

HYDROXYCHLOROQUINE SULFATE- hydroxychloroquine sulfate tablet, film coated

Zydus Lifesciences Limited

Hydroxychloroquine sulfate tablets, USP

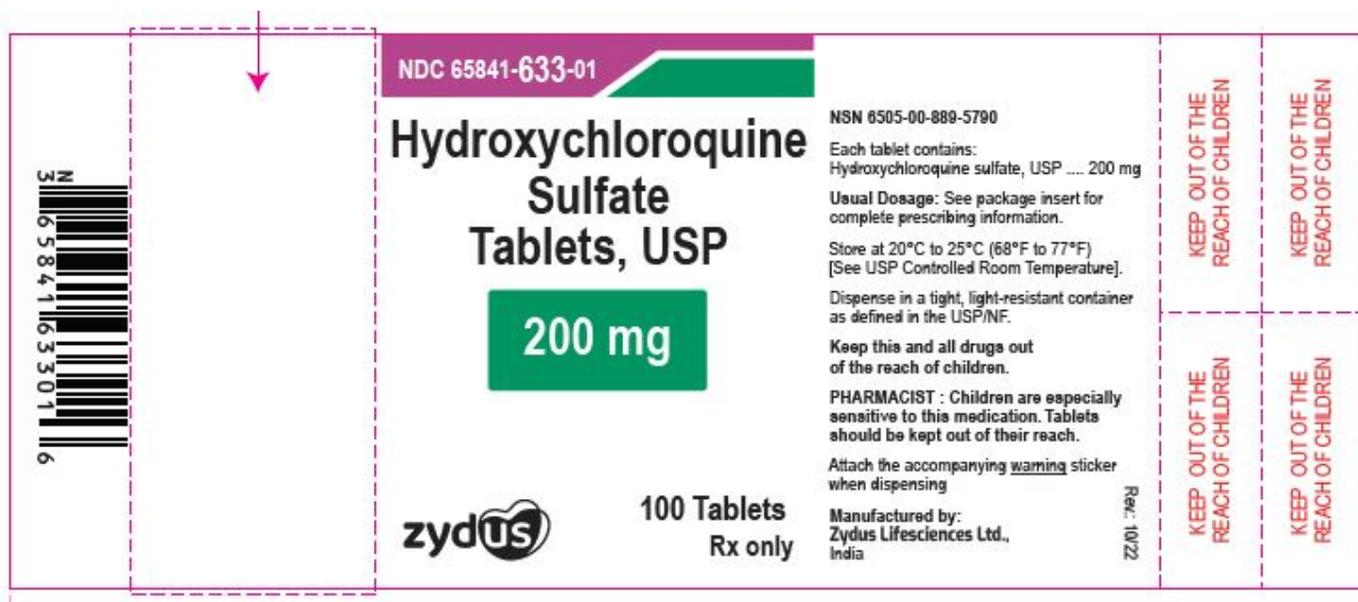
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-633-01 in bottle of 100 tablets

Hydroxychloroquine Sulfate Tablets USP, 200 mg

R_x only

100 tablets



HYDROXYCHLOROQUINE SULFATE

hydroxychloroquine sulfate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-633
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROXYCHLOROQUINE SULFATE (UNII: 8Q2869CNVH) (HYDROXYCHLOROQUINE - UNII:4QWG6N8QKH)	HYDROXYCHLOROQUINE SULFATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL (CAPSULE)	Size	13mm
Flavor		Imprint Code	ZC38
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-633-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	
2	NDC:65841-633-30	10 in 1 CARTON	01/03/2008	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:65841-633-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040657	01/03/2008	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-633) , MANUFACTURE(65841-633)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(65841-633) , MANUFACTURE(65841-633)

Establishment

Name	Address	ID/FEI	Business Operations
Zyduş Lifesciences Limited		677605858	ANALYSIS(65841-633) , MANUFACTURE(65841-633)

Revised: 10/2025

Zyduş Lifesciences Limited