

DOCEtaxel (75), CISplatin (75), 5-Fluorouracil (1000) – Induction/Neoadjuvant (TPF)

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved Reimbursement Status*
Induction treatment of patients with Stage III or IV non-metastatic squamous cell carcinoma of the head and neck.	C76	00315a	N/A

*This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patient's individual clinical circumstances.

Induction Chemotherapy	DOCEtaxel and CISplatin are administered on day 1 and 5-Fluorouracil is administered on days 1-4 of a 21 day cycle for 3 cycles unless disease progression or unacceptable toxicity develops (Ref Treatment Table 1).
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Facilities to treat anaphylaxis MUST be present when systemic anti-cancer therapy (SACT) is administered on Day 1.

G-CSF support (using standard or pegylated form) is required with all cycles.

Table 1: Treatment Table for Induction Chemotherapy with DOCEtaxel, CISplatin and 5-Fluorouracil

Admin. Order	Day	Drug	Dose	Route and Method of Administration	Diluent & Rate	Cycle
1	1	DOCEtaxel	75mg/m ²	IV infusion	^a 250mL 0.9% NaCl over 60 minutes	Every 21 days for 3 cycles
2	1	^b CISplatin	75mg/m ²	IV infusion	1000mL 0.9% NaCl over 60 minutes	Every 21 days for 3 cycles
3	1-4	^c 5-Fluorouracil	1000mg/m ² /day	Continuous IV infusion	^d Over 96 hours in 0.9% NaCl	Every 21 days for 3 cycles

^a75-185mg dose use 250mL infusion bag. For doses > 185mg use 500mL infusion bag
Use non-PVC infusion bag.

^bPre and post hydration therapy required for CISplatin

See local hospital policy recommendations.

Suggested pre hydration for CISplatin therapy:

Administer 10mmol magnesium sulphate (MgSO₄) (+/-KCl 20mmol/L if indicated) in 1000mL NaCl 0.9% over 60-120 minutes. (Refer to relevant local hospital policy for advice on administration of electrolyte infusions)

Administer CISplatin as described above

Post hydration: Administer 1000mL 0.9% NaCl over 60 minutes

Mannitol 10% may be used as per local policy to induce diuresis, although there is no conclusive evidence that this is required. The routine use of furosemide to increase urine flow is not recommended unless there is evidence of fluid overload (4, 5).

^c See dose modifications section for patients with identified partial dihydropyrimidine dehydrogenase (DPD) deficiency

^dAlternatively can be administered at 1000mg/m² in 1000mL 0.9% NaCl as an intravenous infusion over 22 hours on days 1-4 for a total dose of 4000mg/m² over 96 hours.

NCCP Regimen: DOCEtaxel 75mg/m ² , CISplatin 75mg/m ² and 5-Fluorouracil 1000mg/m ² Induction/Neoadjuvant (TPF)	Published: 03/05/2016 Review: 05/12/2030	Version number: 7a
Tumour Group: Head & Neck NCCP Regimen Code: 00315	ISMO Contributor: Prof Maccon Keane, Colm Mac Eochagain	Page 1 of 8

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Note: Administration volumes and fluids have been standardised to facilitate electronic prescribing system builds.

ELIGIBILITY:

- Indications as above
- ECOG status 0-1
- Adequate organ function; ANC > 1.5 x10⁹ cells/L, platelets 100 x10⁹/L
- Planned for definitive chemoradiation and/or surgery

EXCLUSIONS:

- Hypersensitivity to DOCEtaxel, CISplatin, 5-Fluorouracil or any of the excipients
- Pre-existing neuropathies ≥ grade 2
- Significant hearing impairment/tinnitus
- Known complete dihydropyrimidine dehydrogenase (DPD) deficiency
- Pregnancy
- Breastfeeding

CAUTION:

- Pre-existing renal impairment

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist.

TESTS:

Baseline tests:

- FBC, Renal and liver profile
- ECG (if patient has compromised cardiac function)
- Audiology referral and creatinine clearance if clinically indicated
- DPD testing prior to first treatment with 5-Fluorouracil using phenotype and/or genotype testing unless patient has been previously tested
 - In patients with moderate or severe renal impairment, blood uracil levels used for dihydropyrimidine dehydrogenase (DPD) phenotyping should be interpreted with caution, as impaired kidney function can lead to increased uracil blood levels. Consequently, there is an increased risk for incorrect diagnosis of DPD deficiency, which may result in under dosing of 5-Fluorouracil or other fluoropyrimidines, leading to reduced treatment efficacy. Genotype testing for DPD deficiency should be considered for patients with renal impairment.

Regular tests:

- FBC, Renal and liver profile* before each cycle
- *See Regimen specific complications for guidelines regarding hepatic dysfunction with DOCEtaxel

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

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DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant
 - Consider a reduced starting dose of 5-Fluorouracil in patients with identified partial DPD deficiency
 - Initial dose reduction may impact the efficacy of treatment
- In the absence of serious toxicity, subsequent doses may be increased with careful monitoring

Haematological:

Table 2: Dose modification for haematological toxicity

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose of DOCEtaxel, CISplatin and 5-Fluorouracil
≥1.5	and	≥100	100%
<1.5	or	<100	Delay treatment until recovery. Consider reducing docetaxel, CISplatin and 5-Fluorouracil by 25% for subsequent cycles.
		<50	Delay treatment until recovery. Consider reducing docetaxel, CISplatin and 5-Fluorouracil by 25% for subsequent cycles

- If an episode of febrile neutropenia, prolonged neutropenia or neutropenic infection occurs despite G-CSF use, delay until recovery. On recovery, reducing docetaxel, CISplatin and 5-Fluorouracil by 25% for subsequent cycles. If toxicity persist despite reduction and G-CSF support, further alteration should be discussed with treating consultant including possible further dose de-escalation or regimen change.
- Prophylactic G-CSF should be given in all cycles based on high risk of neutropenia with this regimen.

Renal and Hepatic Impairment:

Table 3: Dose modification for renal and hepatic impairment

Drug	Renal Impairment		Hepatic Impairment
DOCEtaxel	No need for dose adjustment is expected.		See Table 4 below
CISplatin	CrCL (mL/min)	Dose	No need for dose adjustment is expected.
	50-59	75% of original dose	
	40-49	50% of original dose	
	<40	Not recommended	
	Haemodialysis	50% of the original dose may be considered	
5-Fluorouracil	No need for dose adjustment is expected.		Mild and moderate (without renal impairment): No need for dose adjustment is expected
	Haemodialysis: No need for dose adjustment is expected		Severe: Not recommended

Renal and hepatic recommendations as per Giraud et al 2023

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Table 4: Dose modification of DOCetaxel in hepatic impairment.

AST Values		ALT Values		Alkaline Phosphatase Values		Bilirubin	Dose Modification
> 1.5–5 x ULN	AND/OR	> 1.5–5 x ULN	AND	> 2.5–5 x ULN	AND	Normal	Consider 75% of the original dose
> 5–10 x ULN	OR	> 5–10 x ULN	AND	< 6 x ULN	AND/OR	≤ 1–1.5 x ULN	Consider 50% of the original dose
> 10 x ULN	OR	> 10 x ULN	OR	> 6 x ULN	OR	> 1.5 x ULN	Not recommended

Non-haematological toxicity:
Table 5: Dose modification schedule based on adverse events

Adverse reactions	Recommended dose modification
Grade 3 diarrhoea 1st episode 2nd episode	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: - Reduce 5-Fluorouracil dose by 20% - Reduce DOCetaxel dose by 20%
Grade 4 diarrhoea 1st episode 2nd episode	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: - Reduce DOCetaxel and 5-Fluorouracil dose by 20% - Discontinue treatment
Grade 3 stomatitis/mucositis 1st episode 2nd episode 3rd episode	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: - Reduce 5-Fluorouracil dose by 20% - Stop 5-Fluorouracil only, at all subsequent cycles - Reduce DOCetaxel dose by 20%
Grade 4 stomatitis/mucositis 1st episode 2nd episode	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: - Stop 5-Fluorouracil only, at all subsequent cycles - Reduce DOCetaxel dose by 20%.
Grade 3 skin reaction	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: Decrease dose of DOCetaxel to 60mg/m ² If the patient continues to experience these reactions at 60 mg/m ² , the treatment should be discontinued

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Grade >2 peripheral neuropathy	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: Decrease dose of DOCEtaxel to 60mg/m ² If the patient continues to experience these reactions at 60 mg/m ² , the treatment should be discontinued Consider dose reduction of CISplatin at discretion of prescribing consultant
Grade ≥ 2 PPE	Delay treatment until toxicity has resolved to Grade 1 or less and reduce the dose for subsequent cycles as follows: Delay 5-Fluorouracil until recovery to Grade ≤ 1 and reduce subsequent doses of 5-Fluorouracil by 20%

SUPPORTIVE CARE:**EMETOGENIC POTENTIAL:**

- As outlined in NCCP Classification Document for Systemic Anti Cancer Therapy (SACT) Induced Nausea and Vomiting-
[Available on the NCCP website](#)

DOCEtaxel: Low (Refer to local policy)**CISplatin: High (Refer to local policy)****5-Fluorouracil: Low (Refer local policy)****For information:**

Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - [Available on the NCCP website](#)
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - [Available on the NCCP website](#)

PREMEDICATIONS:**DOCEtaxel**

- dexAMETHasone 8 mg PO twice daily for 3 days, starting one day prior to each DOCEtaxel administration unless contraindicated. Patient must receive minimum of 3 doses pre-treatment.
- Consideration may be given, at the discretion of the prescribing consultant, to the use of a single dose of dexAMETHasone 20mg IV immediately before chemotherapy where patients have missed taking the oral premedication dexAMETHasone as recommended by the manufacturer.*

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OTHER SUPPORTIVE CARE:

- Hydration prior and post CISplatin administration (**Reference local policy or see recommendations above**)
- Oral hydration should be encouraged for 24 hours.
- G-CSF prophylaxis is required for this regimen (**Refer to local policy**)
- Prophylactic antimicrobial support was provided in the clinical trial of this regimen – Ciprofloxacin 500mg BD Day 5-15, and may be added at the discretion of the prescribing physician. (**Refer to local policy.**)

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

REGIMEN SPECIFIC COMPLICATIONS:

- **Hepatic Dysfunction:** DOCetaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST) may lead to increased toxicity and usually requires a dose reduction
- **DPD deficiency:** DPD is an enzyme encoded by the DPYD gene which is responsible for the breakdown of fluoropyrimidines. Patients with DPD deficiency are therefore at increased risk of fluoropyrimidine-related toxicity, including for example stomatitis, diarrhoea, mucosal inflammation, neutropenia and neurotoxicity. Treatment with 5-Fluorouracil, capecitabine or tegafur-containing medicinal products is contraindicated in patients with known complete DPD deficiency. Consider a reduced starting dose in patients with identified partial DPD deficiency. Initial dose reduction may impact the efficacy of treatment. In the absence of serious toxicity, subsequent doses may be increased with careful monitoring. Therapeutic drug monitoring (TDM) of 5-Fluorouracil may improve clinical outcomes in patients receiving continuous 5-Fluorouracil infusions.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

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Version	Date	Amendment	Approved By
1	02/05/2016		Prof Maccon Keane
2	03/05/2018	Applied new NCCP regimen template Updated treatment table, revised CISplatin hydration regimen recommendations and standardised dosing in renal and hepatic impairment	Prof Maccon Keane
3	09/10/2019	Updated exclusion criteria Amended recommended Dose modification for haematological toxicity	Prof Maccon Keane
4	13/05/2020	Updated exclusion criteria Dosing in renal and hepatic impairment for DOCetaxel updated	Prof Maccon Keane
5	24/08/2020	Updated exclusion criteria, baseline testing, dose modifications and adverse events with respect to DPD deficiency as per DHPC from HPRA June 2020	Prof Maccon Keane

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		Updated Adverse events regarding palmar-plantar erythrodysaesthesia	
6	09/09/2021	Clarification of requirement for non-PVC infusion bag only. Amended emetogenic potential.	Prof Maccon Keane
6a	21/11/2023	Formatting changes and grammatical corrections.	NCCP
6b	08/04/2024	Updated title.	Prof Maccon Keane
6c	25/02/2025	Additional wording added in baseline testing section.	NCCP
7	05/12/2025	Regimen reviewed. Updated title. Updated infusion time for CISplatin. Updated administration route for 5-Fluorouracil. Updated exclusions section. Updated table 2 Dose modification for haematological toxicity. Updated renal and hepatic dose modifications to align with Giraud et al 2023 recommendations. Addition of table 4. Updated supportive care section to add GCSF and antimicrobial prophylaxis. Updated regimen in line with NCCP standardisation.	Dr Colm Mac Eochagain
7a	16/02/2026	Additional comment added to page 1 regarding GCSF support.	NCCP

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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