

DACTINomycin Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
Alternative treatment of low risk gestational trophoblastic neoplasia (GTN) (FIGO score \leq 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 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

Regular tests:

- FBC, renal and liver profile prior to each cycle
- Serum hCG/blood should be done on day one of each cycle or more frequently if required.

NCCP Regimen: DACTINomycin Therapy	Published: 01/02/2016 Review: 06/01/2026	Version number: 3
Tumour Group: Gynaecology NCCP Regimen Code: 00247	ISMO Contributor: Prof Maccon Keane, Prof Seamus O'Reilly	Page 1 of 3
<p>The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer</p> <p><i>This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPchemoregimens</i></p>		

- After remission is achieved, serum hCG should be measured fortnightly for six months then monthly for a further six months and then 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 2: 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.

ATC CODE:

DACTINomycin L01DA01

NCCP Regimen: DACTINomycin Therapy	Published: 01/02/2016 Review: 06/01/2026	Version number: 3
Tumour Group: Gynaecology NCCP Regimen Code: 00247	ISMO Contributor: Prof Maccon Keane, Prof Seamus O'Reilly	Page 2 of 3
<p>The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer</p> <p><i>This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPchemoregimens</i></p>		

REFERENCES:

1. Lurain JR, Chapman-Davis E, Hoekstra AV & Schink JC. Actinomycin D for methotrexate-failed low-risk gestational trophoblastic neoplasia. *J Reprod Med* 2012;57(7-8):283-7
2. Dosage Adjustment for Cytotoxics in Renal Impairment January 2009; North London Cancer Network. Available at <http://londoncancer.org/media/65600/renal-impairment-dosage-adjustment-for-cytotoxics.pdf>
3. Dosage Adjustment for Cytotoxics in Hepatic Impairment January 2009; North London Cancer Network. Available at <http://londoncancer.org/media/65594/hepatic-impairment-dosage-adjustment-for-cytotoxics.pdf>
4. 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>
5. <http://www.hse.ie/eng/services/list/5/cancer/profinfo/guidelines/gtd/gtdguideline.pdf>
6. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V2 2019. 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>

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

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

NCCP Regimen: DACTINomycin Therapy	Published: 01/02/2016 Review: 06/01/2026	Version number: 3
Tumour Group: Gynaecology NCCP Regimen Code: 00247	ISMO Contributor: Prof Maccon Keane, Prof Seamus O'Reilly	Page 3 of 3
<p>The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer</p> <p><i>This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPchemoregimens</i></p>		