

Procysbi - (25, 75 mg; Capsule delayed release)

| Generic Name | Cysteamine Bitartrate | Innovator | Horizon Pharma |
|-----------------------|--|----------------------|---------------------|
| Dosage | 25, 75 mg; Capsule delayed release | 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 | None | Generic Launches | None |
| Indication | PROCYSBI is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older. | | |
| Complexities | Yes | | |

Chronology Of Events

Please Contact <u>contact@researchdelta.com</u> to get Detailed Information.

Executive Summary

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

Patent Status

Please Contact <u>contact@researchdelta.com</u> to get Detailed Information.

Launch Timelines and Competition

Please Contact <u>contact@researchdelta.com</u> to get Detailed Information.

Chronology Of Events

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Procysbi - (75 mg/Packet and 300 mg/Packet ; Delayed-release Granules)

| Generic Name | Cysteamine Bitartrate | Innovator | Horizon Pharma |
|-----------------------|--|----------------------|---------------------|
| Dosage | 75 mg/Packet and 300 mg/Packet ; Delayed-release Granules | 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 | None | Generic Launches | None |
| Indication | PROCYSBI is a cystine-depleting agent indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older. | | |
| Complexities | Yes | | |

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