

2018 HAZARDOUS DRUGS REVIEWS

Reviewer	
Drug	apremilast (Otezla); PDE4 inhibitor
CAS No.	608141-41-9
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	
Formulation and Dosage	Tablets; 30mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	bevacizumab (Avastin); antineoplastic
CAS No.	126974-75-3
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	
New Warning	NEW
Black Box	Gastrointestinal perforations, surgery and wound-healing complications, and hemorrhage
Formulation and Dosage	IV; 5-15mg/kg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	blinatumomab (Blincyto); antineoplastic

CAS No.	853426-35-4
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	Neurotoxicity
Formulation and Dosage	IV; 9mcg/day
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	ceritinib (Zykadia); antineoplastic
CAS No.	1032900-25-6
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	NEW
Black Box	
Formulation and Dosage	Capsules; 750mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. D
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	clobazam (Onfi); antiepileptic
CAS No.	22316-47-8
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	
New Warning	NEW
Black Box	
Formulation and Dosage	tablets, oral suspension; 20mg/kg

Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	cobimetinib (Cotellic); antineoplastic
CAS No.	934660-93-2
Links	PI ; DailyMed ; Drugbank ; MSDS
New Drug	NEW DRUG
New Warning	
Black box	
Formulation and Dosage	tablets; 60mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	darbepoetin alfa (Aranesp); erythropoiesis stimulant
CAS No.	11096-26-7
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	
New Warning	NEW
Black Box	Increased risk of death, myocardial infarction, stroke, venous thromboembolism, thrombosis of vascular access, and tumor progression or recurrence
Formulation and Dosage	IV, SQ; 0.45-2.25mcg/kg
Hazardous Drug? Y or N	
Decision Criteria	
General	

Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	dihydroergotamine (Migranal); 5HT receptor binder
CAS No.	511-12-6
Links	PI ; DailyMed ; Drugbank ; MSDS
New Drug	
New Warning	
Black Box	Serious or life-threatening peripheral ischemia
Formulation and Dosage	IV, IM, SQ, nasal spray; 1mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. X
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	exenatide (Bydureon); antidiabetic
CAS No.	141732-76-5
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	
New Warning	NEW
Black Box	Risk of thyroid C-cell tumors
Formulation and Dosage	SQ; 2mg/week
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	

Organ Tox at low doses	
------------------------	--

Reviewer	
Drug	finafloxacin (Xtoro); antibiotic
CAS No.	209342-40-5
Links	PI ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	
Formulation and Dosage	otic suspension; 0.30%
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	interferon beta-1b (Betaseron), (Extavia); immune modulator
CAS No.	145155-23-3
Links	PI ; PI ; DailyMed ; DrugBank ; MSDS
New Drug	
New Warning	NEW
Black Box	
Formulation and Dosage	SQ; 0.25mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	itraconazole (Sporanox); antifungal
CAS No.	84625-61-6

Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	
New Warning	NEW
Black Box	Congestive heart failure, cardiac effects and drug interactions
Formulation and Dosage	capsules; 200-400mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	ivabradine (Corlanor); HCN blocker
CAS No.	155974-00-8
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	
Formulation and Dosage	tablets; 5-7.5mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	lenvatinib (Lenvima); antineoplastic
CAS No.	417716-92-8
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	
Formulation and Dosage	capsules; 24mg
Hazardous Drug? Y or N	

Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	metreleptin (Myalept); leptin analog
CAS No.	186018-45-1
Links	PI ; DailyMed ; DrugBank ;
New Drug	NEW DRUG
New Warning	
Black Box	Risk of anti-metreleptin antibodies with neutralizing activity and risk of lymphoma
Formulation and Dosage	SQ; 10mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. C
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	miltefosine (Impavido); antibiotic
CAS No.	58066-85-6
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	Embryo-fetal toxicity
Formulation and Dosage	capsules; 50mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. D
Carcinogenicity	

Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	olaparib (Lynparza); antineoplastic
CAS No.	763113-22-0
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	
Formulation and Dosage	capsules; 400mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. D
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	osimertinib (Tagrisso); antineoplastic
CAS No.	1421373-65-0
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	
Formulation and Dosage	tablets; 80mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	sonidegib (Odomzo); antineoplastic
CAS No.	956697-53-3
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	NEW DRUG
New Warning	
Black Box	Embryo-fetal toxicity
Formulation and Dosage	capsules 200mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	trastuzumab (Herceptin); antineoplastic
CAS No.	180288-69-1
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	
New Warning	NEW
Black Box	Cardiomyopathy, infusion reactions, embryo-fetal toxicity and pulmonary toxicity
Formulation and Dosage	IV; 2-6mg/kg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. D
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	triazolam (Halcion); hypnotic
CAS No.	28911-01-5
Links	PI ; DailyMed ; DrugBank ; MSDS
New Drug	

New Warning	NEW
Black Box	
Formulation and Dosage	tablets; 0.25mg
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. X
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	

Reviewer	
Drug	urofollitropin (Bravelle); ovulation stimulator
CAS No.	146479-72-3
Links	PI ; DailyMed ; DrugBank ;
New Drug	
New Warning	NEW
Black Box	
Formulation and Dosage	IM, SQ; 150-450IU
Hazardous Drug? Y or N	
Decision Criteria	
General	
Pregnancy Data (incl. Lactation)	Preg. Cat. X
Carcinogenicity	
Teratogenicity	
Reproductive Toxicity	
Genotoxicity	
Organ Tox at low doses	