ABACAVIR AND LAMIVUDINE- abacavir and lamivudine tablet, film coated
Zydus Lifesciences Limited

ABACAVIR and LAMIVUDINE tablets, for oral use

SPL MEDGUIDE

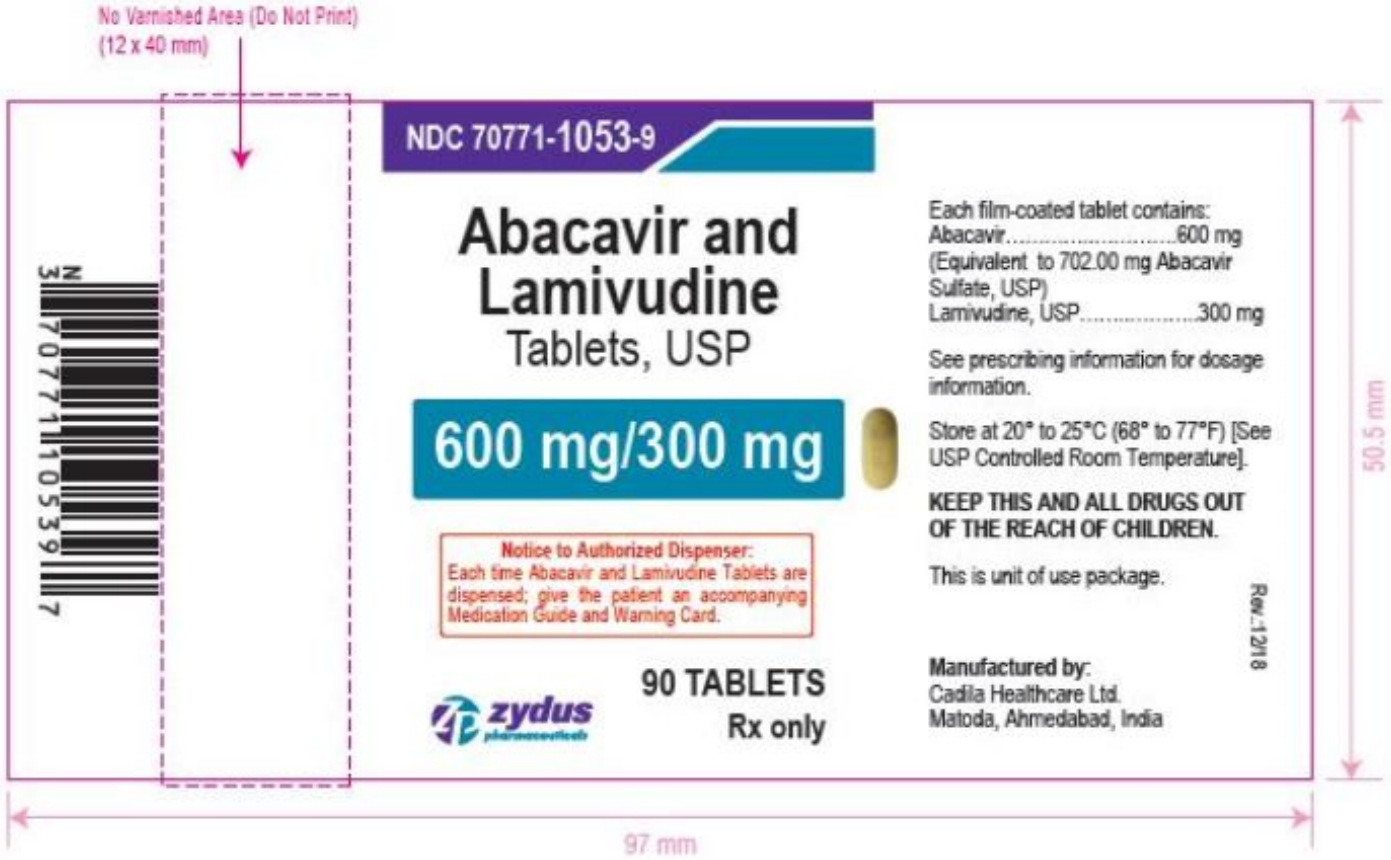
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1053-9

Abacavir and Lamivudine Tablets, 600 mg/300 mg

90 Tablets

Rx only



Abacavir Sulfate and Lamivudine Tablet:

Warning Card

WARNING CARD
Abacavir and Lamivudine Tablets, USP

Patients taking abacavir and lamivudine tablets may have a serious allergic reaction (hypersensitivity reaction) that can cause death. If you get a symptom from 2 or more of the following groups while taking abacavir and lamivudine tablets, call your healthcare provider right away to find out if you should stop taking this medicine.

	Symptom(s)
Group 1	**Fever**
Group 2	**Rash**
Group 3	**Nausea, vomiting, diarrhea, or abdominal (stomach area) pain**
Group 4	**Generally ill feeling, extreme tiredness, or achiness**
Group 5	**Shortness of breath, cough, or sore throat**

Always carry this Warning Card with you to help recognize symptoms of this allergic reaction.

Front Side

WARNING CARD
Abacavir and Lamivudine Tablets, USP

If you must stop treatment with abacavir and lamivudine tablets because you have had an allergic reaction to abacavir, **NEVER** take abacavir and lamivudine tablets or another abacavir-containing medicine (ZIAGEN®, TRIUMEQ®, or TRIZIVIR®) again. If you take abacavir and lamivudine tablets or another abacavir-containing medicine again after you have had an allergic reaction, **WITHIN HOURS** you may get **life-threatening symptoms** that may include **very low blood pressure** or **death.**

Please read the Medication Guide for additional information on abacavir and lamivudine tablets.

Ziagen, Triumeq, and Trizivir are registered trademarks of ViiV Healthcare group of companies.

Rev.: 12/16

Back Side

ABACAVIR AND LAMIVUDINE

abacavir and lamivudine tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1053
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ABACAVIR SULFATE (UNII: J220T4J9Q2) (ABACAVIR - UNII:WR2TIP26VS)	ABACAVIR	600 mg
LAMIVUDINE (UNII: 2T8Q726O95) (LAMIVUDINE - UNII:2T8Q726O95)	LAMIVUDINE	300 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE K30 (UNII: U725QWY32X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW TO YELLOW)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	20mm
Flavor		**Imprint Code**	1049
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1053-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019	
2	NDC:70771-1053-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208990	03/14/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1053) , MANUFACTURE(70771-1053)

Revised: 9/2023 Zydus Lifesciences Limited