BC Cancer Protocol Summary for Palliative Treatment of Metastatic Esophagogastric Adenocarcinoma with DOCEtaxel

Protocol Code	*GIAVDOC*
Tumour Group	*Gastrointestinal*
Contact Physician	*GI Systemic Therapy*

ELIGIBILITY:

Patients must have:

- Metastatic esophagogastric adenocarcinoma unsuitable for, or who have progressed on, platinum-based chemotherapy

Patients should have:

- Adequate marrow reserve, renal and hepatic function
- ECOG status 0 to 2

EXCLUSIONS:

Patients must not have:

- Previous treatment with a taxane
- Grade 2 to 4 peripheral neuropathy

TESTS:

- Baseline: CBC & Diff, creatinine, ALT, alkaline phosphatase, total bilirubin, albumin, sodium, potassium
- Baseline if clinically indicated: CEA, CA 19-9, GGT, ECG
- Before each treatment: CBC & Diff, creatinine, total bilirubin, ALT
- If clinically indicated: CEA, CA 19-9, alkaline phosphatase, albumin, GGT, sodium, potassium, ECG
- For patients on warfarin, weekly INR during DOCEtaxel therapy until stable warfarin dose established, then INR prior to each cycle

PREMEDICATIONS:

- dexamethasone 8 mg PO bid for 3 days, starting one day prior to each DOCEtaxel administration; patient must receive minimum of 3 doses pre-treatment
- Additional antiemetics 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.

Warning: The information contained in these documents are a statement of consensus of BC Cancer 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 at your own risk and is subject to BC Cancer's terms of use available at http://www.bccancer.bc.ca/terms-of-use

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
DOCEtaxel	75 mg/m^2	IV in 250 to 500 mL NS over 1 hour (see Precaution #2 (Use non-DEHP equipment)

Repeat every 21 days until disease progression or unacceptable toxicity.

DOSE MODIFICATIONS:

1. **Hematological**

ANC (x10^9/L)		Platelets (x10^9/L)	Dose	Dose after Neutropenic Sepsis on DOCEtaxel
Greater than or equal to 1.5	and	Greater than or equal to 100	100%	75%
1.0 to less than 1.5	or	75 to less than 100	75 %	75%
Less than 1.0	or	Less than 75	Delay*[1]	Delay*[1]

* if ANC recovers within 14 days, then treatment re-started at 100%
[1] if lengthy grade 4 neutropenia (ANC less than 0.5 x10^9/L) for more than 7 days, then dose reduce to 55 mg/m^2.

2. **Hepatic dysfunction:**

Alkaline Phosphatase		AST or ALT	Dose
Less than 2.5 x ULN	and	Less than or equal to 1.5 x ULN	100%
2.5 to 5 x ULN	and	1.6 to 6 x ULN	75%
Greater than 5 x ULN	or	Greater than 5 ULN	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 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 Protocol Summary for Management of Infusion-Related Reactions to Systemic Therapy Agents: SCDRUGRX .
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. Refer to BC Cancer Febrile Neutropenia Guidelines.
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 (e.g., 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

Warning: The information contained in these documents are a statement of consensus of BC Cancer 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 at your own risk and is subject to BC Cancer's terms of use available at http://www.bccancer.bc.ca/terms-of-use

liver enzymes after 3 cycles (i.e., 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 the GI Systemic Therapy physician at your regional cancer centre or the GI Systemic Therapy Chair Dr. Theresa Chan at (604) 930-2098 with any problems or questions regarding this treatment program.

References:

1. Ford HER, Marshall A, Bridgewater JA et al. Docetaxel versus active symptom control for refractory oesophagogastric adenocarcinoma (COUGAR-02): an open-label, phase 3 randomised controlled trial. Lancet Oncol 2014;15:78-86.

Warning: The information contained in these documents are a statement of consensus of BC Cancer 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 at your own risk and is subject to BC Cancer's terms of use available at http://www.bccancer.bc.ca/terms-of-use