

## Prezista - (75,150,300 mg; Tablet)

|                              |                                                                               |                             |                     |
|------------------------------|-------------------------------------------------------------------------------|-----------------------------|---------------------|
| <b>Generic Name</b>          | Darunavir Ethanolate                                                          | <b>Innovator</b>            | Janssen Pharma      |
| <b>Dosage</b>                | 75,150,300 mg; Tablet                                                         | <b>Branded US Sales</b>     | More Than \$1000 mn |
| <b>Probable FTF</b>          | Less Than 5                                                                   | <b>Known Para IV Filers</b> | More Than 5         |
| <b>Other ANDA developers</b> | More Than 5                                                                   | <b>Tentative Approvals</b>  | More Than 5         |
| <b>Final Approvals</b>       | Less Than 5                                                                   | <b>Generic Launches</b>     | None                |
| <b>Indication</b>            | Indicated for the treatment of human immunodeficiency virus (HIV-1) infection |                             |                     |
| <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

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### Launch Timelines and Competition

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## Prezista - (400 mg, tablet, oral)

|                              |                                                                               |                             |                     |
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| <b>Generic Name</b>          | Darunavir Ethanolate                                                          | <b>Innovator</b>            | Janssen Pharma      |
| <b>Dosage</b>                | 400 mg, tablet, oral                                                          | <b>Branded US Sales</b>     | More Than \$1000 mn |
| <b>Probable FTF</b>          | Less Than 5                                                                   | <b>Known Para IV Filers</b> | More Than 5         |
| <b>Other ANDA developers</b> | Less Than 5                                                                   | <b>Tentative Approvals</b>  | Less Than 5         |
| <b>Final Approvals</b>       | Less Than 5                                                                   | <b>Generic Launches</b>     | Less Than 5         |
| <b>Indication</b>            | Indicated for the treatment of Human Immunodeficiency Virus (HIV-i) infection |                             |                     |
| <b>Complexities</b>          | Yes                                                                           |                             |                     |

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## Prezista - (800mg; Tablet, Oral)

|                              |                                                                               |                             |                     |
|------------------------------|-------------------------------------------------------------------------------|-----------------------------|---------------------|
| <b>Generic Name</b>          | Darunavir Ethanolate                                                          | <b>Innovator</b>            | Janssen Pharma      |
| <b>Dosage</b>                | 800mg; Tablet, Oral                                                           | <b>Branded US Sales</b>     | More Than \$1000 mn |
| <b>Probable FTF</b>          | Less Than 5                                                                   | <b>Known Para IV Filers</b> | More Than 5         |
| <b>Other ANDA developers</b> | Less Than 5                                                                   | <b>Tentative Approvals</b>  | Less Than 5         |
| <b>Final Approvals</b>       | More Than 5                                                                   | <b>Generic Launches</b>     | More Than 5         |
| <b>Indication</b>            | Indicated for the treatment of human immunodeficiency virus (HIV-1) infection |                             |                     |
| <b>Complexities</b>          | Yes                                                                           |                             |                     |

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## Prezista - (600mg; Tablet, Oral)

|                              |                                                                               |                             |                     |
|------------------------------|-------------------------------------------------------------------------------|-----------------------------|---------------------|
| <b>Generic Name</b>          | Darunavir Ethanolate                                                          | <b>Innovator</b>            | Janssen Pharma      |
| <b>Dosage</b>                | 600mg; Tablet, Oral                                                           | <b>Branded US Sales</b>     | Less Than \$1000 mn |
| <b>Probable FTF</b>          | Less Than 5                                                                   | <b>Known Para IV Filers</b> | More Than 5         |
| <b>Other ANDA developers</b> | Less Than 5                                                                   | <b>Tentative Approvals</b>  | Less Than 5         |
| <b>Final Approvals</b>       | More Than 5                                                                   | <b>Generic Launches</b>     | More Than 5         |
| <b>Indication</b>            | Indicated for the treatment of human immunodeficiency virus (HIV-1) infection |                             |                     |
| <b>Complexities</b>          | Yes                                                                           |                             |                     |

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## Prezista - (100MG/1ML ; Suspension)

|                              |                                                                                                                                                                                                                                                                                           |                             |                     |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|---------------------|
| <b>Generic Name</b>          | Darunavir Ethanolate                                                                                                                                                                                                                                                                      | <b>Innovator</b>            | Janssen Pharma      |
| <b>Dosage</b>                | 100MG/1ML ; Suspension                                                                                                                                                                                                                                                                    | <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> | Less Than 5                                                                                                                                                                                                                                                                               | <b>Tentative Approvals</b>  | None                |
| <b>Final Approvals</b>       | None                                                                                                                                                                                                                                                                                      | <b>Generic Launches</b>     | None                |
| <b>Indication</b>            | PREZISTA is a human immunodeficiency virus (HIV-1) protease inhibitor indicated for the treatment of HIV-1 infection in adult and pediatric patients 3 years of age and older. PREZISTA must be co-administered with ritonavir (PREZISTA/ritonavir) and with other antiretroviral agents. |                             |                     |
| <b>Complexities</b>          | Yes                                                                                                                                                                                                                                                                                       |                             |                     |

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