

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

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Launch Timelines and Competition

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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)

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-dependment well differentiated thyroid cancer.		
Complexities	Yes		

Chronology Of Events

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