TRIFLURIDINE & TIPIRACIL (Lonsurf®)

For use in patients with metastatic colorectal cancer who have failed at least 2 previous regimens for advanced disease and PS 0 – 1 (NICE approved Aug 2016)

Blueteq registration is required before treatment may start

Drug/Dosage:	Trifluridine & Tipiracil	35mg/m^2 PO twice daily on Days 1 to 5, and Days 8 to 12 (max 80mg/dose)
Administration:	Available as 15mg and 20mg tablets. The 20mg tablet contains 20mg trifluridine and 8.19mg tipiracil. The 15mg tablet contains 15mg trifluridine and 6.14mg tipiracil. Tablets should be swallowed whole with water within 60 minutes after completion of the morning and evening meals.	
Frequency:	28 day cycle Continue as long as benefit is observed or unacceptable toxicity	
Main Toxicities:	myelosuppression; diarrhoea; ovarian failure/infertility	
Anti- emetics:	mildly emetogenic	
Regular Investigations:	FBC	Day 1
	U&Es	Day 1
	LFTs	Day 1
	CEA	every cycle
	CT scan	after 3 cycles

Dose Modifications

Dosing adjustments may be required; a maximum of 3 dose reductions are permitted to a minimum dose of 20 mg/m^2 twice daily.
Level 1 dose reduction: 30mg/m^2 bd
Level 2 dose reduction: 25mg/m^2 bd
Level 3 dose reduction: 20mg/m^2 bd
Once the dose has been reduced, it should not be increased at a later time.

If doses are missed, or withheld for toxicity, the patient must not make up the missed doses.

Haematological Toxicity:	Neutrophils ≥ 1.5 x 10^9/l and Platelets ≥ 75 x 10^9/l	Proceed with next cycle, with potential dose reduction according to previous counts (see below)
	Neutrophils 0.5 – 1.49 x 10^9/l or Platelets 25 - 74 x 10^9/l	Delay treatment until recovered. Then restart treatment at same dose as previous cycle.
	Neutrophils < 0.5 x 10^9/l or Platelets < 25 x 10^9/l	Delay treatment until recovered. If the delay is more than 1 week, start the next cycle with one dose reduction from the previous dose level.

Interrupt treatment for any episode of febrile neutropenia. When resuming treatment, prescribe with one dose reduction from the previous dose level.

Reason for Update: NICE approved / blueteq statement added	Approved by Consultant: Dr T Dhillon
Version: 2	Approved by Lead Chemotherapy Nurse: P Deery
Supersedes: Version 1	Date: 19.1.17
Prepared by: S Taylor	Checked by: C Tucker

Non-Haematological Toxicities:	For any Grade 3 or 4 non-haematological toxicity (except for Grade 3 nausea or vomiting controlled by antiemetics, or Grade 3 diarrhoea responsive to anti-diarrhoeals), interrupt dosing until toxicity resolves to Grade 1 or baseline, then resume dosing with one dose reduction from the previous dose level.
Renal Impairment:	No dosage adjustment is recommended for patients with mild or moderate renal impairment (CrCl ≥ 30 ml/min). However, patients with CrCl 30 – 59ml/min are likely to experience a greater incidence of Grade 3 toxicities, dose reductions and delays. Not recommended in patients with CrCl < 30ml/min.
Hepatic Impairment:	Not recommended in patients with moderate or severe hepatic impairment as there are no data available
References:	Mayer, RJ et al; NEJM 2015; 372 (20): 1909 - 1919