

Gemcitabine and DOCEtaxel Therapy - 21 day

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Treatment of locally advanced unresectable or metastatic soft tissue sarcoma ⁱ	C47, 49	00501a	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.

Gemcitabine is administered on Day 1 and Day 8 and DOCEtaxel on Day 8 of a 21-day cycle for up to 6 cycles unless the patient experiences disease progression or unacceptable toxicity.

Facilities to treat anaphylaxis MUST be present when systemic anticancer therapy (SACT) is administered.

Admin. Order	Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	1, 8	Gemcitabine	675mg/m ²	IV	250mL NaCl 0.9% over 90 minutes	Every 21 days for up to 6 cycles
2	8	^a DOCEtaxel	75mg/m ²	IV	250mL NaCl 0.9% over 60 minutes	Every 21 days for up to 6 cycles
^a Concentration of final volume should be <0.74mg/mL Use non-PVC infusion bag.						

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

ELIGIBILITY:

- Indication as above
- ECOG 0-2
- Adequate haematological and organ function

EXCLUSIONS:

- Hypersensitivity to DOCEtaxel, gemcitabine or any of the excipients
- Pregnancy
- Breastfeeding

CAUTION:

- Hepatic dysfunction

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist

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TESTS:

Baseline tests:

- FBC, renal and liver profile
- Bone profile

Regular tests:

- FBC, renal and liver profile prior to each cycle

Disease monitoring:

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

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.

Table 1: Dose reduction levels for gemcitabine and DOCetaxel

Starting Dose	Gemcitabine 675mg/m ²	DOCetaxel 75mg/m ²
Level -1	540 mg/m ²	60 mg/m ²
Level -2	450 mg/m ²	50 mg/m ²
Level-3	Discontinue	Discontinue

Haematological:

Table 2: Dose modifications for haematological toxicity

Day	ANC (x10 ⁹ /L)		Platelets (x10 ⁹ /L)	Dose
1	≥1	and	≥100	100%
	<1	and/or	<100	Delay for 1 week or until recovery
8	≥1	and	≥75	100%
	<1	and/or	<75	Delay for one week, if recovered sufficiently by day 15, the gemcitabine and DOCetaxel can be administered but with a dose reduction as indicated in the table 1 for all subsequent cycles
Febrile Neutropenia 1st occurrence 2nd occurrence				Hold chemotherapy for remainder of cycle and consider addition of GCSF to subsequent cycles. Consider dose reduction by 1 dose level (Table 1)

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Renal and Hepatic Impairment:

Table 3: Dose modifications in renal and hepatic impairment

Drug	Renal Impairment		Hepatic Impairment					
DOCetaxel	Renal impairment: no need for dose adjustment is expected		Serum bilirubin		AST and/or ALT		Alkaline Phosphatase	Dose
			Normal	and	> 1.5 - 5 ULN	and	> 2.5 - 5 ULN	Consider 75 % of the original dose
	Haemodialysis (HD): no need for dose adjustment is expected		< 1-1.5 ULN	and/ or	>5-10 ULN (AST or ALT)	and	< 6 ULN	Consider 50% of the original dose
			> 1.5 ULN	or	> 10 ULN (AST / ALT)	and	> 6 ULN	Not recommended
Gemcitabine	CrCl (mL/min)	Dose	Total Bilirubin (micromol/L)		Dose			
	>30	No dose adjustment is needed	<27		No dose adjustment is needed			
	<30	No need for dose adjustment is expected						
	HD	No need for dose adjustment is expected. Start HD 6-12 hours after administration.	≥27		Either start at 80% of the original dose and increase the dose if tolerated or start with full dose with active monitoring			

ULN = upper limit of normal
Renal and hepatic impairment – Giraud et al 2023

Management of adverse events:

Table 4: Dose Modifications for Adverse Events

Adverse reactions	Recommended dose modification
Grade 2 peripheral neuropathy 1 st occurrence 2 nd occurrence	Reduce dose of gemcitabine and DOCEtaxel by 1 dose level Reduce dose of gemcitabine and DOCEtaxel by 1 dose level
Grade ≥3 Non haematological toxicities	Withhold treatment until toxicity resolved to Grade ≤1 and then reduce dose by 1 level
Severe cutaneous adverse reactions (SCARs) e.g. Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP)	Discontinue gemcitabine

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SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

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

Gemcitabine: Low (Refer to local policy)

DOCEtaxel: Low (Refer to local policy)

For information:

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

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

PREMEDICATIONS:

- dexAMETHasone 8 mg PO twice daily for 3 days, starting one day prior to each DOCEtaxel administration (day 7) unless contraindicated. Patient must receive minimum of 3 doses pre-treatment.

OTHER SUPPORTIVE CARE:

- Prophylactic G-CSF may be used to mitigate the risk of haematological toxicities G-CSF (Refer to local policy)

ADVERSE EFFECTS:

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

REGIMEN SPECIFIC COMPLICATIONS:

Gemcitabine

- Renal Toxicity:** Irreversible renal failure associated with hemolytic uremic syndrome may occur (rare) with gemcitabine. Use caution with pre-existing renal dysfunction.
- Pulmonary Toxicity:** Acute shortness of breath may occur with gemcitabine. Discontinue treatment with gemcitabine if drug-induced pneumonitis is suspected.
- Cardiovascular:** Due to the risk of cardiac and/or vascular disorders with gemcitabine, particular caution must be exercised with patients presenting a history of cardiovascular events.

DOCEtaxel

- Fluid Retention:** dexAMETHasone premedication must be given prior to administration of DOCEtaxel to reduce the incidence and severity of fluid retention. It can also reduce the severity of the hypersensitivity reaction.
- Hypersensitivity Reactions:** Patients should be observed closely for hypersensitivity reactions especially during the first and second infusions. Hypersensitivity reactions may occur within a few minutes following the initiation of the infusion of DOCEtaxel, thus facilities for the treatment of hypotension and bronchospasm should be available. If hypersensitivity reactions occur, minor symptoms such as flushing or localized cutaneous reactions do not require interruption of therapy. However, severe reactions, such as severe hypotension, bronchospasm or generalised

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rash/erythema require immediate discontinuation of DOCEtaxel and appropriate therapy. Patients who have developed severe hypersensitivity reactions should not be re-challenged with DOCEtaxel.

DRUG INTERACTIONS:

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

REFERENCES:

1. Seddon B, Strauss SJ, Whelan J, Leahy M, Woll PJ, Cowie F, et al. Gemcitabine and docetaxel versus doxorubicin as first-line treatment in previously untreated advanced unresectable or metastatic soft-tissue sarcomas (GeDDiS): a randomised controlled phase 3 trial. *Lancet Oncol*. 2017 Oct;18(10):1397–410.
2. University College London. GeDDiS: A prospective randomised controlled phase III trial of gemcitabine and docetaxel compared with doxorubicin as first line treatment in previously untreated advanced unresectable or metastatic soft tissue sarcomas [Internet]. Available from: https://www.ctc.ucl.ac.uk/TrialDocuments/Uploaded/GeDDiS%20Protocol%20v8.0%2022Mar2016_06062017_0.pdf
3. Chouhan et al. Single premedication dose of dexamethasone 20mg IV before DOCEtaxel administration. *J Oncol Pharm Practice* 2010;17(3): 155–159
4. Rogers ES et al. Efficacy and safety of a single dose of dexamethasone pre DOCEtaxel treatment: The Auckland experience. *Annals of Oncology* (2014) 25 (suppl_4): iv517-iv541
5. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: <https://pubmed.ncbi.nlm.nih.gov/37269847/>
6. DOCEtaxel (Taxotere®) 20mg/0.5mL Concentrate and Solvent for Solution for Infusion. Summary of Product Characteristics. Accessed August 2025 Available at: https://www.ema.europa.eu/en/documents/product-information/taxotere-epar-product-information_en.pdf
7. Gemcitabine Teva 40 mg/mL Concentrate for Solution for Infusion Summary of Product Characteristics Accessed August 2025. Available at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2059-039-005_13022020104725.pdf

Version	Date	Amendment	Approved By
1	13/08/2018		Dr Michael McCarthy
2	30/07/2020	Standardisation of treatment table Updated exclusion criteria Standardisation of pre-medication Updated adverse events section	Prof Maccon Keane
3	09/09/2021	Clarification of requirement for non-PVC infusion bag only	Prof Maccon Keane
4	18/11/2025	Regimen Reviewed. Standard Wording updates. Renal and hepatic impairment updated to Giraud et al. Updated adverse events table (Table 3) to include information on SCARs.	Prof Maccon Keane

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Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

ⁱ This regimen is outside its licensed indication in Ireland. Patients should be informed of the unlicensed nature of this indication and consented to treatment in line with the hospital's policy on the use of unlicensed medication and unlicensed or "off label" indications. Prescribers should be aware of their responsibility in communicating any relevant information to the patient and also in ensuring that the unlicensed or "off label" indication has been acknowledged by the hospital's Drugs and Therapeutics Committee, or equivalent, in line with hospital policy.

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