DACTINomycin Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
Alternative treatment of low risk gestational trophoblastic neoplasia (GTN) (FIGO score ≤ 6).	D39	00247a	Hospital

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.

DACTINomycin is administered every **14 days** until human chorionic gonadotropin (hCG) levels fall below the upper limit of normal or unacceptable toxicity develops.
Treatment should be continued for 3 cycles of maintenance treatment after hCG normalisation.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	**DACTINomycin**	2mg	IV bolus	n/a	Every 14 days (see note above)

ELIGIBILITY:

- Indications as above
- Women with low-risk GTN who have not responded to methotrexate with a hCG <1,000 IU/L

EXCLUSIONS:

- Hypersensitivity to DACTINomycin or any of the excipients

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Serum hCG using a validated test method

Regular tests:

- FBC, renal and liver profile prior to each cycle.
- Serum hCG (using a validated test method) should be done on day one of each cycle or more frequently if required.
    - After remission is achieved, serum hCG (using a validated test method) should be measured fortnightly for six months then monthly for a further six months and every two months for two years.

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:

- Due to the curative aim of treatment, dose modifications should be avoided and made only made after discussion with the Consultant in charge of treatment.
- G-CSF support may be considered.

Renal and Hepatic Impairment:

Table 1: Dose modification of DACTINomycin in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
Clinical decision – unlikely to require a reduction.	Consider dose reduction in severe hepatic disease.

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Moderate **(Refer to local policy).**

PREMEDICATIONS: Not usually required.

OTHER SUPPORTIVE CARE: G-CSF may be used to mitigate the risk of haematological toxicities.

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS:

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated appropriately.
- **Extravasation:** DACTINomycin causes pain and tissue necrosis if extravasated.

DRUG INTERACTIONS:

- No known drug interactions except for increased risk of infection with live vaccines.
- Current drug interaction databases should be consulted for more information.

REFERENCES:

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2. NCCP National Clinical Guideline (Draft) - Diagnosis, staging and treatment of patients with Gestational Trophoblastic Disease. July 2021.
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4. Charing Cross Gestational Trophoblast Disease Service. Chemotherapy Regimens For Trophoblast Disease. Available at: https://hmole-chorio.org.uk/info-for-clinicians/clinicians_info_chemo_regimens/
5. Dosage Adjustment for Cytotoxics in Renal Impairment January 2009; North London Cancer Network.
6. Dosage Adjustment for Cytotoxics in Hepatic Impairment January 2009; North London Cancer Network.
7. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V3 2021. 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
8. DACTINomycin (COSMEGEN® LYOVAC). Summary of Product Characteristics. Last updated: 21/10/2019. Accessed October 2020 Available at: https://www.medicines.org.uk/emc/product/5360 http://www.hse.ie/eng/services/list/5/cancer/profinfo/guidelines/gtd/gtdguideline.pdf

Version	Date	Amendment	Approved By
1	01/02/2016		Prof Maccon Keane
2	07/02/2018	Updated with new NCCP regimen template, updated title	Prof Maccon Keane
3	07/01/2021	Updated treatment dosing and schedule, updated eligibility, updated hCG monitoring requirements	Prof Seamus O'Reilly
4	22/10/2021	Updated hCG testing (added to baseline tests, updated in regular tests).	Prof. Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.