

ENTECAVIR - entecavir tablet, film coated
Zydus Lifesciences Limited

ENTECAVIR TABLETS

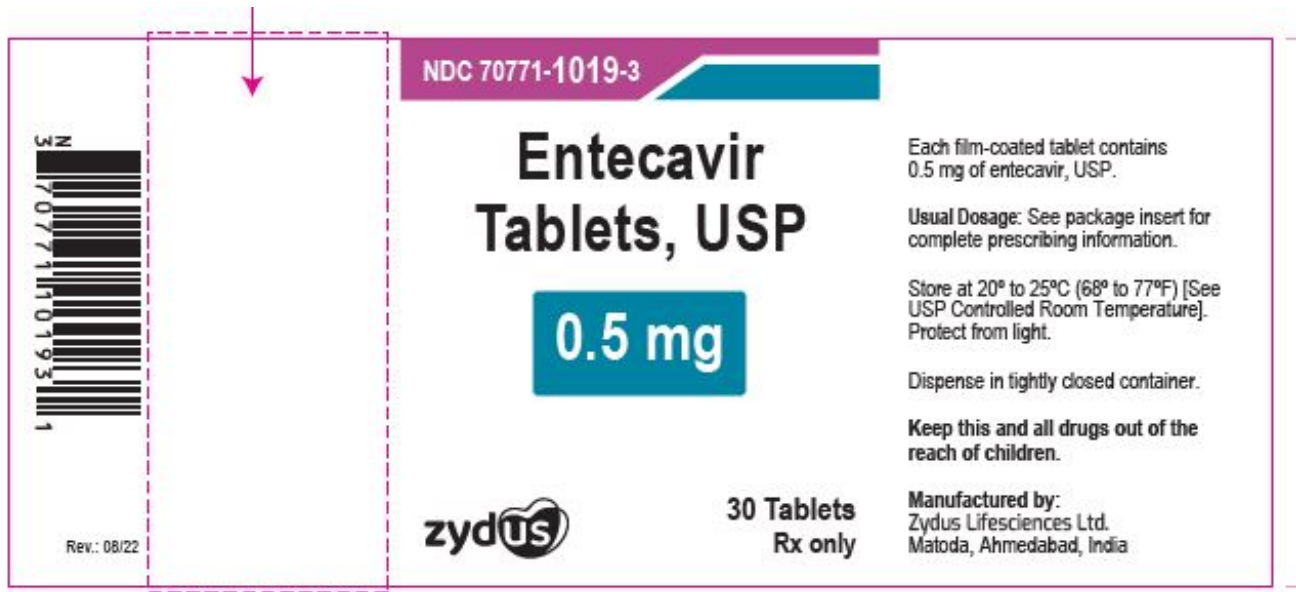
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1019-3

Entecavir Tablets USP, 0.5 mg

Rx Only

30 tablets



NDC 70771-1020-3

Entecavir Tablets USP, 1 mg

Rx Only

30 tablets

NDC 70771-1020-3



Rev.: 08/22

Entecavir Tablets, USP

1 mg



30 Tablets
Rx only

Each film-coated tablet contains 1 mg of entecavir, USP.

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light.

Dispense in tightly closed container.

Keep this and all drugs out of the reach of children.

Manufactured by:
Zydus Lifesciences Ltd.
Matoda, Ahmedabad, India

ENTECAVIR

entecavir tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1019
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENTECAVIR (UNII: 5968Y6H45M) (ENTECAVIR ANHYDROUS - UNII: NNU2O4609D)	ENTECAVIR	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	920
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1019-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
2	NDC:70771-1019-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
3	NDC:70771-1019-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
4	NDC:70771-1019-4	10 in 1 CARTON	08/10/2017	
4	NDC:70771-1019-2	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	ANDA206745	08/10/2017	

ENTECAVIR

entecavir tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1020
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENTECAVIR (UNII: 5968Y6H45M) (ENTECAVIR ANHYDROUS - UNII: NNU2O4609D)	ENTECAVIR	1 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK (LIGHT-PINK TO PINK)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	921
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1020-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
2	NDC:70771-1020-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
3	NDC:70771-1020-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/10/2017	
4	NDC:70771-1020-4	10 in 1 CARTON	08/10/2017	
4	NDC:70771-1020-2	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	ANDA206745	08/10/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1019, 70771-1020) , MANUFACTURE(70771-1019, 70771-1020)

Revised: 8/2022

Zydus Lifesciences Limited