

**HYDROXYCHLOROQUINE SULFATE- hydroxychloroquine sulfate tablet, film coated**  
**Cadila Healthcare Limited**

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**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<sub>x</sub> only

100 tablets



**HYDROXYCHLOROQUINE SULFATE**

hydroxychloroquine sulfate tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-633
<b>Route of Administration</b>	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)	

<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

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

### Packaging

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

### Marketing Information

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

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

### Establishment

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