

Auszug aus der UAW-Datenbank des BfArM

Stand der Datenbank: 02.11.2009

Tabelle der Verdachtsfälle im Zusammenhang mit der Anwendung des Arzneimittels bzw. des/der Wirkstoff(e)

Duogynon, Cumorit, Terminolut

Hinweise zur Interpretation der Daten:

Es handelt sich bei den Berichten sowohl um Spontanmeldungen als auch um Berichte aus systematisierten Untersuchungen, aus Projekten oder aus der Literatur. Die Meldungen sind dem Bundesinstitut für Arzneimittel und Medizinprodukte durch pharmazeutische Unternehmer, durch die Arzneimittelkommissionen der Heilberufe, direkt durch niedergelassene oder in Krankenhäusern tätige Ärzte sowie durch sonstige Meldequellen, z. B. von Patienten, berichtet worden. Es muss beachtet werden, dass es sich um Verdachtsfälle unerwünschter Arzneimittelwirkungen handelt, dass also ein Kausalzusammenhang im Einzelfall nicht sicher belegt ist. Ferner lassen sich auf der Grundlage von Spontanberichten keine Aussagen darüber machen, wie häufig eine bestimmte unerwünschte Wirkung unter der Anwendung eines Arzneimittels vorkommt, und auch vergleichende Angaben darüber, wie viel mal häufiger eine bestimmte unerwünschte Wirkung bei einem Arzneimittel im Verhältnis zu einem anderen Medikament auftritt, sind anhand solcher Berichte kaum möglich.

Line Listing zum Arzneimittel CUMORIT SCHERING

DE-BFARM-80001374 receipt-date: 10.09.1980, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
cumorit schering (estradiol benzoate, progesterone)	Suspect	Intramuscular	unk/	1979-		Injection site abscess ()

DE-BFARM-80001375 receipt-date: 10.09.1980, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
cumorit schering (estradiol benzoate, progesterone)	Suspect	Intramuscular	unk/	1979-		Injection site abscess ()

DE-BFARM-80001376 receipt-date: 10.09.1980, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
cumorit schering (estradiol benzoate, progesterone)	Suspect		unk/	1979-		Injection site abscess ()

DE-BFARM-81001231 receipt-date: 14.01.1981, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
cumorit schering (estradiol benzoate, progesterone)	Suspect	Intramuscular	unk/	-		Injection site inflammation () Injection site abscess ()

DE-BFARM-81001296 receipt-date: 22.05.1981, sex: female, age: 25 Year, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
cumorit schering (estradiol benzoate, progesterone)	Suspect	Intramuscular	3 Df/ T	198003-198004		Stillbirth ()
*hormon tabl. o.n.a. /praeparate	Concomitant		unk/	-198003		Anencephaly ()
ovoresta m tabl (lynestrenol, ethinylestradiol)	Concomitant	Oral	unk/	198005-19800715		

number of reports: 5

Line Listing zum Arzneimittel DUOGYNON

DE-BFARM-97007525 receipt-date: 15.10.1997, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon (estradiol benzoate, progesterone)	Suspect	Unknown	unk/	-	1976	Multiple congenital abnormalities (Unknown)
					1976	Scoliosis (Unknown)
					1976	Raynaud's phenomenon (Unknown)
					1976	Coordination abnormal (Unknown)
					1976	Glaucoma (Unknown)
					1976	Hearing impaired (Unknown)
					1976	Urinary incontinence (Unknown)
					1976	Mental retardation (Unknown)
					1976	Faecal incontinence (Unknown)
					1976	Visual impairment (Unknown)
1976	Congenital foot malformation (Unknown)					
1976	Dissociative disorder (Unknown)					

DE-BFARM-98002617 receipt-date: 06.04.1998, sex: female, age: 62 Year, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
cyclo-progynova (estradiol valerate, norgestrel)	Suspect	Oral	unk/	-	1998	Ovarian cyst (Unknown)
progylut (norethisterone acetate, ethinylestradiol)	Suspect	Oral	unk/	-		
duogynon (estradiol benzoate, progesterone)	Suspect	Unknown	unk/	-		

DE-BFARM-99006750 receipt-date: 14.10.1999, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon (estradiol benzoate, progesterone)	Suspect	Intramuscular	unk/	-		Epilepsy (Unknown)

DE-BFARM-99006750 receipt-date: 14.10.11 sex: female, age: not stated, report-type: Spontaneous report, country: DE

Convulsion in childhood
(Unknown)

DE-BFARM-01004724 receipt-date: 18.06.2001, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon (estradiol benzoate, progesterone)	Suspect	Oral	unk/ C	1975-1975	1975	Dyskinesia (not recovered/not resolved)
immunoglobulins (immunoglobulins)	Concomitant	Unknown	unk/	-	19930605	Epilepsy (not recovered/not resolved)
					1975	Mental impairment (not recovered/not resolved)
					19930605	Mood swings (not recovered/not resolved)
					19930605	Nervousness (not recovered/not resolved)
					19930605	Gait disturbance (not recovered/not resolved)
					19930605	Weight decreased (not recovered/not resolved)
					19930605	Muscle twitching (not recovered/not resolved)
					19930605	Hyperventilation (not recovered/not resolved)

DE-BFARM-02009443 receipt-date: 19.08.2002, sex: female, age: 42 year, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon (estradiol benzoate, progesterone)	Suspect	Oral	unk/	1974-1974	200002	Diabetes mellitus (not recovered/not resolved)
					200002	Diabetes mellitus (not recovered/not resolved)

DE-BFARM-04002905 receipt-date: 05.03.2004, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon (estradiol benzoate, progesterone)	Suspect	Unknown	unk/	-		Sexual dysfunction (Unknown)
						Blood testosterone increased (Unknown)
						Adenoma benign (Unknown)

DE-BFARM-07005711 receipt-date: 06.03.2007 12:15:58, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon (estradiol benzoate, progesterone)	Suspect		unk/	-		Congenital musculoskeletal anomaly (not recovered/not resolved)

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DE-BFARM-07005711 receipt date: 06.03.2009 12:15:58, sex: female, age: not stated, report type: Spontaneous report, country: DE

Drug exposure during pregnancy
(Unknown)

DE-BFARM-09130829 receipt date: 02.10.2009 18:17:21, sex: female, age: 0, report type: Spontaneous report, country: DE

<i>drug name (substance)</i>	<i>role</i>	<i>route of admin.</i>	<i>dose/interval</i>	<i>medication dates</i>	<i>onset</i>	<i>preferred term (outcome)</i>
duogynon (estradiol benzoate, progesterone)	Suspect	Transplacental	unk/	-	19710708	Atrioventricular septal defect (recovering/resolving)
					19710708	Somnolence (recovered/resolved)
					19710708	Visual impairment ()
						Mental impairment (not recovered/not resolved)
						Vital capacity decreased (not recovered/not resolved)

number of reports: 8

Line Listing zum Arzneimittel DUOGYNON TABL.

DE-BFARM-79000980 receipt-date: 22.01.1979, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon tabl. (norethisterone acetate, ethinylestradiol)	Suspect	Oral	2 Df/D	197004-		Congenital foot malformation Congenital hand malformation

DE-BFARM-79001052 receipt-date: 23.04.1979, sex: female, age: not stated, report-type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
kompensan tabl (dihydroxyaluminum sodium carbonate)	Concomitant	Oral	unk/	-		Premature baby
microgynon drag (ethinylestradiol, levonorgestrel)	Concomitant	Oral	unk/	-197707		
duogynon tabl. (norethisterone acetate, ethinylestradiol)	Suspect	Oral	unk/	19781116-19781117		
lenotan drag (pyridoxine hydrochloride, calcium phosphate, dicycloverine hydrochloride, doxylamine succinate)	Suspect	Oral	1 Df/D	19781220-		

number of reports: 2

Line Listing zum Arzneimittel DUOGYNON-ORAL

DE-BFARM-87009341 receipt date: 07.04.1987, sex: female, age: not stated, report type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon-oral (norethisterone acetate, ethinylestradiol)	Suspect	Oral	unk/ C	-		Congenital foot malformation (recovered/resolved with sequel) Congenital hypertrichosis (recovered/resolved with sequel) Asthenia (recovered/resolved with sequel)

DE-BFARM-89003751 receipt date: 18.05.1989, sex: female, age: not stated, report type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon-oral (norethisterone acetate, ethinylestradiol)	Suspect	Oral	2 Df/ T	197807-		Congenital brain damage (Unknown) 19790306 Jaundice neonatal (Unknown)

DE-BFARM-91901155 receipt date: 05.12.1991, sex: female, age: not stated, report type: Spontaneous report, country: DE

drug name (substance)	role	route of admin.	dose/interval	medication dates	onset	preferred term (outcome)
duogynon-oral (norethisterone acetate, ethinylestradiol)	Suspect	Oral	unk/	-		Dyskinesia (Unknown)
cyclo-progynova (estradiol valerate, norgestrel)	Suspect	Oral	1 Df/ C	-		Coordination abnormal (Unknown)

number of reports: 3

Line Listing zum Arzneimittel TERMINOLUT SCHERING

DE-BFARM-81001311 receipt-date: 22.05.1981 sex: female age: not stated report-type: Spontaneous report country: DE

<i>drug name (substance)</i>	<i>role</i>	<i>route of admin.</i>	<i>dose/interval</i>	<i>medication dates</i>	<i>onset</i>	<i>preferred term (outcome)</i>
terminolut schering	Suspect	Oral	unk/	-		Cleft palate 0

number of reports: 1