

API Portfolio

October 2026

Dipharma Since 1949

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PRODUCT NAME	CAS No.	THERAPEUTIC CLASS	EU CTD	CEP	US DMF	GDUFA	CANADA DMF	JAPAN DMF	BRAZIL DMF	BRAZIL CADIFA	CHINA DMF
AMINOCAPROIC ACID	60-32-2	Treatment of bleeding disorders	●		●	●					●
AMITRIPTYLINE HCl	549-18-8	Antidepressant	●	●	●				●		
BENSERAZIDE HCl	14919-77-8	Antiparkinson, Restless legs syndrome	●								
BIPERIDEN HCl	1235-82-1	Antiparkinson	●								
BUPROPION HCl	31677-93-7	Antidepressant	●		●	●	●		●		
CANDESARTAN CILEXETIL	145040-37-5	Antihypertensive	●	○							
CHENODEOXYCHOLIC ACID*	474-25-9	Bile stone therapy	●		●	●					
CHOLIC ACID*	81-25-4	Bile acid synthesis disorders			●	●					
CRISABOROLE	906673-24-3	Treatment of atopic dermatitis and psoriasis	●								
CYCLOBENZAPRINE HCl	6202-23-9	Muscle relaxant	●		●	●	●	●	●	○	
DAPSONE	80-08-0	Antibacterial	●		●	●					
DEXLANSOPRAZOLE ANHYDROUS CRYSTALLINE	138530-94-6	Antiulcerative	●		●	●					
DICLOFENAC EPOLAMINE	119623-66-4	Anti-inflammatory									
DICLOFENAC POTASSIUM	15307-81-0	Anti-inflammatory	●		●						
DICLOFENAC SODIUM	15307-79-6	Anti-inflammatory	●		●	●	●				
DOTHIEPIN HCl (DOSULEPIN HCl)	897-15-4	Antidepressant	●								
DOXEPIN HCl	1229-29-4	Antidepressant	●		●	●	●				
EFINACONAZOLE	164650-44-6	Antifungal, treatment of onychomycosis	●		●	●	●				
ELINZANETANT	929046-33-3	Neurokinin NK-1 and NK-3 receptor antagonist									
ETRIPAMIL	1593673-23-4	Antiarrhythmic			●						
FESOTERODINE FUMARATE	286930-03-8	Antimuscarinic, treatment of urinary incontinence			●	●	●				
FEXOFENADINE HCl	153439-40-8	Antihistaminic	●		●	●		●			
GLIBENCLAMIDE (GLYBURIDE)	10238-21-8	Antidiabetic	●		●			●			
GLYCOCHOLIC ACID	475-31-0	Excipient									
IBUPROFEN LYSINE SALT	57469-76-8	Analgesic, Anti-inflammatory	●		●						
ISOSORBIDE DINITRATE	87-33-2	Vasodilator	●	●	●	●	●	●	●		●
ISOSORBIDE-5-MONONITRATE	16051-77-7	Vasodilator	●	●	●	●	●	●	●		●

* only for specific markets

● filed ○ under preparation

For certain products, submissions have also been filed with regulatory authorities beyond those listed. Dipharma is available to support customers according to their specific requirements, including the customisation of regulatory submissions.

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LETERMOVIR	917389-32-3	Antiviral			○						
METARAMINOL*	33402-03-8	Antihypotensive	●								●
MINODRONIC ACID	155648-60-5	Treatment of osteoporosis	●					●			
MODAFINIL	68693-11-8	Psychostimulant	●		●	●					
NIFEDIPINE	21829-25-4	Antihypertensive	●	●	●	●					●
NITROGLYCERINE (GLYCERYL TRINITRATE)	55-63-0	Vasodilator	●		●	●	●				●
NORTRIPTYLINE HCl	894-71-3	Antidepressant	●		●	●	●	●	●		
PIRFENIDONE	53179-13-8	Immunosuppressant	●	●	●	●		●			
PIROXICAM	36322-90-4	Anti-inflammatory	●		●	●	●				
RUFINAMIDE	106308-44-5	Anticonvulsant	●		●	●	●				
SELEGILINE BASE*	14611-51-9	Antidepressant, antiparkinson	●		●	●					
SELEGILINE HCl	14611-52-0	Antiparkinson	●	●	●	●	●	●			
SODIUM PHENYLBUTYRATE	1716-12-7	Metabolic disorder	●		○						
TAUROURSODEOXYCHOLIC ACID	14605-22-2	Bile stone therapy	●								
TOLBUTAMIDE	64-77-7	Antidiabetic	●		●						
TRADIPITANT	622370-35-8	Substance P / Neurokinin NK-1 receptor antagonist									
TRIAMTERENE	396-01-0	Diuretic	●	●	●	●	●				
URSODEOXYCHOLIC ACID	128-13-2	Cholelitholytic agent	●	●	●	●	●		●	●	●
VORTIOXETINE HBr	960203-27-4	Antidepressant			●	●					
ZONISAMIDE	68291-97-4	Anticonvulsant	●		●			●			

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