DRUG ADMINISTRATION SCHEDULE

Day	Drug	Daily Dose	Route	Diluent & Rate
Day 1	Metoclopramide	10mg	IV bolus	
	Topotecan	**1.5 mg/m^2**	IV bolus	50 ml Sodium Chloride 0.9% over 30 minutes
Day 2	Metoclopramide	10mg	IV bolus	
	Topotecan	**1.5 mg/m^2**	IV bolus	50 ml Sodium Chloride 0.9% over 30 minutes
Day 3	Metoclopramide	10mg	IV bolus	
	Topotecan	**1.5 mg/m^2**	IV bolus	50 ml Sodium Chloride 0.9% over 30 minutes
Day 4	Metoclopramide	10mg	IV bolus	
	Topotecan	**1.5 mg/m^2**	IV bolus	50 ml Sodium Chloride 0.9% over 30 minutes
Day 5	Metoclopramide	10mg	IV bolus	
	Topotecan	**1.5 mg/m^2**	IV bolus	50 ml Sodium Chloride 0.9% over 30 minutes

CYCLE LENGTH AND NUMBER OF DAYS

21 day cycle

APPROVED INDICATIONS

Second-line (or subsequent) treatment only for those women with platinum-refractory or platinum-resistant advanced ovarian cancer, or those who are allergic to platinum- based compounds, for whom pegylated liposomal doxorubicin hydrochloride and single-agent paclitaxel are considered inappropriate

ELIGIABILITY CRITERIA

ECOG performance status 0 to 2

EXCLUSION CRITERIA

In patients who

have a history of hypersensitivity reactions to topotecan have
severe bone marrow depression
have severe renal or severe hepatic impairment

RECOMMENDED TAKE HOME MEDICATION

Metoclopramide 10mg three times daily as required* see CINV policy for precautions
Ondansetron 8mg twice daily for five days for where nausea not controlled with metoclopramide.
Loperamide as required (4mg after first loose stool and 2mgs every 2 hours, to a maximum of 16 (2mg) tablets in 24 hours.

Ciprofloxacin 250mg twice daily if diarrhoea lasts >24hrs *(see administration notes)*

INVESTIGATIONS / MONITORING REQUIRED

FBC, U&E's, LFT's, tumour markers as appropriate pre each cycle

ASSESSMENT OF RESPONSE

Treatment response is monitored by serial CA125 measurement before each cycle of treatment, and additionally radiologically prior to starting topotecan and after 3 cycles of treatment

REVIEW BY CLINICIAN

Every other cycle

NURSE / PHARMACIST LED REVIEW

On cycles where not seen by clinician.

ADMINISTRATION NOTES

Refer to NICE Technology Appraisal No.91 issued May 2005 for guidance on the use of Topotecan in advanced ovarian cancer
Patients must be made aware of the risk of diarrhoea occurring during and after the administration of topotecan and at any time before the next cycle.

Diarrhoea must be treated immediately with high dose Loperamide (4mg after first loose stool and 2mgs every 2 hours, to a maximum of 16 (2mg) tablets in 24 hours. Hospitalise if condition not resolved within 48 hours.

For diarrhoea lasting greater than 24 hours add ciprofloxacin 250mg BD. *Note* many units give patient a supply of loperamide and ciprofloxacin at the start of treatment.

EXTRAVASATION *See NECN/Local Policy*

TOXICITIES

Risk of hypersensitivity and anaphylaxis, particularly on first and second cycle, start within a few minutes of administration
Bone Marrow Depression; anaemia, neutropenia, thrombocytopenia
Diarrhoea – risk of severe delayed diarrhoea
Abdominal Pain Nausea &
Vomiting Fatigue
Alopecia
Rash

DOSE MODIFICATION / TREATMENT DELAY

Haematological Toxicity:

- Delay 1 week if WBC<3.0, ANC <1.0 Platelets <100
- No dose modification for CTC grade I/II ANC
- Grade III/IV ANC → delay chemotherapy until recovered, if decide to continue dose as below:
- Patients who experience severe neutropenia (neutrophil count < 0.5 x 10^9/l) for 7 days or more, or severe neutropenia associated with fever or infection, or who have had treatment delayed due to neutropenia, the dose should be reduced by
- 0.25 mg/m^2/day to 1.25 mg/m^2/day (or subsequently down to 1.0 mg/m^2/day if necessary).

Non- Haematological Toxicity:

Diarrhoea

For patients who experience Grade 3 or 4 diarrhoea, the dose should be reduced by 0.4 mg/m2/day for subsequent courses.
Patients with Grade 2 diarrhoea may need to follow the same dose modification guidelines.

Renal Function

Dosing recommendations for patients receiving topotecan with CrCl< 60 ml/min have not been established
Avoid in moderate to severe renal failure, e.g. CrCl < 20ml/min and impaired hepatic function (serum bilirubin ≥ 10 mg/dl)

TREATMENT LOCATION

Should be given at Cancer Centre only

REFERENCES:

Ten Bokkel W, Gore M, Carmichael J *et al*. (1997) Topotecan versus paclitaxel for the treatment of recurrent epithelial ovarian cancer. *J Clin Oncol*. **15**: 2183-93

Document Control

Document Title:	Topotecan IV CNTW protocol CRP09 GY004		
Document No:	CRP09 GY004	**Current Version:**	1.3
Author:	Steve Williamson, Consultant Pharmacist	**Approval Signature***	
Approved by:	Calum Polwart Cancer Pharmacist	**Date Approved:**	29.05.14
Due for Review:	May 2016		
Summary of Changes	1.1	Reformatted from old NCN/CCA versions	
	1.2	Protocol reviewed. Typing errors corrected.	
	1.3	Protocol reviewed and approval dates updated	