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Angeliq (Drospirenone and Estradiol)

??? ??????: 30 ??????/?????? 2017

See BOXED WARNINGS, WARNINGS, AND PRECAUTIONS.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

The following are adverse events reported with ANGELIQ (drospirenone and estradiol) occurring in > 5% of subjects:

Table 4: Adverse Events Regardless of Drug Relationship Reported at a Frequency of > 5% in a 1-year Double-blind Clinical Trial

ANGELIQ (drospirenone and estradiol) (N=227) n (%)	E2 1 MG (N=226) n (%)	ADVERSE EVENT
		BODY AS A WHOLE
25 (11)	29 (12.8)	Abdominal pain
19 8 (.4)	15 (6.6)	Pain in extremity
16 (7)	11 (4.9)	Back pain
16 (7)	15 (6.6)	Flu syndrome
13 (5 .7)	15 (6.6)	Accidental injury
16 (7)	17 (7.5)	Abdomen enlarged
12 (5.3)	6 (2.7)	Surgery
		DISORDERSMETABOLIC & NUTRITIONAL
4 (1 .8)	12 (5.3)	Peripheral edema
		NERVOUS SYSTEM
22 (9.7)	26 (11.5)	Headache
		RESPIR ATORY SYSTEM
43 (18.9)	40 (17.7)	Upper respiratory infection
12 (5.3)	8 (3.5)	Sinusitis
		SKIN AND APPENDAGES
43 (18.9)	34 (15)	Breast pain
		UROGENITAL
21 (9.3)	43 (19)	Vaginal hemorrhage
4 (1.8)	22 (9.7)	Endometrial disorder
3 (1.3)	14 (6.2)	Leukorrhea

The following additional adverse reactions have been reported with estrogen and or estrogen/progestin therapy:

Genitourinary system

Changes in vaginal bleeding pattern and abnormal withdrawal bleeding or flow; breakthrough bleeding, spotting, dysmenorrhea, increase in size of uterine leiomyomata, vaginitis, including vaginal candidiasis, change in amount of cervical secretion, changes in cervical ectropion, ovarian cancer, endometrial hyperplasia, endometrial cancer.

Breasts

Tenderness, enlargement, pain, nipple discharge, galactorrhea, fibrocystic breast changes, breast cancer.

Cardiovascular

Deep and superficial venous thrombosis, pulmonary embolism, thrombophlebitis, myocardial infarction, stroke, increase in blood pressure.

Gastrointestinal

Nausea, vomiting, abdominal cramps, bloating, cholestatic jaundice, increased incidence of gall bladder disease, pancreatitis, enlargement of hepatic hemangiomas.

Skin

Chloasma or melasma, which may persist when drug is discontinued, erythema multiforme, erythema nodosum, hemorrhagic eruption, loss of scalp hair, hirsutism, pruritus, rash.

Eyes

Retinal vascular thrombosis, intolerance to contact lenses.

Central nervous system

Headache, migraine, dizziness, mental depression, chorea, nervousness, mood disturbances, irritability, exacerbation of epilepsy, dementia.

Miscellaneous

Increase or decrease in weight, reduced carbohydrate tolerance, aggravation of porphyria, edema, arthralgias, leg cramps, changes in libido, anaphylactoid/anaphylactic reactions including urticaria and angioedema, hypocalcemia, exacerbation of asthma, increased triglycerides.