

ESTRADIOL- estradiol patch, extended release
ZyduS Lifesciences Limited

ESTRADIOL transdermal system, USP (TWICE-WEEKLY)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Package Label - 0.025 mg

NDC 70771-1563-8

Estradiol Transdermal System, USP

(Twice-Weekly)

Delivers 0.025 mg/day

Includes 8 Systems

Rx Only

zyduS pharmaceuticals

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.025 mg/day**

Patient Instruction :

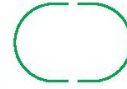
1. Start at notched corner, tear pouch open. Remove patch from pouch.
2. Hold patch with protective liner facing you.
3. Peel off one side of protective liner and discard.
4. Apply sticky side of patch to clean and dry area of the abdomen.
5. Carefully remove the other piece of protective liner and discard. Press patch firmly in place.

To open

Pull here



OPEN



HERE

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers

0.025 mg/day



Manufactured by:
Cadila Healthcare Limited, Ahmedabad, India



Rev: 12/22

gumRUC/1081

Dosage and Administration: See package insert.

Store at controlled room temperature at 20° to 25°C (68° to 77°F).

Do not store unpouched.

Apply immediately upon removal from pouch.

Keep out of the reach of children.

Important: Package not child-resistant

For Transdermal Use Only

polyethylene backing film, polyester release liner,

oleic acid, povidone, propylene glycol,

silicone adhesive, colloidal silicon dioxide,

Inactive components: acrylic adhesive,

estradiol USP.

Each 2.7 cm² system contains 0.405 mg of

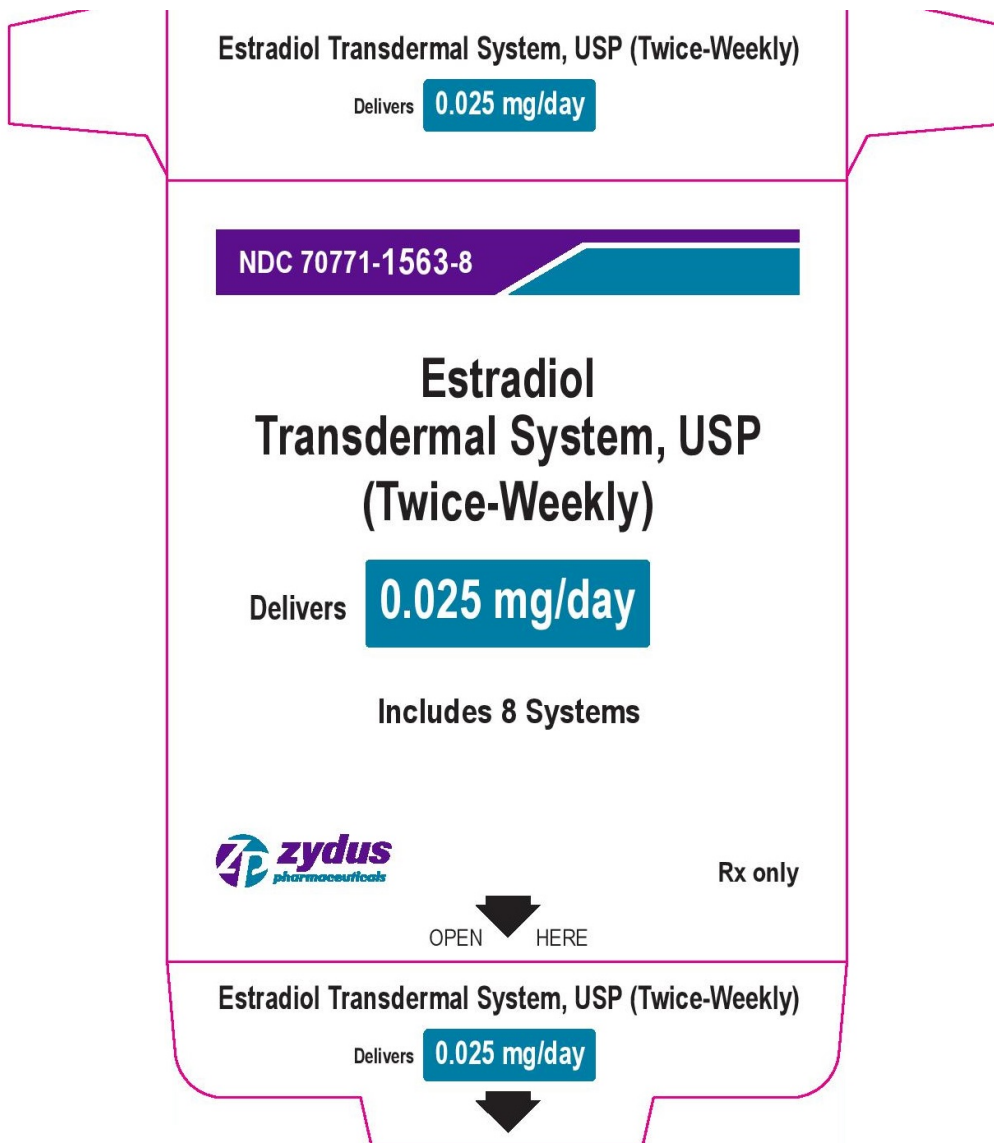
Contents: 8 Systems

Delivers

0.025 mg/day

Estradiol Transdermal System, USP (Twice-Weekly)

**Unvarnished Area
For Lot and Expiry
55 x 25 mm**



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Package Label - 0.0375 mg

NDC 70771-1564-8

Estradiol Transdermal System, USP
(Twice-Weekly)

Delivers 0.0375 mg/day

Includes 8 Systems

Rx Only

zydus pharmaceuticals

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.0375 mg/day**

Contents: 8 Systems

Each 4.05 cm² system contains 0.608 mg of estradiol USP.

Inactive components: acrylic adhesive, silicone adhesive, colloidal silicon dioxide, oleic acid, povidone, propylene glycol, polyethylene backing film, polyester release liner.

For Transdermal Use Only

Important: Package not child-resistant.

Keep out of the reach of children.

Apply immediately upon removal from pouch.

Do not store unpouched.

Store at controlled room temperature

at 20° to 25°C (68° to 77°F).

Dosage and Administration: See package insert.

GUJ/RUG/1081

Rev.: 12/22



**Unvarnished Area
For Lot and Expiry
55 x 25 mm**

OPEN

HERE

Pull

To open

here

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.0375 mg/day**

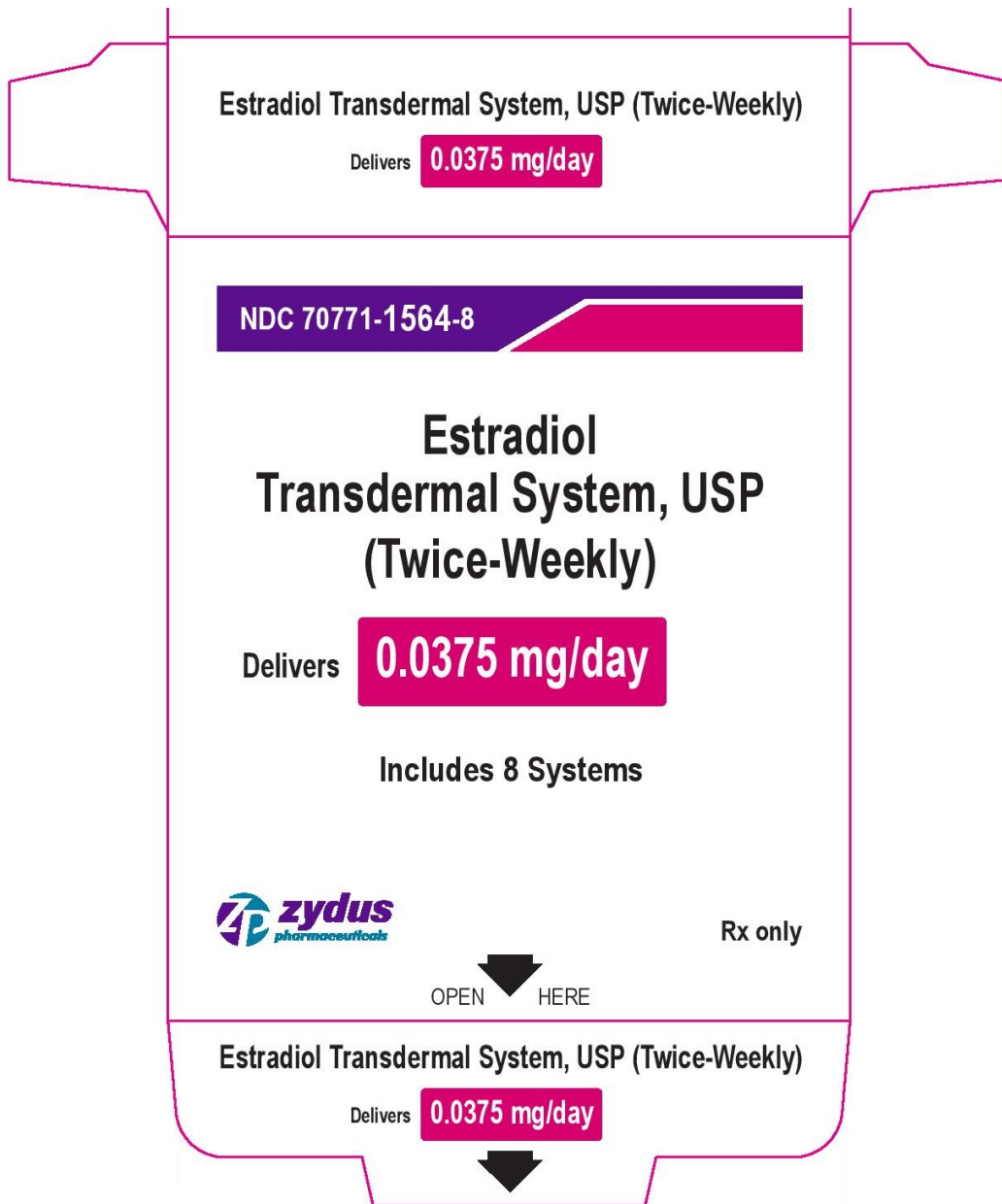
Patient Instruction :

1. Start at notched corner, tear pouch open. Remove patch from pouch.
2. Hold patch with protective liner facing you.
3. Peel off one side of protective liner and discard.
4. Apply sticky side of patch to clean and dry area of the abdomen.
5. Carefully remove the other piece of protective liner and discard. Press patch firmly in place.

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.0375 mg/day**

Manufactured by:
Cadila Healthcare Limited, Ahmedabad, India



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Package Label - 0.05 mg

NDC 70771-1565-8

Estradiol Transdermal System, USP
(Twice-Weekly)

Delivers 0.05 mg/day

Includes 8 Systems

Rx Only


zydus pharmaceuticals

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.05 mg/day**

Patient Instruction :

1. Start at notched corner, tear pouch open. Remove patch from pouch.
2. Hold patch with protective liner facing you.
3. Peel off one side of protective liner and discard.
4. Apply sticky side of patch to clean and dry area of the abdomen.
5. Carefully remove the other piece of protective liner and discard. Press patch firmly in place.

To open
Pull  here

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.05 mg/day**

Manufactured by:
Cadilla Healthcare Limited, Ahmedabad, India

OPEN  HERE 

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.05 mg/day**

Contents: 8 Systems


Each 5.40 cm² system contains 0.810 mg of estradiol USP.

Inactive components: acrylic adhesive, silicone adhesive, colloidal silicon dioxide, oleic acid, polydome, propylene glycol, polyethylene backing film, polyester release liner.

For Transdermal Use Only

Important: Package not child-resistant. Keep out of the reach of children. Apply immediately upon removal from pouch. Do not store unopened. Store at controlled room temperature at 20° to 25°C (68° to 77°F). **Dosage and Administration:** See package insert.

GUJRURGI081 Rev: 12/22


3 7077115658 0

**Unvarnished Area
For Lot and Expiry
55 x 25 mm**

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.05 mg/day**

NDC 70771-1565-8

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers

0.05 mg/day

Includes 8 Systems



Rx only

OPEN  HERE

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers

0.05 mg/day

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Package Label - 0.075 mg

NDC 70771-1566-8

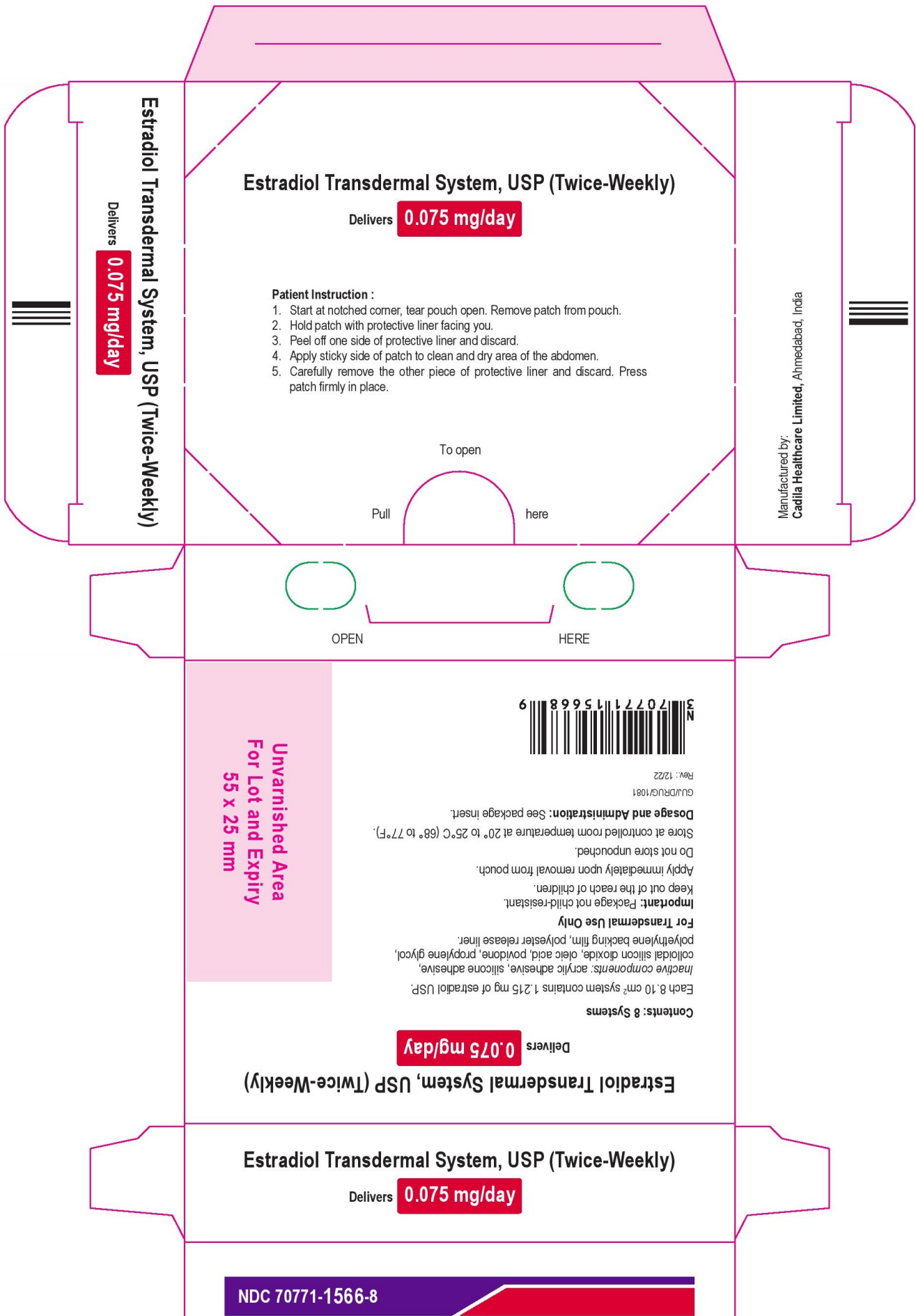
Estradiol Transdermal System, USP
(Twice-Weekly)

Delivers 0.075 mg/day

Includes 8 Systems

Rx Only

zydus pharmaceuticals



Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.075 mg/day**

Patient Instruction :

1. Start at notched corner, tear pouch open. Remove patch from pouch.
2. Hold patch with protective liner facing you.
3. Peel off one side of protective liner and discard.
4. Apply sticky side of patch to clean and dry area of the abdomen.
5. Carefully remove the other piece of protective liner and discard. Press patch firmly in place.

To open

Pull here



OPEN

HERE

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.075 mg/day**



Manufactured by:
Cadila Healthcare Limited, Ahmedabad, India



Rev: 12/22

GUORUG1081

Dosage and Administration: See package insert.

Store at controlled room temperature at 20° to 25°C (68° to 77°F).

Do not store unpoached.

Apply immediately upon removal from pouch.

Keep out of the reach of children.

Important: Package not child-resistant.

For Transdermal Use Only

Inactive components: acrylic adhesive, silicone adhesive, colloidal silicon dioxide, oleic acid, polyethylene glycol, polyethylene backing film, polyester release liner.

Each 8.10 cm² system contains 1.215 mg of estradiol USP.

Contents: 8 Systems

Delivers **0.075 mg/day**

Estradiol Transdermal System, USP (Twice-Weekly)

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.075 mg/day**

NDC 70771-1566-8

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.075 mg/day**

Includes 8 Systems



Rx only

OPEN  HERE

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.075 mg/day**



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Package Label - 0.1 mg

NDC 70771-1567-8

Estradiol Transdermal System, USP
(Twice-Weekly)

Delivers 0.1 mg/day

Includes 8 Systems

Rx Only

zydus pharmaceuticals

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers

0.1 mg/day

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.1 mg/day**

Patient Instruction :

1. Start at notched corner, tear pouch open. Remove patch from pouch.
2. Hold patch with protective liner facing you.
3. Peel off one side of protective liner and discard.
4. Apply sticky side of patch to clean and dry area of the abdomen.
5. Carefully remove the other piece of protective liner and discard. Press patch firmly in place.

To open

Pull

here

Manufactured by:
Cadila Healthcare Limited, Ahmedabad, India



OPEN



HERE

**Unvarnished Area
For Lot and Expiry
55 x 25 mm**



Rev: 12/22

GUJRU1081

Dosage and Administration: See package insert.

Store at controlled room temperature at 20° to 25°C (68° to 77°F).

Do not store unpouchesd.

Apply immediately upon removal from pouch.

Keep out of the reach of children.

Important: Package not child-resistant.

For Transdermal Use Only

polyethylene backing film, polyester release liner, colloidal silicon dioxide, oleic acid, polydioxane, propylene glycol, inactive components: acrylic adhesive, silicone adhesive.

Each 10.8 cm² system contains 1.620 mg of estradiol USP.

Contents: 8 Systems

Delivers **0.1 mg/day**

Estradiol Transdermal System, USP (Twice-Weekly)

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.1 mg/day**

NDC 70771-1567-8

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.1 mg/day**

Includes 8 Systems



Rx only

OPEN  HERE

Estradiol Transdermal System, USP (Twice-Weekly)

Delivers **0.1 mg/day**

ESTRADIOL

estradiol patch, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1563
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
OLEIC ACID (UNII: 2UMI9U37CP)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1563-8	8 in 1 BOX	04/13/2023	
1	NDC:70771-1563-1	1 in 1 POUCH		

1	3.5 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	ANDA206241	04/13/2023	

ESTRADIOL

estradiol patch, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1564
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		
OLEIC ACID (UNII: 2UMI9U37CP)			
POVIDONE (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1564-8	8 in 1 BOX	04/13/2023	
1	NDC:70771-1564-1	1 in 1 POUCH		
1		3.5 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	ANDA206241	04/13/2023	

ESTRADIOL

estradiol patch, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1565
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
OLEIC ACID (UNII: 2UMI9U37CP)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1565-8	8 in 1 BOX	04/13/2023	
1	NDC:70771-1565-1	1 in 1 POUCH		
1		3.5 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	ANDA206241	04/13/2023	

ESTRADIOL

estradiol patch, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1566
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	
OLEIC ACID (UNII: 2UMI9U37CP)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1566-8	8 in 1 BOX	04/13/2023	
1	NDC:70771-1566-1	1 in 1 POUCH		
1		3.5 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	ANDA206241	04/13/2023		

ESTRADIOL				
estradiol patch, extended release				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1567	
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	
OLEIC ACID (UNII: 2UMI9U37CP)				
POVIDONE (UNII: FZ989GH94E)				

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1567-8	8 in 1 BOX	04/13/2023	
1	NDC:70771-1567-1	1 in 1 POUCH		
1		3.5 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	ANDA206241	04/13/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1563, 70771-1564, 70771-1565, 70771-1566, 70771-1567) , MANUFACTURE(70771-1563, 70771-1564, 70771-1565, 70771-1566, 70771-1567)

Revised: 12/2022

Zydus Lifesciences Limited