MINIVLAR 30- ethinyl estradiol, levonorgestrel 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.

Ethinyl Estradiol, Levonorgestrel

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

MINIVLAR 30

Drug Facts

Active Ingredients (in one tablet)

Purpose

Ethinyl Estradiol 0.03mg Levonorgestrel 0.15mg Combined oral contraceptive pill

Uses

Oral contraception.

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.

Directions

1 tab daily for 28 days; repeat.

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

MINIVLAR 30

ethinyl estradiol, levonorgestrel tablet

Di	rn	du	ct	In	fn:	rm	atio	nn
П	KU.	ш	CL	ш	LU.		au	ш

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72689-0011

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ETHINYL ESTRADIOL (UNII: 423D2T571U) (ETHINYL ESTRADIOL - UNII:423D2T571U) LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW) LEVONORGESTREL (UNII: 5W7SIA7YZW) (LEVONORGESTREL - UNII:5W7SIA7YZW)

Inactive Ingredients				
Ingredient Name	Strength			
STEARIC ACID (UNII: 4ELV7Z65AP)				
STARCH, CORN (UNII: O8232NY3SJ)				
POLYETHYLENE GLYCOL 6000 (UNII: 30 IQ X730 WE)				

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

Packaging					
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:72689-0011-1	21 in 1 BLISTER PACK; Type 0: Not a Combination Product	11/21/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		11/21/2018		

Labeler - OASIS TRADING (689991468)

$\pmb{Registrant - \text{OASIS TRADING } (689991468)}$

Establishment				
Name	Address	ID/FEI	Business Operations	
OASIS TRADING		689991468	manufacture(72689-0011), label(72689-0011)	

Revised: 11/2018 OASIS TRADING