

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[f SHARE](#)
[TWEET](#)
[LINKEDIN](#)
[PIN IT](#)
[EMAIL](#)
[PRINT](#)

[Home](#) | [Back to Product Details](#)

Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N200603

Product 003
LURASIDONE HYDROCHLORIDE (LATUDA) TABLET 20MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
003	5532372	Jul 2, 2018	DS			
003	5532372*PED	Jan 2, 2019				
003	8729085	May 26, 2026		DP		
003	8729085*PED	Nov 26, 2026				
003	8883794	May 26, 2026		DP		
003	8883794*PED	Nov 26, 2026				
003	9174975	Jun 25, 2026			U-1770	
003	9174975*PED	Dec 25, 2026				
003	9259423	May 23, 2031			U-1822	
003	9259423*PED	Nov 23, 2031				
003	9555027	May 26, 2026		DP	U-543	
003	RE45573	Jun 23, 2025	DS			
003	RE45573*PED	Dec 23, 2025				

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
003	M-195	Jan 27, 2020
003	NPP	Jan 27, 2020
003	PED	Jul 27, 2020
003	PED	Jul 27, 2020

[View a list of all patent use codes](#)

[View a list of all exclusivity codes](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)



[Accessibility](#)

[Careers](#)

[FDA Basics](#)

[FOIA](#)

[No FEAR Act](#)

[Site Map](#)

[Nondiscrimination](#)

[Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

[Contact FDA](#)



[FDA Archive](#)

[Combination Products](#)

[Advisory Committees](#)

[Regulatory Information](#)

[Safety](#)

[Emergency Preparedness](#)

[International Programs](#)

[News & Events](#)

[Training & Continuing Education](#)

[Inspections & Compliance](#)

[Federal, State & Local Officials](#)

[Consumers](#)

[Health Professionals](#)

[Science & Research](#)

[Industry](#)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[f SHARE](#)
[TWEET](#)
[LINKEDIN](#)
[PIN IT](#)
[EMAIL](#)
[PRINT](#)

[Home](#) | [Back to Product Details](#)

Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N200603

Product 001
LURASIDONE HYDROCHLORIDE (LATUDA) TABLET 40MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
001	5532372	Jul 2, 2018	DS			
001	5532372*PED	Jan 2, 2019				
001	8729085	May 26, 2026		DP		
001	8729085*PED	Nov 26, 2026				
001	8883794	May 26, 2026		DP		
001	8883794*PED	Nov 26, 2026				
001	9174975	Jun 25, 2026			U-1770	
001	9174975*PED	Dec 25, 2026				
001	9259423	May 23, 2031			U-1822	
001	9259423*PED	Nov 23, 2031				
001	9555027	May 26, 2026		DP	U-543	
001	RE45573	Jun 23, 2025	DS			
001	RE45573*PED	Dec 23, 2025				

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	M-195	Jan 27, 2020
001	NPP	Jan 27, 2020
001	PED	Jul 27, 2020
001	PED	Jul 27, 2020

[View a list of all patent use codes](#)

[View a list of all exclusivity codes](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)



[Accessibility](#)

[Careers](#)

[FDA Basics](#)

[FOIA](#)

[No FEAR Act](#)

[Site Map](#)

[Nondiscrimination](#)

[Website Policies](#)

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

[Contact FDA](#)



[FDA Archive](#)

[Combination Products](#)

[Advisory Committees](#)

[Regulatory Information](#)

[Safety](#)

[Emergency Preparedness](#)

[International Programs](#)

[News & Events](#)

[Training & Continuing Education](#)

[Inspections & Compliance](#)

[Federal, State & Local Officials](#)

[Consumers](#)

[Health Professionals](#)

[Science & Research](#)

[Industry](#)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[f SHARE](#)
[TWEET](#)
[LINKEDIN](#)
[PIN IT](#)
[EMAIL](#)
[PRINT](#)

[Home](#) | [Back to Product Details](#)

Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N200603

Product 005
LURASIDONE HYDROCHLORIDE (LATUDA) TABLET 60MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
005	5532372	Jul 2, 2018	DS			
005	5532372*PED	Jan 2, 2019				
005	8729085	May 26, 2026		DP		
005	8729085*PED	Nov 26, 2026				
005	8883794	May 26, 2026		DP		
005	8883794*PED	Nov 26, 2026				
005	9174975	Jun 25, 2026			U-1770	
005	9174975*PED	Dec 25, 2026				
005	9259423	May 23, 2031			U-1822	
005	9259423*PED	Nov 23, 2031				
005	9555027	May 26, 2026		DP	U-543	
005	RE45573	Jun 23, 2025	DS			
005	RE45573*PED	Dec 23, 2025				

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.