

ESTRADIOL- estradiol patch
Zydu Lifesciences Limited

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-**1400**-4

Estradiol Transdermal System, USP

0.014 mg/day

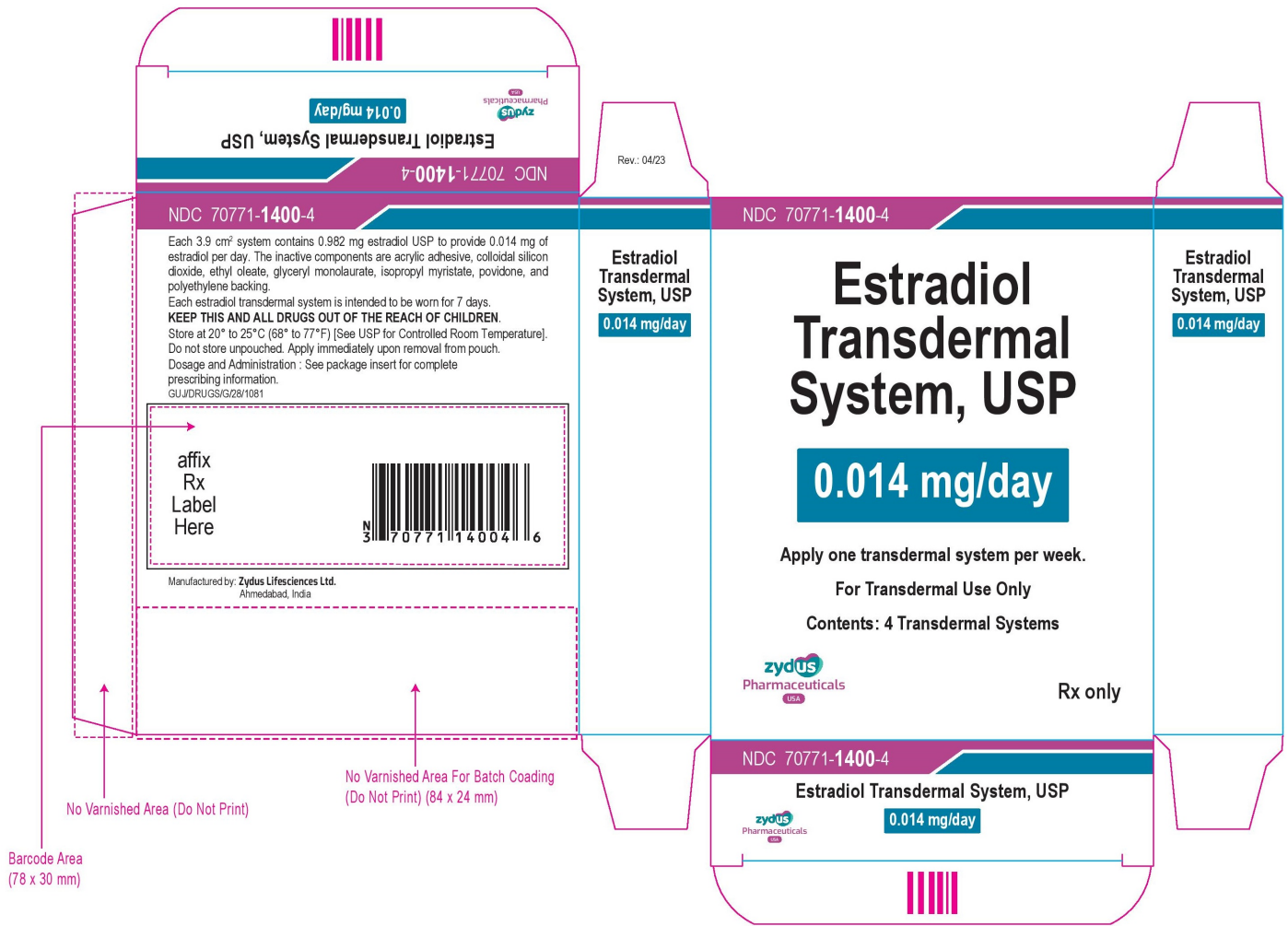
Apply one transdermal system per week.

For Transdermal Use Only

Contents: 4 Transdermal Systems

Rx Only

zydu Pharmaceuticals USA



ESTRADIOL

estradiol patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1400
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	0.014 mg in 1 d

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERYL LAURATE (UNII: Y98611C087)	

POVIDONE (UNII: FZ989GH94E)	
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)	
GLYCIDYL METHACRYLATE (UNII: R8WN29J8VF)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1400-4	4 in 1 CARTON	11/02/2023	
1	NDC:70771-1400-1	1 in 1 POUCH		
1		7 d in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204379	11/02/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1400) , MANUFACTURE(70771-1400)

Revised: 4/2023

Zydus Lifesciences Limited