

Risk minimization activity / Risk minimization measure

Risk minimization measures are interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicine, or to reduce their severity or impact on the patient should adverse reactions occur. Planning and implementing risk minimization measures and assessing their effectiveness are key elements of risk management.

No.	Product	Risk	Measures
1.	Thalidomide (Thalidomide[®] Celgene)	- Embryo-Fetal Toxicity.	-Restricted program
2.	Lenalidomide (Revlimid[®] Hard Capsule)	- Embryo-Fetal Toxicity.	- Restricted program
3.	Lenalidomide (Sotira[®] Capsule)	- Embryo-Fetal Toxicity.	- Restricted program
4.	Isotretinoin (Roaccutane[®] Capsules)	- Risk of teratogenicity.	- Educational material - Consent form
5.	Isotretinoin (Curacne[®] Capsules)	- Risk of teratogenicity.	- Educational material - Consent form
6.	Isotretinoin (Xeractan[®] Capsules)	- Risk of teratogenicity	- Educational material - Consent form
7.	Isotretinoin (Isosupra[®] hard gelatin capsule)	- Risk of teratogenicity	- Educational material - Consent form
8.	Isotretinoin (Ruatine[®] capsule)	- Risk of teratogenicity	- Educational material - Consent form
9.	Mycophenolate mofetil (cellcept[®])	- Teratogenicity - spontaneous abortions - congenital malformations following exposure during pregnancy.	- Educational materials for HCPs & patients.
10.	Mycophenolate mofetil (Myora[®])	- Teratogenicity	- Educational materials

		<ul style="list-style-type: none"> - spontaneous abortions - congenital malformations following exposure during pregnancy. 	for HCPs & patients.
11.	Mycophenolic acid (Myfortic[®])	<ul style="list-style-type: none"> - Teratogenicity - spontaneous abortions - congenital malformations following exposure during pregnancy. 	- Educational materials for HCPs & patients.
12.	Mycophenolate mofetil (Mofetab[®])	<ul style="list-style-type: none"> - Teratogenicity - spontaneous abortions - congenital malformations following exposure during pregnancy. 	- Educational materials for HCPs & patients.
13.	Infliximab (Remicade[®])	<ul style="list-style-type: none"> - Risk of infection - Risk of Cancer 	<ul style="list-style-type: none"> - Infusion card, - HCP safety sheet
14.	Infliximab (Remsima[®])	<ul style="list-style-type: none"> - Risk of infection - Risk of Cancer 	<ul style="list-style-type: none"> - Infusion card, - HCP safety sheet
15.	Rituximab (Mabthera[®])	<ul style="list-style-type: none"> - Infections (including serious infections) Progressive Multifocal leukoencephalopathy 	<ul style="list-style-type: none"> - Patient alert card (for RA and GPA/MPA (non-oncology) indications only). - Educational Material for healthcare professional and patients (for RA & GPA/MPA (non-oncology) indications only).
16.	Rituximab (Mabthera[®] S.C)	<ul style="list-style-type: none"> - Off-label use of the Subcutaneous Formulation indication: (subcutaneous formulation – NHL/CLL only) - administration route error indication (subcutaneous formulation – NHL/CLL only) 	- Educational Material for Healthcare Professionals)
17.	Bendamustine Hydrochloride (Ribomustin[®])		- Educational material

18.	Zoledronic Acid (Aclasta[®])	- Osteonecrosis of the Jaw	- Educational material
19.	Denosumab (Xgeva[®])	- Osteonecrosis of the Jaw	- Patient Card
20.	Denosumab (Prolia[®])	- Osteonecrosis of the Jaw	- Patient Card
21.	Zoledronic Acid (Zometa[®])	- Osteonecrosis of the Jaw	- Patient Card
22.	Zoledronic Acid (Zoledronic Acid Hikma)	- Osteonecrosis of the Jaw	- Patient Card
23.	Zoledronic Acid (Zoldria[®])	- Osteonecrosis of the Jaw	- Patient Card
24.	Ibandronic acid (Bonviva)	- Osteonecrosis of the Jaw	-Patient Card
25.	Valproate (depakine chrono)	- malformations and developmental problems	- patient card
26.	Valproate (convulex)	- malformations and developmental problems	- patient card
27.	Tocilizumab (Actemra)	- Serious Infections - Complication of diverticulitis - Severe Hypersensitivity Reactions - Neutropenia -Neutropenia & the potential risk of infection - thrombocytopenia and potential risk of bleeding - liver enzyme and bilirubin elevations & potential risk of hepatotoxicity - Elevated lipid levels & potential risk of cardiovascular/cerebrovascular events -Malignancies - demyelinating disorders -MAS FOR sJIA	- Patient alert card, HCP Brochure, patient brochure, rheumatoid arthritis dosing guide
28.	Trastuzumab (Herceptin)	- Cardiac dysfunction	- DHPC
29.	Ado-trastuzumabemtansine (Kadcyla)	- Medication errors and confusion between Kadcyla& Herceptin	- Provide medication and HCP education material to minimize medication errors & confusion between Kadcyla& Herceptin

30.	methoxy polyethylene glycol-epoetin beta (Mircera[®])	- AEAB-mediated pure red cell aplasia	- Educational material on AEAB-mediated PRCA.
31.	Erythropoietin Beta (Recormon[®])	- AEAB-mediated pure red cell aplasia	- Educational material on AEAB-mediated PRCA.
32.	Erlotinib (Tarceva[®])	- Interstitial lung disease	- Educational material for prescribers to anticipate and manage ILD
33.	Nivlumab (Opdivo[®])	- Immune-Mediated adverse reactions	- Immune-Mediated adverse reaction management guide - Patient alert card
34.	Ipilimumab (Yervoy[®])	- Immune-Mediated adverse reactions	- Immune-Mediated adverse reaction management guide - Patient alert card
35.	Atezolizumab(Tecentriq[®])	- Immune-related pneumonitis, - Immune-related hepatitis - Immune-related colitis - Immune-related hypothyroidism - Immune-related hyperthyroidism - Immune-related adrenal insufficiency - Immune related hypophysitis - Immune-related type 1 diabetes mellitus - Immune-related neuropathies - Immune-relatedmeningoencephalitis - Immune-related pancreatitis - Immune-related myocarditis - Immune-related infusion related reactions.	- Healthcare Provider Brochure
36.	Methoxy Polyethylene Glycol-	- AEAB-mediated pure red cell aplasia	- Educational material

	Epoetin Beta (Mircera[®])		on AEAB-mediated PRCA.
37.	Rivastigmine (Exelon[®])	<ul style="list-style-type: none"> - Gastrointestinal symptoms (nausea, vomiting, diarrhoea) - Worsening of motor symptoms associated with Parkinson's disease - Pancreatitis - Cardiac arrhythmias - Exacerbations of asthma and chronic obstructive pulmonary disease (COPD) - Hypertension - Gastrointestinal ulceration, hemorrhage, and perforation - Seizures - Hallucinations - Syncope and loss of consciousness - Liver disorders - Application site skin reactions and irritations (patch formulation only) - Severe skin reactions (bullous reactions) 	- Patient/caregiver reminder card
38.	Vemurafenib (Zelboraf[®])	- Potentiation of Radiation Toxicity	- DHCP Dear HealthCare Professional Communication
39.	Daptomycin (Cubici[®])	<ul style="list-style-type: none"> - Severe skeletal muscle toxicity - Reduced susceptibility to daptomycin in S. Aureus - Peripheral neuropathy - Severe hypersensitivity reactions (including pulmonary eosinophilia) - Eosinophilic pneumonia 	- Daptomycin Dosage card for Physicians
40.	Fingolimod (Gilenya[®])	<ul style="list-style-type: none"> - Bradyarrhythmia (including conduction defects and bradycardia complicated by hypotension) occurring post-first dose - Hypertension - Liver transaminase elevation - Posterior reversible encephalopathy syndrome (PRES) - Macular edema 	- Educational material for physicians and patients: physician's checklist and patient reminder card.

		<ul style="list-style-type: none"> - Infections, including opportunistic infections (PML, VZV, herpes viral - infections other than VZV, fungal infection) - Leukopenia and lymphopenia - Reproductive toxicity - Basal cell carcinoma - Hypersensitivity 	
41.	Fingolimod (Melior[®])	<ul style="list-style-type: none"> - Bradyarrhythmia (including conduction defects and bradycardia complicated by hypotension) occurring post-first dose - Hypertension - Liver transaminase elevation - Posterior reversible encephalopathy syndrome (PRES) - Macular edema - Infections, including opportunistic infections (PML, VZV, herpes viral - infections other than VZV, fungal infection) - Leukopenia and lymphopenia - Reproductive toxicity - Basal cell carcinoma - Hypersensitivity 	<ul style="list-style-type: none"> - Educational material for physicians and patients: physician's checklist and patient reminder card.
42.	Ranibizumab(Lucentis[®])	<ul style="list-style-type: none"> - Infectious - Endophthalmitis - Traumatic - Cataract - Intraocular inflammation - Intraocular pressure increased - Vitreous hemorrhage 	<ul style="list-style-type: none"> - Educational programme including: Healthcare professional educational plan Educational plan for patients. Healthcare professional educational plan for pre-filled syringe
43.	Nilotinib (Tasigna)	<ul style="list-style-type: none"> - QT prolongation - Myelosuppression - Cardiovascular events - Significant bleeding - Severe infections - Hepatotoxicity - Pancreatitis, lipase and amylase elevations - Fluid retention 	<ul style="list-style-type: none"> - Patient / HCPs educational materials.

		<ul style="list-style-type: none"> - Blood glucose increased - Blood cholesterol increased - Use in patients with hepatic impairment - Interaction with strong CYP3A4 inhibitors 	
44.	Bosentan Monohydrate (Bosentan)	<ul style="list-style-type: none"> - Teratogenicity - Hepatotoxicity - Decrease in haemoglobin concentration - Decrease in sperm count 	- Controlled distribution system HCP and Patient educational materials.
45.	Agomelatine (Valdoxan[®])	- liver Function (hepatotoxicity)	- patient booklet - Doctor guide
46.	Menotrophin (Humog[®])	- Ovarian Hyperstimulation Syndrome (OHSS)	- Doctor guide
47.	Pioglitazone/glimepride (Duetact[®])	<ul style="list-style-type: none"> - congestive heart failure - not recommended in patients with symptomatic heart failure - d NYHA Class III or IV heart failure is contraindicated 	- prescriber guide
48.	Misoprestol (Misodel[®])	- uterine tachysystole	- prescriber guide
49.	Acitretin (Neotigasone[®])	- Risk of malformation and formation of a compound (etretinate), which may be harmful to an unborn child	- pregnancy prevention program (HCP, patient) educational material
50.	Bendamustine (Bendavival[®])	<ul style="list-style-type: none"> - Myelosuppression - Infections - Anaphylaxis and Infusion Reactions - Tumor Lysis Syndrome - Skin Reactions - Hepatotoxicity - Extravasation Injury - Embryo-fetal toxicity 	- physician guide - pharmacist guide
51.	Rivastigmine (Rivaxel[®])	<p>Gastrointestinal symptoms (nausea, vomiting, diarrhoea)</p> <ul style="list-style-type: none"> - Worsening of motor symptoms associated with Parkinson's disease - Pancreatitis - Cardiac arrhythmias - Exacerbations of asthma and chronic obstructive pulmonary disease (COPD) 	- patient card

		<ul style="list-style-type: none"> - Hypertension - Gastrointestinal ulceration, hemorrhage, and perforation - Seizures - Hallucinations - Syncope and loss of consciousness - Liver disorders - Application site skin reactions and irritations (patch formulation only) - Severe skin reactions (bullous reactions) 	
52.	Ulipristal (Esmya®)	acute liver injury	Patient card
53.	dolutegravir / abacavir / lamivudine (Triumeq®)	Allergic reactions with dolutegravir	DHCP
54.	Dapagliflozin (Forxiga)	Rare occurrences of a serious infection of the genital area (Fourniers gangrene)	DHCP
55.	Dapagliflozin (Divinus)	Rare occurrences of a serious infection of the genital area (Fourniers gangrene)	DHCP
56.	Empagliflozin (Synjardy tablet, Jaradiance tablet, Glyxambi tablet)	Rare occurrences of a serious infection of the genital area (Fourniers gangrene)	DHCP
57.	Daratumumab (Darzalex®)	Risk minimization of daratumumab with blood compatibility testing	<ul style="list-style-type: none"> - Patient card - Health care provider information's
58.	Adalimumab (Humira®)	Important safety information about the drug	<ul style="list-style-type: none"> -Adult Patient reminder card - Pediatric Patient reminder card - Safety monograph - TB brochure
59.	Adalimumab (Amgevita®)	Important safety information about the drug	<ul style="list-style-type: none"> -Adult Patient reminder card - Pediatric Patient reminder card

			- Safety monograph - TB brochure
60.	Tofacitinib (Xeljanz[®])	-Prescriber brochure to provide guidance on assessments prior to prescribing, management, monitoring and safety considerations related to the Risk Management Plan. -Patient alert card to help patients understand the risks associated with XELJANZ, and remind them to seek immediate medical attention if they experience any listed signs and symptoms.	-patient alert card -Healthcare professional Brochure
61.	Valproic acid, sodium valproate (Pravia CR)	- malformations and developmental problems	- patient card
62.	Insulin Degludec (Tresiba[®])	-Direct Healthcare Professional Communication for Tresiba [®] 100U and 200U FlexTouch [®] correct use of Tresiba [®] (insulin degludec) to minimise medication errors	-DHCP
63.	Gadoteric acid (clariscan[®])	- - Nephrogenic Systemic Fibrosis (NSF) - Anaphylactoid and other serious hypersensitivity reactions - Gadolinium is retained for months or years in brain, bone, and other organs. - Acute renal failure	-medication guide
64.	Gadodiamide (omniscan[®])	- Nephrogenic Systemic Fibrosis (NSF) - Anaphylactoid and other serious hypersensitivity reactions - Gadolinium is retained for months or years in brain, bone, and other organs. - Acute renal failure	-medication guide