Valcyte - (EQ 450mg BASE; Tablet)

| Generic Name | Valganciclovir Hydrochloride | Innovator | Roche |
|-----------------------|---|----------------------|---------------------|
| Dosage | EQ 450mg BASE; Tablet | Branded US Sales | Less Than \$1000 mn |
| Probable FTF | Less Than 5 | Known Para IV Filers | Less Than 5 |
| Other ANDA developers | Less Than 5 | Tentative Approvals | None |
| Final Approvals | More Than 5 | Generic Launches | More Than 5 |
| Indication | Used in adults to prevent infection with cytomegalovirus (CMV) that may occur after an organ transplant (heart, kidney, or pancreas). | | |
| 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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Valcyte - (50 mg/mL for Oral Solution)

| Generic Name | Valganciclovir Hydrochloride | Innovator | Hoffmann La Roche |
|-----------------------|--|----------------------|---------------------|
| Dosage | 50 mg/mL for Oral Solution | Branded US Sales | Less Than \$1000 mn |
| Probable FTF | Less Than 5 | Known Para IV Filers | Less Than 5 |
| Other ANDA developers | Less Than 5 | Tentative Approvals | None |
| Final Approvals | More Than 5 | Generic Launches | More Than 5 |
| Indication | Valcyte is a cytomegalovirus (CMV) nucleoside analogue DNA polymerase inhibitor indicated for: Adult Patients (1.1) • Treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS) • Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk Pediatric Patients (1.2) • Prevention of CMV disease in kidney and heart transplant patients at high risk | | |
| Complexities | Yes | | |

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