

NORELGESTROMIN AND ETHINYL ESTRADIOL- norelgestromin and ethinyl estradiol patch
Zydus Lifesciences Limited

NORELGESTROMIN AND ETHINYL ESTRADIOL transdermal system

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1777-3

Norelgestromin and Ethinyl Estradiol Transdermal System 150/35 mcg per day

This product is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

For Transdermal Use Only

Contents: 3 Transdermal Systems

Rx only

Each 15.75 cm² system contains 4.678 mg norelgestromin, USP and 0.53 mg ethinyl estradiol, USP. The inactive components are polyisobutylene/polybutene adhesive, crospovidone, lauryl lactate, non-woven polyester fabric, polyester backing film laminate and polyester release liner.

See patient instructions. Apply immediately upon removal from pouch. Each transdermal system is intended to be worn 7 days as prescribed.

Package not child-resistant. Keep out of reach of children.

Do not store unpouched. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Manufactured by:

Zydus Lifesciences Ltd.

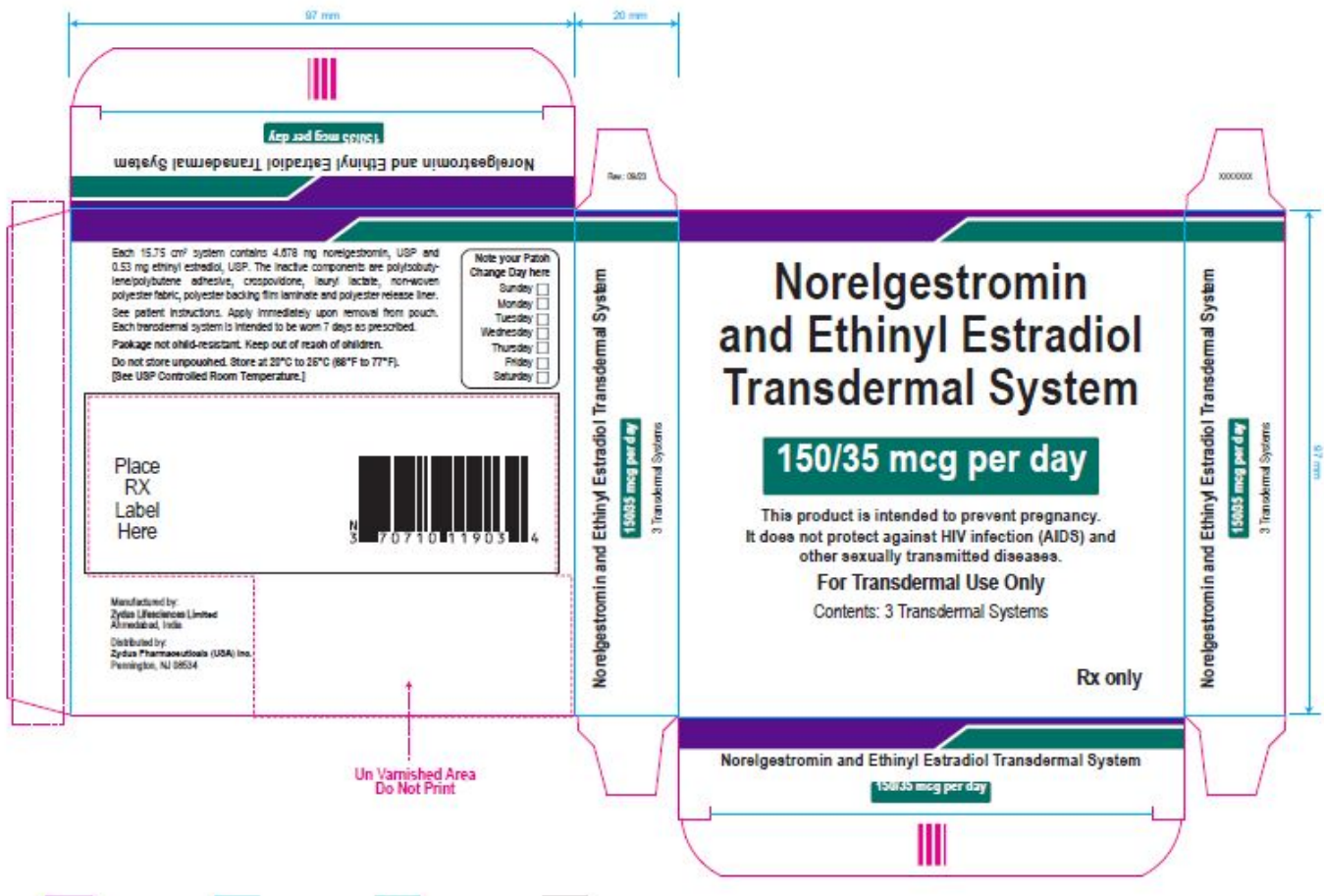
Ahmedabad, India

Distributed by:

Zydus Pharmaceuticals (USA) Inc.

Pennington, NJ 08534

Rev.: 10/22



NORELGESTROMIN AND ETHINYL ESTRADIOL

norelgestromin and ethinyl estradiol patch

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1777
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NORELGESTROMIN (UNII: R0TAY3X631) (NORELGESTROMIN - UNII:R0TAY3X631)	NORELGESTROMIN	150 ug in 1 mg
ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U)	ETHINYL ESTRADIOL	35 ug in 1 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 2S7830E561)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1777-3	3 in 1 CARTON	11/21/2023	
1	NDC:70771-1777-1	1 in 1 POUCH		
1		7 mg in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214594	11/21/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1777) , MANUFACTURE(70771-1777)

Revised: 9/2023

Zydus Lifesciences Limited