MERCILON- desogestrel, ethinyl estradiol tablet OASIS TRADING

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Desogestrel, Ethinyl Estradiol

Oral contraception

Keep out of reach of children

1 tab daily for 21 days; repeat.

Warnings/Precautions:

Smokers over 35yrs of age: not recommended. Uncontrolled hypertension. Hypertriglyceridemia. Discontinue if jaundice, visual disturbances, migraine or other severe headaches occur. Do regular complete physical exams. May need barrier contraception with Sunday starts or postpartum use (see literature). Nursing mothers: not recommended

Contraindications

Thrombophlebitis or thromboembolic disorders. Cerebral vascular or coronary artery disease. Breast or other estrogen-dependent neoplasms. Undiagnosed abnormal genital bleeding. Cholestatic jaundice of pregnancy or jaundice with prior OC use. Hepatic adenoma or carcinoma. Pregnancy (Cat.X).

Interactions

Antagonized by hepatic enzyme inducing drugs (eg, rifampin, griseofulvin, St. John's wort), possibly others. May affect measurement of sex hormone-binding globulin levels

Adverse Reactions:

Hypertension, nausea, vomiting, breakthrough bleeding, amenorrhea, transient delay of ovulation after discontinuation, edema, chloasma, mastodynia, headache, intolerance to contact lenses. Increased risk of gallbladder disease, thromboembolic disorders.

Stearic acid, corn starch, polyethylene glycol 6000

For oral use only

MERCILON

Drug Facts

Active Ingredients (in one tablet)

Purpose

Desogestrel 0.15mg

Combined oral -

Ethinyl Estradiol 0.02mg

contraceptive pill

Uses

Oral contraception.

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Directions

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Other Information

■ Store at room temperature

Inactive Ingredient

Stearic acid, corn starch, polyethylene glycol 6000

Questions or comments?

Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405

Distributed By: P&K FRONTIER MARKETING CORP.

329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA

Made in South Korea

MERCILON

desogestrel, ethinyl estradiol tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72689-0020
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DESO GESTREL (UNII: 81K9 V7M3A3) (DESOGESTREL - UNII:81K9 V7M3A3)	DESOGESTREL	0.15 mg	
ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U)	ETHINYL ESTRADIOL	0.02 mg	

Inactive Ingredients		
Ingredient Name	Strength	
STEARIC ACID (UNII: 4ELV7Z65AP)		
STARCH, CORN (UNII: O8232NY3SJ)		
POLYETHYLENE GLYCOL 6000 (UNII: 30 IQX730 WE)		

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	5mm
Flavor		Imprint Code	ORGANON
Contains			

ı	Pá	ackaging			
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:72689-0020-1	21 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/22/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/22/2018	

Labeler - OASIS TRADING (689991468)

Registrant - OASIS TRADING (689991468)

Establishment			
Name	Address	ID/FEI	Business Operations
OASIS TRADING		689991468	manufacture(72689-0020), label(72689-0020)

Revised: 12/2018 OASIS TRADING