

# Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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## 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			<a href="#">U-1770</a>	
003	9174975*PED	Dec 25, 2026				
003	9259423	May 23, 2031			<a href="#">U-1822</a>	
003	9259423*PED	Nov 23, 2031				
003	9555027	May 26, 2026		DP	<a href="#">U-543</a>	
003	RE45573	Jun 23, 2025	DS			
003	RE45573*PED	Dec 23, 2025				

## Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
003	<a href="#">M-195</a>	Jan 27, 2020
003	<a href="#">NPP</a>	Jan 27, 2020
003	<a href="#">PED</a>	Jul 27, 2020
003	<a href="#">PED</a>	Jul 27, 2020

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## 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				
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## 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		
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