

BC Cancer Protocol Summary For Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with DOCEtaxel

Protocol Code: HNAVDOC
Tumour Group: Head and Neck
Contact Physician: Dr. Cheryl Ho

ELIGIBILITY:

- Recurrent or metastatic squamous cell carcinoma of the head and neck including primary unknown
- ECOG performance status 0, 1 or 2

TESTS:

- Baseline: CBC & differential, platelets, bilirubin, ALT, Alk Phos, albumin.
 - If clinically indicated: GGT, LDH.
 - Before each treatment: CBC & differential, platelets
 - Before Cycle 4 and anytime if clinically indicated*: bilirubin, ALT, Alk Phos, GGT, LDH
- *See Precaution #5 for guidelines regarding hepatic dysfunction

PREMEDICATIONS:

- Dexamethasone 8 mg PO bid for 3 days starting one day prior to each administration of DOCEtaxel
- A minimum of 3 doses of dexamethasone pre-treatment are required
- Additional antiemetics are not usually required
- DOCEtaxel-induced onycholysis and cutaneous toxicity of the hands may be prevented by wearing frozen gloves starting 15 minutes before DOCEtaxel infusion until 15 minutes after end of DOCEtaxel infusion; gloves should be changed after 45 minutes of wearing to ensure they remain cold during the entire DOCEtaxel infusion.

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
DOCEtaxel	75 mg/m ²	IV in NS or D5W 250 to 500 mL over 1 hour (use non-DEHP equipment)

- Repeat every 21 days x 6 cycles
- Discontinue if no clinical benefit after 2 cycles

DOSE MODIFICATIONS:

1. Hematology

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose*
greater than or equal to 1.5	and	greater than 100	100%
1 to 1.49	or	75 to 100	75%
less than 1	or	less than 75	Delay
*Consider decreasing DOCEtaxel to 75% if an episode of febrile neutropenia occurs with the prior cycle of treatment			

2. **Hepatic dysfunction:**

Alkaline phosphatase		ALT	Dose
less than 2.5 x ULN	and	less than 1.5 x ULN	100%
2.5 to 5 x ULN	and	1.5 to 5 x ULN	75%
greater than 5 x ULN	or	greater than 5 x ULN	Delay*
*Discuss with contact physician			

ULN = upper limit of normal

PRECAUTIONS:

1. **Fluid retention:** Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.
2. **Hypersensitivity** reactions to DOCEtaxel are common but it is not necessary to routinely initiate the infusion slowly. If slow initiation of infusion is needed, start infusion at 30 mL/h x 5 minutes, then 60 mL/h x 5 minutes, then 120 mL/h x 5 minutes, then complete infusion at 250 mL/h (for 500 mL bag, continue 250 mL/h for 5 minutes and then complete infusion at 500 mL/h). Refer to BC Cancer Hypersensitivity Guidelines.
3. **Extravasation:** DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.
4. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
5. **Hepatic Dysfunction:** DOCEtaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST) may lead to increased toxicity and usually requires a dose reduction. Baseline liver enzymes are recommended before cycle 1 and then if clinically indicated (eg, repeat liver enzymes prior to each treatment if liver enzymes are elevated, liver metastases are present or there is severe toxicity such as neutropenia). If liver enzymes are normal and there is no evidence of liver metastases or severe toxicity, check liver enzymes after 3 cycles (ie, at cycle 4). Note: this information is intended to provide guidance but physicians must use their clinical judgment when making decisions regarding monitoring and dose adjustments.

Call Dr. Cheryl Ho or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

REFERENCES:

1. Guardiola E, Peyrade F, Chaigneau L, et al. Results of a randomised phase II study comparing docetaxel with methotrexate in patients with recurrent head and neck cancer. *Eur J Cancer* 2004;40(14):2071-6.
2. Couteau C, Chouaki N, Leyvraz S, et al. A phase II study of docetaxel in patients with metastatic squamous cell carcinoma of the head and neck. *Br J Cancer* 1999;81(3):457-62.
3. Dreyfuss AI, Clark JR, Norris CM, et al. Docetaxel: an active drug for squamous cell carcinoma of the head and neck. *J Clin Oncol* 1996;14(5):1672-8.
4. Catimel G, Verweij J, Mattijssen V, et al. Docetaxel (Taxotere): an active drug for the treatment of patients with advanced squamous cell carcinoma of the head and neck. EORTC Early Clinical Trials Group. *Ann Oncol* 1994;5(6):533-7.