

Tirosint - (75, 150 mcg; Capsule, Oral)

| | | | |
|------------------------------|---|-----------------------------|---------------------|
| Generic Name | Levothyroxine Sodium | Innovator | IBSA |
| Dosage | 75, 150 mcg; Capsule, Oral | Branded US Sales | Less Than \$1000 mn |
| Probable FTF | Less Than 5 | Known Para IV Filers | Less Than 5 |
| Other ANDA developers | More Than 5 | Tentative Approvals | None |
| Final Approvals | None | Generic Launches | None |
| Indication | Indicated as a replacement therapy in adults and pediatric patients 6 years and older with primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. | | |
| Complexities | Yes | | |

Chronology Of Events

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

Executive Summary

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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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Tirosint - (88, 100, 125 mcg; Capsule, Oral)

| | | | |
|------------------------------|---|-----------------------------|---------------------|
| Generic Name | Levothyroxine Sodium | Innovator | IBSA |
| Dosage | 88, 100, 125 mcg; Capsule, Oral | Branded US Sales | Less Than \$1000 mn |
| Probable FTF | Less Than 5 | Known Para IV Filers | Less Than 5 |
| Other ANDA developers | More Than 5 | Tentative Approvals | None |
| Final Approvals | None | Generic Launches | None |
| Indication | TIROSINT is indicated as a replacement therapy in adults and pediatric patients 6 years and older with primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism. | | |
| Complexities | Yes | | |

Chronology Of Events

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Tirosint - (200 mcg ; Capsules)

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|------------------------------|---|-----------------------------|---------------------|
| Generic Name | Levothyroxine Sodium | Innovator | IBSA |
| Dosage | 200 mcg ; Capsules | Branded US Sales | Less Than \$1000 mn |
| Probable FTF | None | Known Para IV Filers | None |
| Other ANDA developers | More Than 5 | Tentative Approvals | None |
| Final Approvals | None | Generic Launches | None |
| Indication | TIROSINT is L-thyroxine (T4) indicated for adults and pediatric patients 6 years and older with: • Hypothyroidism - As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism • Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer | | |
| Complexities | Yes | | |

Chronology Of Events

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Tirosint - (137 and 175 mcg; Capsule)

| | | | |
|------------------------------|--|-----------------------------|---------------------|
| Generic Name | Levothyroxine Sodium | Innovator | IBSA |
| Dosage | 137 and 175 mcg; Capsule | 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 | Less Than 5 | Generic Launches | None |
| Indication | Tirosint is used as replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, or in the treatment or prevention of various types of euthyroid goiters, as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well differentiated thyroid cancer. | | |
| Complexities | Yes | | |

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