ESTRADIOL- estradiol patch
Zydus Lifesciences Limited

ESTRADIOL transdermal system

SPL UNCLASSIFIED

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-**1401**-4

Estradiol Transdermal System, USP

0.025 mg/day

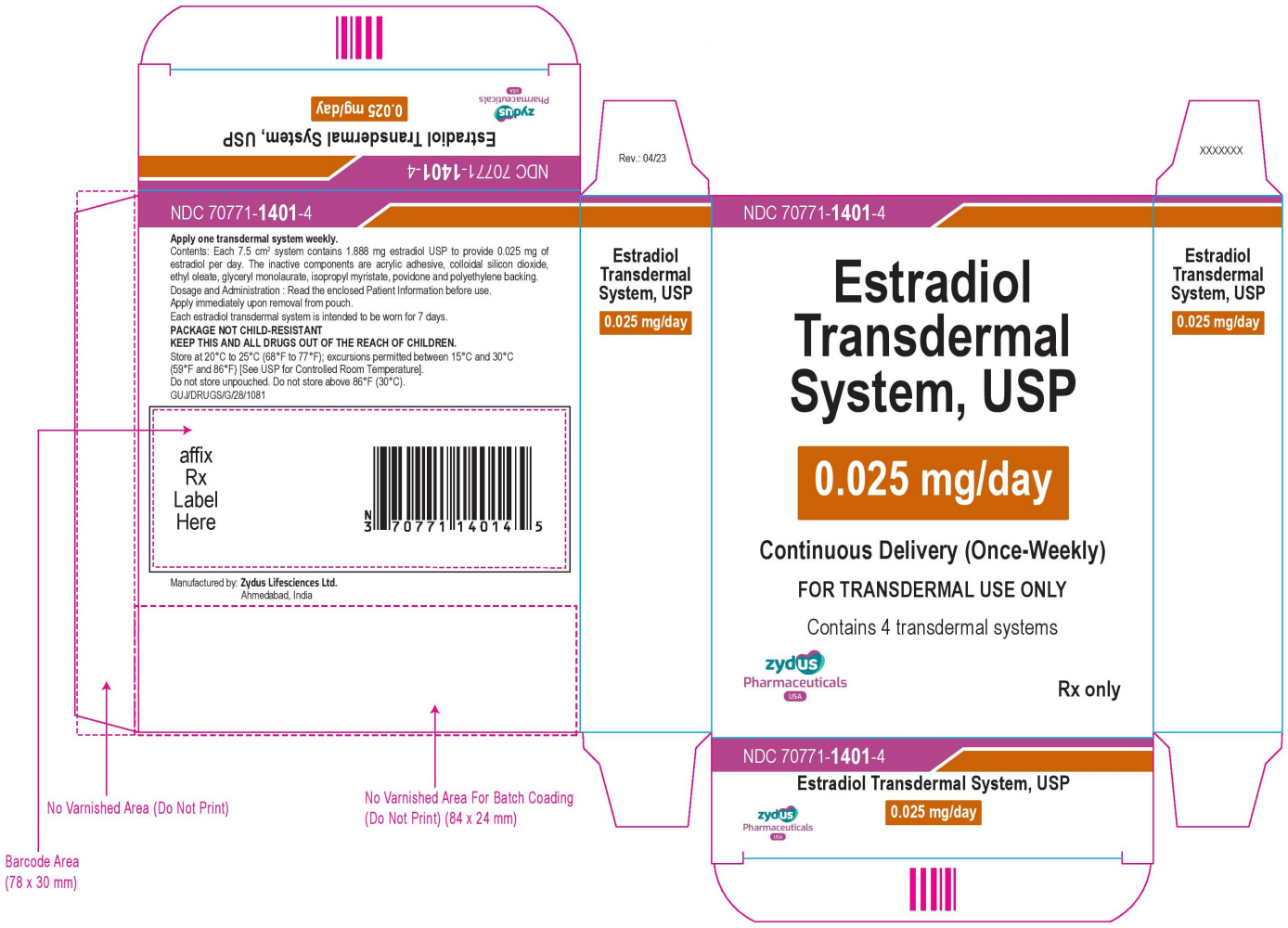
Continuous Delivery (Once-Weekly)

FOR TRANSDERMAL USE ONLY

Contains 4 transdermal systems

Rx only

zydus Pharmaceuticals USA



NDC 70771-**1402**-4

Estradiol Transdermal System, USP

0.0375 mg/day

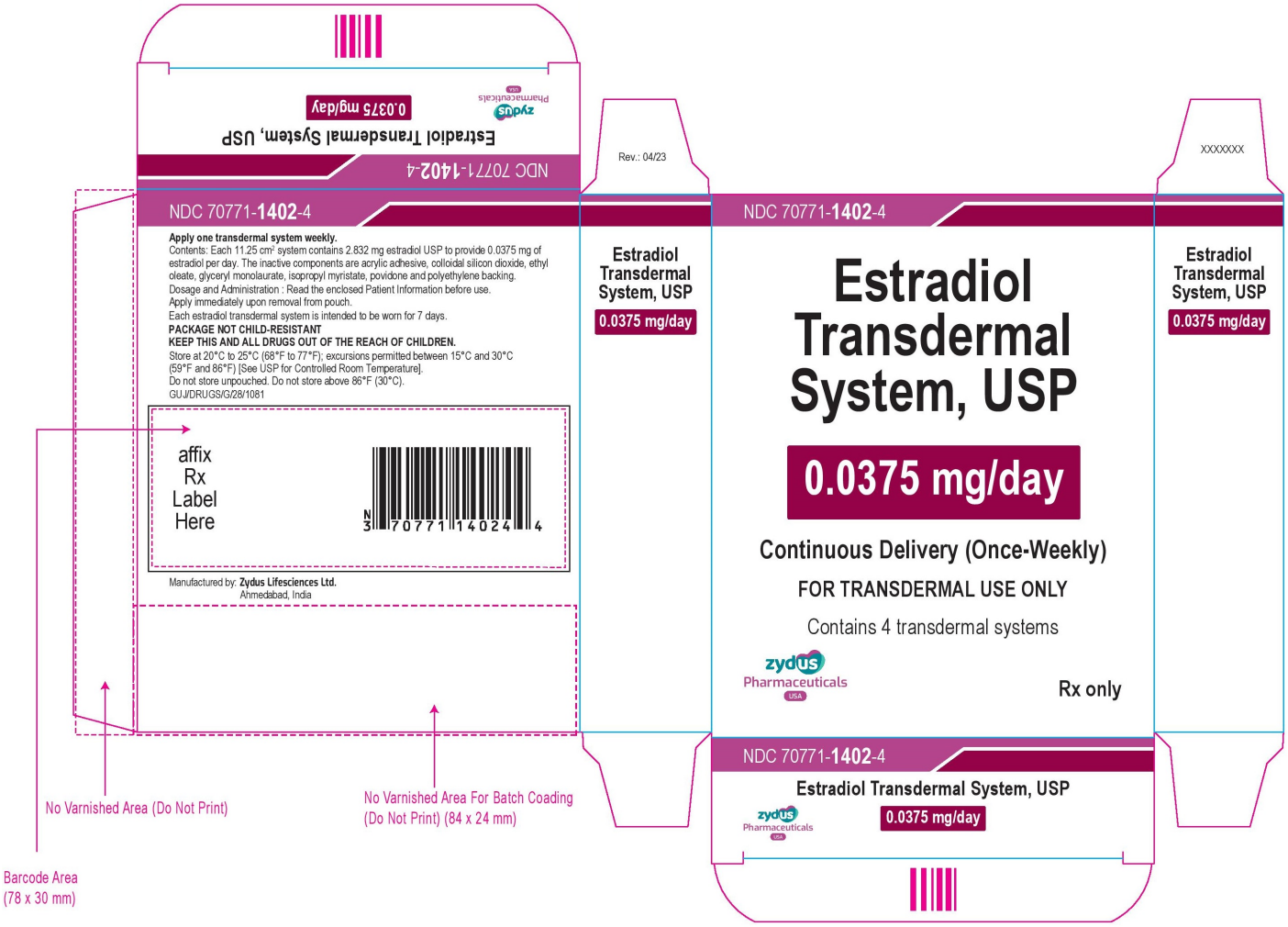
Continuous Delivery (Once-Weekly)

FOR TRANSDERMAL USE ONLY

Contains 4 transdermal systems

Rx only

zydus Pharmaceuticals USA



NDC 70771-**1403**-4

Estradiol Transdermal System, USP

0.05 mg/day

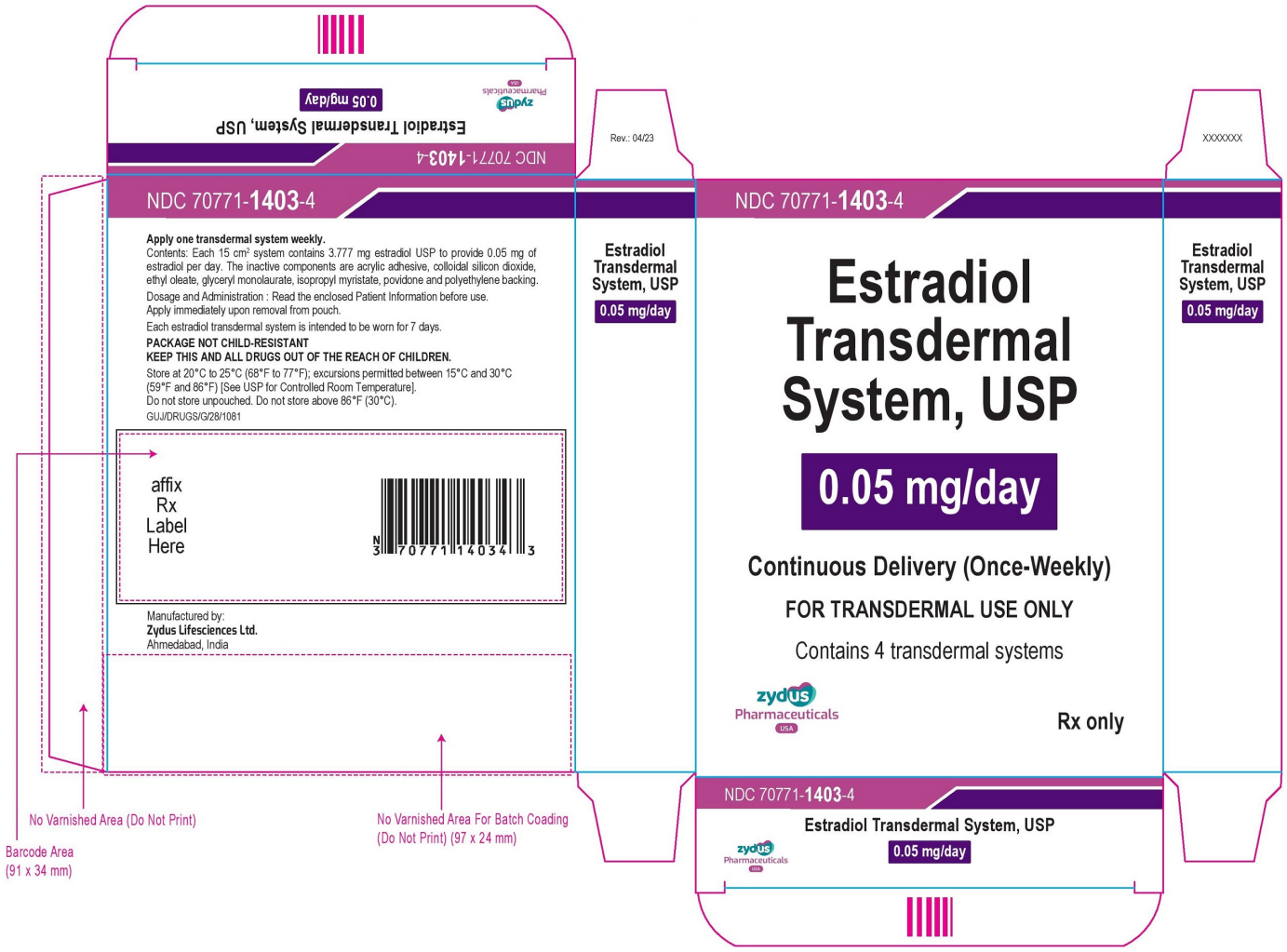
Continuous Delivery (Once-Weekly)

FOR TRANSDERMAL USE ONLY

Contains 4 transdermal systems

Rx only

zydus Pharmaceuticals USA



NDC 70771-**1404**-4

Estradiol Transdermal System, USP

0.06 mg/day

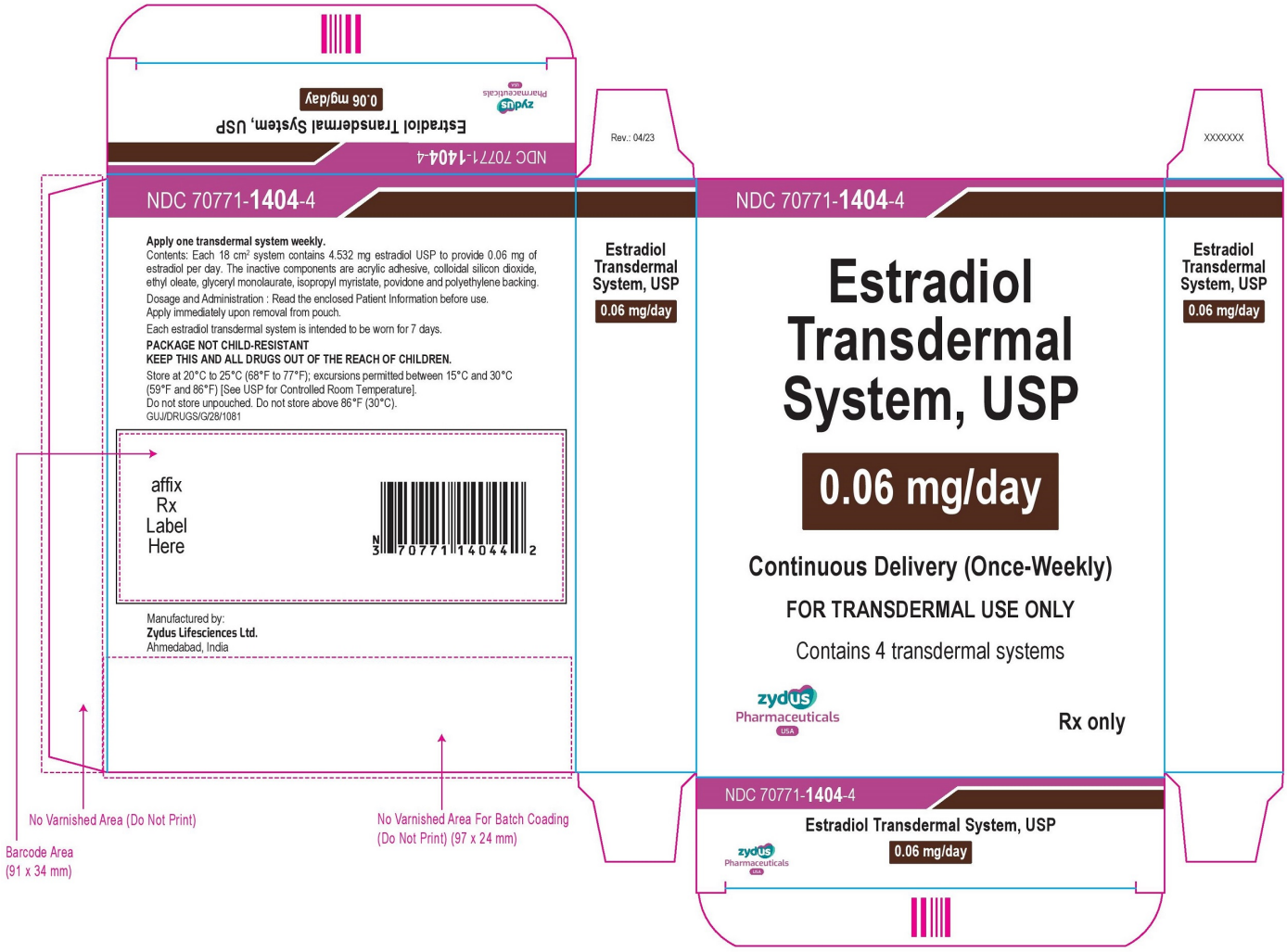
Continuous Delivery (Once-Weekly)

FOR TRANSDERMAL USE ONLY

Contains 4 transdermal systems

Rx only

zydus Pharmaceuticals USA



NDC 70771-**1405**-4

Estradiol Transdermal System, USP

0.075 mg/day

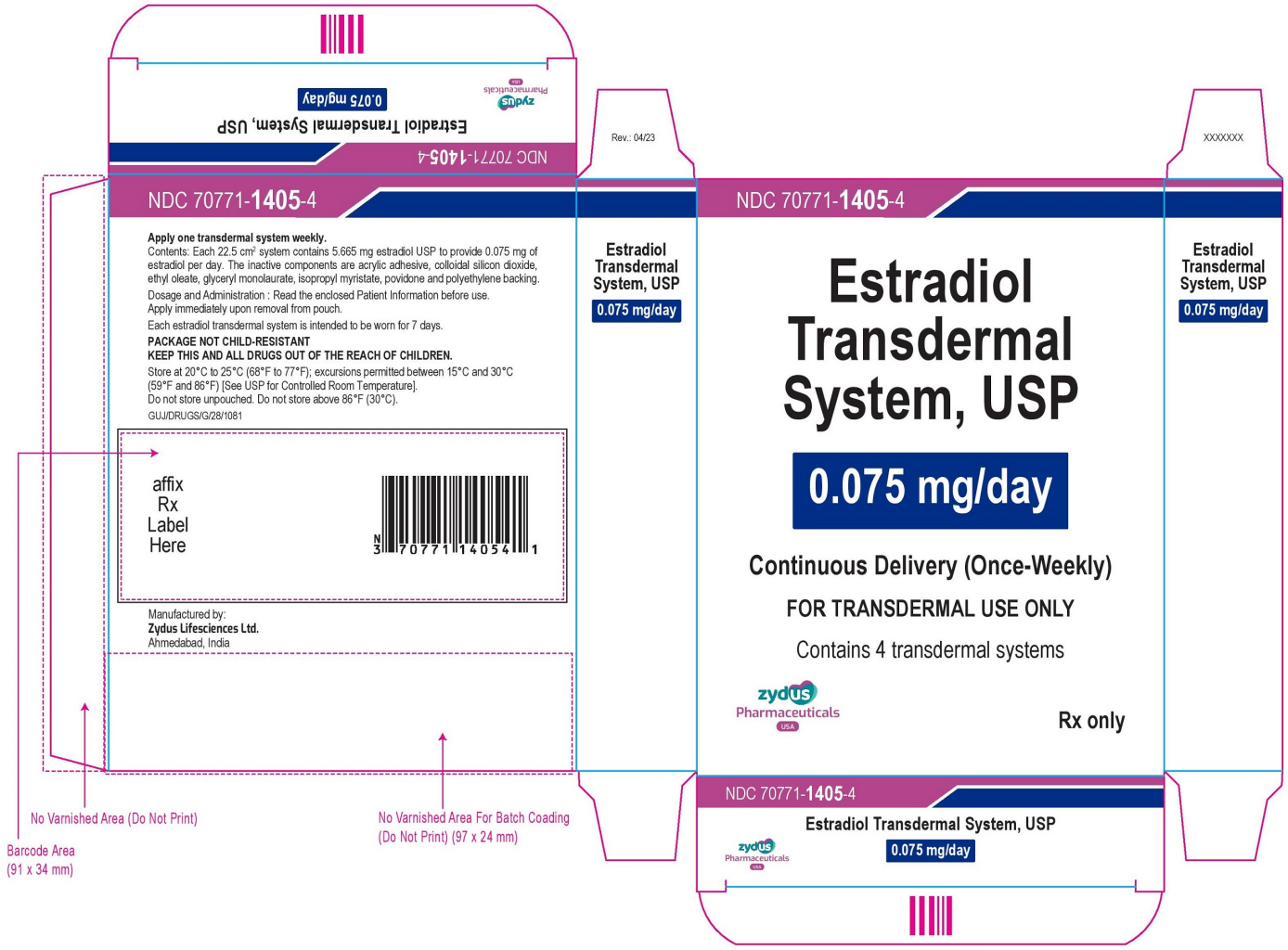
Continuous Delivery (Once-Weekly)

FOR TRANSDERMAL USE ONLY

Contains 4 transdermal systems

Rx only

zydus Pharmaceuticals USA



NDC 70771-**1406**-4

Estradiol Transdermal System, USP

0.1 mg/day

Continuous Delivery (Once-Weekly)

FOR TRANSDERMAL USE ONLY

Contains 4 transdermal systems

Rx only

zydus Pharmaceuticals USA

ESTRADIOL

estradiol patch

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1401
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	0.025 mg in 1 d

Inactive Ingredients	
Ingredient Name	**Strength**
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
GLYCERYL LAURATE (UNII: Y98611C087)	

GLYCIDYL METHACRYLATE (UNII: R8WN29J8VF)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
VINYL ACETATE (UNII: L9MK238N77)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1401-4	4 in 1 CARTON	11/02/2023	
1	NDC:70771-1401-1	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	ANDA202985	11/02/2023	

ESTRADIOL

estradiol patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1402
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	0.0375 mg in 1 d

Inactive Ingredients

Ingredient Name	Strength
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCIDYL METHACRYLATE (UNII: R8WN29J8VF)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
VINYL ACETATE (UNII: L9MK238N77)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1402-4	4 in 1 CARTON	11/02/2023	
1	NDC:70771-1402-1	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	ANDA202985	11/02/2023	

ESTRADIOL

estradiol patch

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1403
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	0.05 mg in 1 d

Inactive Ingredients	
Ingredient Name	**Strength**
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCIDYL METHACRYLATE (UNII: R8WN29J8VF)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
VINYL ACETATE (UNII: L9MK238N77)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:70771-1403-4	4 in 1 CARTON	11/02/2023	
1	NDC:70771-1403-1	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	ANDA202985	11/02/2023	

ESTRADIOL

estradiol patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1404
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	0.06 mg in 1 d

Inactive Ingredients

Ingredient Name	Strength
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCIDYL METHACRYLATE (UNII: R8WN29J8VF)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
VINYL ACETATE (UNII: L9MK238N77)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1404-4	4 in 1 CARTON	11/02/2023	
1	NDC:70771-1404-1	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	ANDA202985	11/02/2023	

ESTRADIOL

estradiol patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1405
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	0.075 mg in 1 d

Inactive Ingredients

Ingredient Name	Strength
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCIDYL METHACRYLATE (UNII: R8WN29J8VF)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
VINYL ACETATE (UNII: L9MK238N77)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1405-4	4 in 1 CARTON	11/02/2023	
1	NDC:70771-1405-1	1 in 1 POUCH		
1		7 d in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
ANDA	ANDA202985	11/02/2023	

ESTRADIOL

estradiol patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1406
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ESTRADIOL (UNII: 4TI98Z838E) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL	0.1 mg in 1 d

Inactive Ingredients

Ingredient Name	Strength
2-ETHYLHEXYL ACRYLATE (UNII: HR49R9S6XG)	
2-HYDROXYETHYL ACRYLATE (UNII: 25GT92NY0C)	
ETHYL OLEATE (UNII: Z2Z439864Y)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCIDYL METHACRYLATE (UNII: R8WN29J8VF)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
VINYL ACETATE (UNII: L9MK238N77)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1406-4	4 in 1 CARTON	11/02/2023	
1	NDC:70771-1406-1	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	ANDA202985	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(70771-1401, 70771-1402, 70771-1403, 70771-1404, 70771-1405, 70771-1406) , MANUFACTURE(70771-1401, 70771-1402, 70771-1403, 70771-1404, 70771-1405, 70771-1406)

Revised: 4/2023 Zydus Lifesciences Limited