Mirvetuximab Soravtansine

Indication

Indicated as monotherapy for the treatment of folate receptor-alpha (FRα) positive, platinum-resistant high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received one to three prior systemic treatment regimens.

Regimen details

Mirvetuximab Soravtansine 6mg/Kg (calculated using adjusted ideal body weight) by intravenous infusion in 250 ml Glucose 5%.

See administration details below.

The AIBW is calculated using the following formula:
Glossary - AIBW = Adjusted ideal body weight, IBW = Ideal body weight
Female IBW [kg] = (0.9 x height [cm]) – 92

AIBW = IBW [kg] + [0.4 x (Actual weight [kg] – IBW)]

E.g. For a female patient who is 165 cm in height and 80 kg in weight

First, calculate IBW	IBW = (0.9 x 165) – 92 = 56.5 kg
Then calculate AIBW	AIBW = 56.5 + [0.4 x (80 – 56.5)] = 65.9kg

Cycle frequency

Every 21 days

Number of cycles

Continue until disease progression or unacceptable toxicity.

Administration

Administer as an intravenous infusion only in 5% Dextrose at a rate of 1 mg/min, using a 0.2 or 0.22 µm polyethersulfone (PES) in-line filter. If well tolerated after 30 minutes, the infusion rate can be increased to 3 mg/min. If well tolerated after 30 minutes at 3 mg/min, the infusion rate can be increased to 5 mg/min.

Initial rate	**After 30 mins (if tolerated)**	**After further 30 mins (if tolerated)**
1mg/min	3mg/min	5mg/min

• If no infusion-related reactions occur with the previous dose, subsequent infusions should be started at the maximally tolerated rate and may be increased up to a maximum infusion rate of 5 mg/min, as tolerated.
• Following the infusion, flush the intravenous line with 5% glucose to ensure delivery of the full dose. Do not use any other intravenous fluids for flushing.
Observe patient for 60-90 minutes post infusion.

Infusion-related reactions/ hypersensitivity

Grade 1	Maintain infusion rate unless progression of symptoms to ≥G2, refer to G2 guideline.
Grade 2	• Interrupt infusion and administer supportive treatment. • After recovery from symptoms, resume the infusion at 50% of the previous rate, and if no further symptoms appear, increase rate as appropriate until infusion is completed. • Administer additional pre-medication with dexamethasone 8 mg oral BID the day before infusion (or local equivalent) for future cycles
Grade 3 or 4	• Immediately stop infusion and administer supportive treatment. • Advise patient to seek emergency treatment and immediately notify their healthcare professional if the infusion related symptoms recur after discharge from the infusion area. • Permanently discontinue.

Pre-medication

Paracetamol 1000mg PO
Chlorphenamine 10mg IV
Dexamethasone 10mg IV
Ondansetron 8mg IV
H_2 antagonist – 1 hour before treatment

Patients who have an infusion reaction Grade 2 or higher must be premedicated with dexamethasone 8mg bd, the day before treatment.

Emetogenicity

Mild-Moderate

Additional supportive medication

Ondansetron 8mg BD PO for 1 day post chemo.
Preservative free lubricating eye drops to be used 4-6 times a day throughout treatment.

Patients should be informed to avoid wearing contact lenses, use UVA/UVB sunglasses in daylight and maintain good eyelid hygiene with warm compresses

Extravasation

Pain and erythema. Management of extravasation is symptomatic.

Investigations – pre first cycle

Investigation	**Validity period**
FBC	14 days
U+E (including creatinine)	14 days
LFT (including AST)	14 days
Bone profile	14 days

Random glucose	14 days
Serum magnesium	14 days
Ca125	14 days
Ophthalmic examination including VA and slit lamp	28 days

An ophthalmic exam including visual acuity and slit lamp exam should be conducted before the initiation and if a patient develops any new or worsening ocular symptoms prior to the next dose.

Eye care to be arranged with / via local ophthalmology departments

Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT (including AST), bone profile, serum magnesium, random glucose, Ca125.

Ophthalmic examination:

Before the start of each cycle, the patient should be advised to report any new or worsening symptoms to the treating physician or qualified individual. In patients who develop new or worsening ocular symptoms, an ophthalmic exam should be conducted before dosing.

In patients with ≥ Grade 2 ocular adverse reactions, additional ophthalmic exams should be conducted at a minimum of every other cycle and as clinically indicated until resolution or return to baseline.

Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Investigation	**Limit**
Neutrophil count	≥ 1.5 x 10^9/L
Platelet count	≥ 100 x 10^9/L
Hb	> 90g/L
Creatinine clearance	≥ 30 mL/min
Bilirubin	≤ 1.5 x ULN
AST	< 2 x ULN

Dose modifications

In patients that develop ocular symptom, the treating physician should review the patient's ophthalmic examination report before dosing and determine the dose based on the severity of findings in the most severely affected eye - see table below.

Dose reduction schedule:

	Mirvetuximab dose levels
Starting dose	6 mg/kg AIBW
First dose reduction	5 mg/kg AIBW
Second dose reduction	4 mg/kg AIBW*

* Permanently discontinue in patients who cannot tolerate 4 mg/kg AIBW.

Adverse reaction	**Severity of adverse reaction**	**Dose modification**
Haematological	Grade 3 or 4	Withhold dose until Grade 1 or less, then resume at one lower dose level.
Corneal (Keratitis/ keratopathy)	G1 Asymptomatic, Non-confluent superficial keratitis/keratopathy, Asymptomatic.	Monitor. Continue MIRV dosing

	G2 Symptomatic; Confluent superficial keratitis/keratopathy, a cornea epithelial defect, or moderate decrease in VA, 3-line or more loss in best corrected visual acuity or best corrected visual acuity 20/40.	Withhold dose until improved to nonconfluent superficial keratitis/keratopathy or better or resolved, then maintain at same dose level. Consider dose reduction for patients with recurrent confluent keratitis/keratopathy despite best supportive care or in patients with ocular toxicity lasting longer than 14 days
	G3 Symptomatic, Corneal ulcer or stromal opacity or marked decrease in VA, best corrected distance visual acuity 6/60 or worse (or VA 20/40 or worse) or more than 3 lines of decreased vision from known baseline,); limiting self-care ADL.	Withhold dose until improved to (grade 0 or 1) nonconfluent superficial keratitis/keratopathy or better or resolved, then reduce by one dose level.
	G4 corneal Perforation	Permanently discontinue
Pneumonitis 10% risk Median time to onset 18 weeks	Grade 1	Monitor
	Grade 2	Withhold dose until Grade 1 or less, then maintain at same dose level or preferably do dose reduction (if recurrent, lasts longer than 28 days, or at physician discretion).
	Grade 3 or 4	Permanently discontinue
Peripheral neuropathy 36% risk Median time to onset 6 weeks	Grade 2	Withhold dose until Grade 1 or less, then reduce by one dose level.

	Grade 3 or 4	Permanently discontinue
Other adverse reactions	Grade 3	Withhold dose until Grade 1 or less, then resume at one lower dose level.
	Grade 4	Permanently discontinue

Renal impairment:
No dose adjustment is recommended for patients with mild to moderate renal impairment (creatinine clearance [CLcr] 30 to <60 mL/min). Mirvetuximab has not been evaluated in patients with severe renal impairment (CLcr 15 to <30 mL/min) or end-stage renal disease and the potential need for dose adjustment in these patients cannot be determined

Hepatic impairment:
No dose adjustment is recommended for patients with mild hepatic impairment (total bilirubin ≤ ULN and aspartate aminotransferase [AST] > ULN OR total bilirubin >1 to 1.5 times ULN and any AST). Mirvetuximab should be avoided in patients with moderate to severe hepatic impairment (total bilirubin >1.5 ULN with any AST).

Adverse effects - for full details consult product literature/ reference texts

In particular, be vigilant for ocular adverse reactions, pneumonitis and peripheral neuropathy.

- **Serious side effects**

Pneumonitis, obstruction of the small intestine, pleural effusion, abdominal pain, dehydration, constipation, nausea, ascites and thrombocytopenia

- **Frequently occurring side effects**

Blurred vision, nausea, vomiting, diarrhoea, constipation, abdominal pain, decrease appetite, keratopathy, dry eye, peripheral neuropathy, headache, asthenia, tiredness weakness, increased liver enzyme levels, arthralgia.

Ocular adverse reactions:
Eye care to be arranged with / via local ophthalmology departments
In patients with ≥ Grade 2 ocular adverse reactions, additional ophthalmic exams should be conducted at a minimum of every other cycle and as clinically indicated until resolution or return to baseline.
Ophthalmic topical steroids: For patients found to have signs of Grade 2 or higher corneal adverse reactions (keratopathy) on slit lamp examination, secondary prophylaxis with ophthalmic topical steroids (prednisolone 1% ie predforte eye drops) is recommended for subsequent cycles, unless the patient's eye care professional determines that the risks outweigh the benefits of such therapy.
Prednisolone 1% eye drop should be administered six times per day, 1 day before treatment to D4 then four times per day on day 5 to day 8 of each cycle or as per treating physician direction. Patients should be advised to wait at least 15 minutes after ophthalmic topical steroid administration before instilling lubricating eye drops.
During treatment with ophthalmic topical steroids the measurement of intraocular pressure and an examination with slit lamp should be carried out regularly.

Significant drug interactions – for full details consult product literature/ reference texts

Mirvetuximab soravtansine is a CYP3A4 substrate. Concomitant use of with strong CYP3A4 inhibitors may increase unconjugated DM4 exposure which may increase the risk of adverse reaction. If concomitant use with strong CYP3A4 inhibitors (e.g. ceritinib, clarithromycin, cobicistat, idelalisib, itraconazole, ketoconazole, nefazodone, posaconazole, ritonavir, telithromycin, voriconazole) cannot be avoided, patients should be closely monitored for adverse reactions. Strong CYP3A4 inducers (e.g., phenytoin, rifampicin, carbamazepine) may decrease the exposure of unconjugated DM4. Avoid grapefruit juice.

Additional comments

References

Mirvetuximab Soravtansine SPC https://www.medicines.org.uk/emc/product/101216/smpc Accessed September 2025.
Mirvetuximab soravtansine for treating folate receptor-alpha-positive platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer
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THIS PROTOCOL HAS BEEN DIRECTED BY DR YIANNAKIS, DESIGNATED LEAD CLINICIAN FOR GYNAE CANCERS

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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