Gemcitabine (800mg/m^2) Monotherapy - 28 Day

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement Status*
For the treatment of advanced breast cancer following two or more lines of therapy	C50	00749a	N/A

*This applies to post 2012 indications only

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 patients individual clinical circumstances.

Gemcitabine is administered on Day 1, 8 and 15 of a 28 day cycle for 6 to 8 cycles or until disease progression or unacceptable toxicity develops.

Facilities to treat anaphylaxis MUST be present when the systemic anti-cancer therapy (SACT) is administered.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1, 8, 15	Gemcitabine	800mg/m^2	IV infusion	250mL NaCl 0.9% over 30 minutes	Every 28 days

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

ELIGIBILITY:

- Indication as above
- ECOG 0-2
- Adequate marrow reserve (ANC >1.5 x10^9/L, platelets >100x10^9/L)
- Adequate renal (creatinine ≤ 1.5xULN) and liver (transaminase levels ≤ 3xULN) function

EXCLUSIONS:

- Hypersensitivity to gemcitabine or any of the excipients
- Pregnancy
- Breast feeding

PRESCRIPTIVE AUTHORITY:

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

TESTS:

Baseline tests:

- FBC, renal and liver profile

Regular tests:

- FBC prior to each treatment
- 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 test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.

Haematological:

Prior to commencing a new treatment cycle (i.e. day 1), ANC must be >1x10^9/L and platelets >100x10^9/L.

Dose modifications for **gemcitabine within a cycle (i.e. day 8 and 15)**

Table 1: Dose modifications for gemcitabine within a cycle (i.e. day 8 and 15)

ANC (x 10^9 /L)		Platelet count (x 10^9 /L)		Other toxicity	Recommended dose of Gemcitabine
>1	and	> 100			100%
0.5- 1	or	50-100			75%
<0.5	or	<50			Omit. Do not restart treatment until ANC >0.5 and platelets >50
ANC <0.5 for >5 days **or** ANC <0.1 for >3 days **or** Any incidence of febrile neutropenia	**or**	< 25	**or**	cycle delay of >1 week due to any toxicity	Reduce dose to 75% of the original cycle initiation dose for all subsequent cycles.

Renal and Hepatic Impairment:

Table 2: Dose modification of gemcitabine in renal and hepatic impairment

Renal Impairment		Hepatic Impairment	
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	≥27	Either start at 80% of the original dose and increase the dose if tolerated or start with full dose with active monitoring
Haemodialysis	No need for dose adjustment is expected. Start haemodialysis 6-12 hours after administration.		

Management of adverse events:

Table 3: Dose Modification of gemcitabine for Adverse Events

Adverse reactions	Recommended dose modification
Grade > 3 Non-haematological toxicity (except nausea/vomiting)	Therapy with gemcitabine should be withheld (until toxicity has resolved to grade ≤1) and may be resumed with 50% dose reduction or treatment discontinued at discretion of prescribing consultant.
Grade > 4 Non-haematological toxicity	Discontinue treatment

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in the NCCP Classification Document for Systemic Anti-cancer Therapy (SACT) Induced Nausea and Vomiting - link here
- Low **(Refer to local policy)**

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) - link here
- NCCP Supportive Care Antiemetic Medicines for Inclusion in NCIS (Haemato-oncology) - link here

PREMEDICATIONS: None usually required

OTHER SUPPORTIVE CARE: No specific recommendations

ADVERSE EFFECTS:

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

DRUG INTERACTIONS:

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

REFERENCES:

1. Modi S et al. A Phase II Trial of Gemcitabine in Patients with Metastatic Breast Cancer Previously Treated with an Anthracycline and Taxane. Clin Breast Cancer 2005 Apr;6(1):55-60
2. BCCA Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using Gemcitabine http://www.bccancer.bc.ca/chemotherapy-protocols-site/Documents/Breast/BRAVGEM_Protocol.pdf
3. 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/
4. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V5 2023. Available at: https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf
5. Gemcitabine Summary of Product Characteristics Last updated: 15/03/2024. Accessed May 2024. Available at: https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2059-039-002_15032024145253.pdf

Version	Date	Amendment	Approved By
1	26/08/2024		Prof Michaela Higgins

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