DRUG NAME: Mirvetuximab soravtansine

SYNONYM(S): IMGN853[1]

COMMON TRADE NAME(S): ELAHERE®

CLASSIFICATION: miscellaneous

Special pediatric considerations are noted when applicable, otherwise adult provisions apply.

MECHANISM OF ACTION:

Mirvetuximab soravtansine is an antibody-drug conjugate (ADC) composed of a chimeric IgG1 monoclonal antibody directed against folate receptor-alpha (FRα) which is linked to a maytansoid antitubulin agent (DM4) via a cleavable linker.[1,2] FRα is a cell-surface glycoprotein that facilitates the transport and accumulation of folate into cells through endocytosis and is aberrantly expressed in endothelial tumours. High receptor expression is characteristic of several common human malignancies.[3] Each molecule of mirvetuximab is conjugated to an average of 3 to 4 molecules of DM4.[4] Following binding to the target FRα antigen on the cell surface, mirvetuximab soravtansine is internalized and the linker cleaved through a proteolytic process. The cytotoxic payload (DM4) is released within the cell where it disrupts the microtubule network, ultimately resulting in cell cycle arrest and apoptotic cell death. Mirvetuximab soravtansine is cell cycle phase-specific, inducing cell cycle arrest in the G_2/M phase.[1,2]

PHARMACOKINETICS:

Absorption	peak concentrations observed near end of IV infusion[4]; peak concentrations of DM4 and S-methyl-DM4 were observed on days 2 and 3 after administration[5,6]	
Distribution	minimal accumulation[5]; low Vd suggests limited distribution outside vascular space	
	cross blood brain barrier?	limited penetration (<3%)[7]
	volume of distribution[6]	2.6 L
	plasma protein binding	DM4, S-methyl-DM4: >99%
Metabolism	monoclonal antibody portion is expected to be metabolized into small peptides by catabolic pathways; unconjugated DM4 and S-methyl-DM4 metabolism is primarily mediated by CYP 3A4	
	active metabolite(s)	DM4, S-methyl-DM4
	inactive metabolite(s)	DM4-sulfo-SPDB-lysine[5]
Excretion	DM4 and S-methyl-DM4 are primarily eliminated by biliary excretion in feces	
	urine[6]	0.7% (S-methyl-DM4 and DM4-sulfo-SPDB-lysine are detected within 24 h)[5,6]
	feces	major route of elimination[7]
	terminal half life[6]	5 days; unconjugated DM4: 2.8 days; S-methyl-DM4: 5 days
	clearance[6]	19 mL/h; unconjugated DM4: 14 L/h; S-methyl-DM4: 4.3 L/h
Sex	no differences observed	
Elderly	no difference in Cmax and AUC observed	
Ethnicity	no differences observed	

Adapted from standard reference[8] unless specified otherwise.

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USES:

Primary uses:
*Ovarian cancer

Other uses:

*Health Canada approved indication

SPECIAL PRECAUTIONS:

Caution:
- ***premedication with corticosteroid, antihistamine, and antipyretics*** is recommended prior to each dose for prevention of infusion-related reactions[2]
- ***premedication with antiemetics*** is recommended prior to each dose[2]
- ***ophthalmic exams*** are recommended prior to starting treatment with mirvetuximab soravtansine[2]
- ***lubricating eye drops*** are recommended throughout treatment with mirvetuximab soravtansine[2]
- the ability to ***drive and/or operate machinery*** may be impaired during treatment (e.g., impairment secondary to visual disturbances, peripheral neuropathy, fatigue, or dizziness)[2]
- ***folate-containing supplements*** are not recommended during treatment with mirvetuximab soravtansine[8]

Carcinogenicity: no information found

Mutagenicity: DM4 and S-methyl-DM4 are not mutagenic in Ames test. DM4 and S-methyl-DM4 are clastogenic in a mammalian *in vivo* chromosome test[8]

Fertility: Fertility studies have not been conducted. However, DM4 is genotoxic and can be toxic to actively dividing cells. Based on its mechanism of action and its genotoxic component, mirvetuximab soravtansine may cause drug-related fertility effects.[8]

Pregnancy: There is no available human data to inform a drug-associated risk in pregnant women and no reproductive or developmental toxicity studies in animals. Human immunoglobulin G (IgG) is known to cross the placental barrier; therefore, mirvetuximab soravtansine has the potential to be transmitted from the pregnant patient to the developing fetus. DM4 is genotoxic and can be toxic to actively dividing cells, suggesting it has the potential to cause embryotoxicity and teratogenicity. Based on its mechanism of action and its genotoxic component, mirvetuximab soravtansine may cause embryo-fetal harm when administered during pregnancy. Consider pregnancy tests prior to treatment. Contraception is recommended during treatment and for 7 months following the last dose for female patients of reproductive potential.[8]

Breastfeeding is not recommended due to the potential secretion into breast milk. Mirvetuximab is a chimeric IgG1 molecule[8] and human IgG is known to pass into human breast milk.[9] The amount of mirvetuximab in breast milk is expected to be very low because of its large molecular size and infant absorption will probably be minimal due to the likelihood that mirvetuximab will be partially destroyed in the infant's gastrointestinal tract. However, mirvetuximab is conjugated with a small-molecule compound which might also be excreted into milk.[5] Women should not breastfeed during treatment and for one month following the last dose.[8]

SIDE EFFECTS:

The table includes adverse events that presented during drug treatment but may not necessarily have a causal relationship with the drug. Because clinical trials are conducted under very specific conditions, the adverse event rates observed may not reflect the rates observed in clinical practice. Adverse events are generally included if they were reported in more than 1% of patients in the product monograph or pivotal trials, and/or determined to be clinically important. [10,11] When placebo-controlled trials are available, adverse events will generally be included if the incidence is ≥5% higher in the treatment group.

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ORGAN SITE	SIDE EFFECT
Clinically important side effects are in ***bold, italics***	
blood and lymphatic system/ febrile neutropenia	anemia (18-25%, severe 1-3%)
	leukocytopenia (23-26%, severe 1%)
	lymphocytopenia (27-35%, severe 3-7%)
	neutropenia (22-26%, severe 1-3%)
	thrombocytopenia (17-18%, severe 1-2%)
eye (see paragraph following **Side Effects** table)	***blurred vision*** (43-50%, severe 5-9%)
	cataract (4-18%, severe 3%)
	dry eye (27-29%, severe 2-3%)
	eye pain (10%)
	keratopathy (29-37%, severe 5-11%)
	photophobia (17-18%, severe 1%)
gastrointestinal	*emetogenic potential:* low[12]
	abdominal distension (11%)
	abdominal pain (30-36%, severe 3-7%)
	constipation (26-30%, severe 1%)
	diarrhea (29-39%, severe 1-3%)
	intestinal obstruction (3%)
	nausea (27-41%, severe 2%)
	small bowel obstruction (3%)
	vomiting (18-23%, severe 3%)
general disorders and administration site conditions	*extravasation hazard:* none[13]
	fatigue, asthenia (35-49%, severe 3%)
immune system	***infusion related reaction/hypersensitivity*** (8%, severe 0%)
investigations	albumin decrease (21-31%, severe 1%)
	alkaline phosphatase increase (30%, severe 1%)
	ALT increase (38-39%, severe 2%)
	AST increase (16-57%, severe 2%)
	bicarbonate decrease (11%)
	creatinine increase (10-16%)
metabolism and nutrition	appetite decrease (18-22%, severe 1%)
	dehydration (4%, severe <1%)
	hypercalcemia (12%)
	hypokalemia (15%, severe 1-4%)
	hypomagnesemia (21-27%, severe 1-2%)

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ORGAN SITE	SIDE EFFECT
Clinically important side effects are in ***bold, italics***	
	hyponatremia (16%)
musculoskeletal and connective tissue	arthralgia (16-17%)
	musculoskeletal pain (31%, severe 1%)
	myalgia (10%)
nervous system (see paragraph following **Side Effects** table)	headache (14%)
	hypoesthesia (1%)
	neurotoxicity (3%)
	paresthesia (6%)
	peripheral motor neuropathy (1%)
	peripheral neuropathy (20%, severe 2-4%)
	peripheral sensorimotor neuropathy (<1%)
	peripheral sensory neuropathy (9%)
	polyneuropathy (<1%)
respiratory, thoracic and mediastinal	dyspnea (12%)
	pneumonitis (4-10%, severe 1%); see paragraph following **Side Effects** table
	pleural effusion (2%)

Adapted from standard reference[2,14] unless specified otherwise.

Severe and life-threatening ***interstitial lung disease,*** including ***pneumonitis,*** has been reported with mirvetuximab soravtansine. Some fatalities have been recorded. Median time to onset is 18 weeks (range 1.6 to 97 weeks). Monitor for hypoxia, cough, and dyspnea, and interstitial infiltrates on radiologic exams. Withhold mirvetuximab soravtansine for persistent or recurrent grade 2 pneumonitis and consider dose reduction. Permanently discontinue mirvetuximab soravtansine for grade 3 or 4 pneumonitis. Asymptomatic patients may continue receiving mirvetuximab soravtansine if closely monitored.[2,14]

Ocular adverse events (e.g., blurred vision, keratopathy, dry eye) have been observed with antibody-drug conjugates and may be a result of an off-target effect.[1] Median time to onset of ocular events is 5 weeks (range 0.1 to 69 weeks). Most patients experience either partial improvement or complete resolution of their symptoms. Lubricating eye drops are recommended throughout treatment. Contact lens use should be avoided. Ophthalmic exams are recommended prior to starting treatment with mirvetuximab soravtansine and if any new or worsening ocular symptoms occur prior to the next dose. The frequency of ophthalmic exams should be increased following toxicity and continue until resolution of symptoms or return to baseline (suggested minimum frequency every 2 weeks). Patients experiencing ***corneal adverse reactions*** such as keratopathy may require secondary prophylaxis with ophthalmic topical steroids in subsequent cycles. For patients with grade 2 or greater corneal toxicity, instruct patients to use steroid eye drops for each subsequent infusion, administering the drops on the day of the infusion plus the next 7 days after the infusion in each treatment cycle. Regular measurement of intraocular pressure and ophthalmic exams are recommended if topical steroids are used. When using steroid eye drops, instruct patients to wait at least 15 minutes after the steroid eye drops before administering lubricating eye drops. Depending on the severity and persistence of the adverse reaction, mirvetuximab soravtansine may be withheld, dose reduced, or permanently discontinued to manage symptoms. Patients experiencing visual disturbances should be instructed not to drive or operate machinery until symptoms have resolved.[2,14]

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Peripheral neuropathies, including sensory/motor neuropathy and paresthesias, are reported in approximately one-third of patients. Grade 3 reactions are reported in 2-4% of patients. Median time to onset is 6 weeks (range 0.1 to 127 weeks). Monitor patients for paresthesia, neuropathic pain, muscle weakness, or dysesthesia. New or worsening symptoms are managed by dose reduction and/or withholding or permanently discontinuing mirvetuximab soravtansine. One-quarter of patients who experience peripheral neuropathy report complete resolution of their symptoms; however, others report only partial improvement after treatment discontinuation.[2,14]

INTERACTIONS:

Folate containing supplements may interact with the mechanism of action of mirvetuximab soravtansine.[8]

DM4 (the maytansoid antitubulin agent linked to mirvetuximab in the antibody drug conjugate) is a CYP 3A4 substrate. Concurrent use of mirvetuximab soravtansine with strong CYP 3A4 inhibitors may increase exposure to unconjugated DM4 and increase the toxicity of mirvetuximab soravtansine. Avoid concurrent use if possible. Monitor for increased toxicity if concurrent use cannot be avoided. Strong inducers of CYP 3A4 may reduce exposure to unconjugated DM4. Clinical significance is unknown.[2]

SUPPLY AND STORAGE:

Injection: AbbVie Corporation supplies mirvetuximab soravtansine as 100 mg ready-to-use, single use (preservative free) vials in a concentration of 5 mg/mL. Refrigerate. Protect from light. [8]

For basic information on the current brand used at BC Cancer, see Chemotherapy Preparation and Stability Chart in Appendix.

SOLUTION PREPARATION AND COMPATIBILITY:

For basic information on the current brand used at BC Cancer, see Chemotherapy Preparation and Stability Chart in Appendix.

Additional information:

- administer using 0.2 or 0.22 micron polyethersulfone in-line filter [8]
- compatible with infusion bags made of PVC (DEHP plasticized and non-DEHP PVC), polyolefin, EVA, polypropylene, and polycarbonate[15]
- compatible with infusion sets made of PVC (DEHP plasticized PVC and non-DEHP PVC) and sllicone[15]
- not compatible with normal saline; dilute with D5W only [8]

Compatibility: consult detailed reference

PARENTERAL ADMINISTRATION:

BC Cancer administration guideline noted in ***bold***, ***italics***

Subcutaneous	do not use
Intramuscular	do not use
Direct intravenous	do not use

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BC Cancer administration guideline noted in ***bold***, ***italics***

Intermittent infusion [8]	• ***first dose: initial rate of 1 mg/min***
	  ○ if tolerated at 1 mg/min, rate may be increased to 3 mg/min after 30 min
	  ○ if tolerated at 3 mg/min, rate may be increased to 5 mg/min after 30 min
	• ***subsequent doses:*** maximally tolerated rate of previous dose
	• ***max rate of 5 mg/min***
	• administer using 0.2-0.22 micron polyethersulfone in-line filters

Continuous infusion	do not use
Intraperitoneal	no information found
Intrapleural	no information found
Intrathecal	no information found
Intra-arterial	no information found
Intravesical	no information found

DOSAGE GUIDELINES:

Refer to protocol by which patient is being treated. Numerous dosing schedules exist and depend on disease, response and concomitant therapy. Guidelines for dosing also include consideration of absolute neutrophil count (ANC). Dosage may be reduced, delayed or discontinued in patients with bone marrow depression due to cytotoxic/radiation therapy or with other toxicities.

Adults:

BC Cancer usual dose noted in ***bold, italics***

Intravenous:	Cycle Length: 3 weeks[8]:	6 mg/kg AIBW IV for one dose on day 1 (total dose per cycle 6 mg/kg AIBW) **To calculate AIBW (adjusted ideal body weight):** all weights are measured/calculated in kg height is measured in cm IBW = ideal body weight IBW in kg (female) = (0.9 x height) – 92 AIBW in kg = IBW + 0.4(actual weight - IBW)
Concurrent radiation:	no information found	
Dosage in myelosuppression:	modify according to protocol by which patient is being treated	
Dosage in renal failure:	mild to moderate impairment (CrCl ≥30 mL/min): no adjustment required[8] severe impairment (CrCl <30 mL/min); no information found	
Dosage in hepatic failure:	mild impairment (bilirubin ≤ULN and AST >ULN OR bilirubin 1-1.5 x ULN and any AST): no adjustment required[8] moderate to severe impairment (bilirubin >1.5 x ULN with any AST): no information found	

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Dosage in dialysis: no information found

Children: safety and efficacy is not established[8]

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