

BC Cancer Protocol Summary for Maintenance Therapy of Advanced Non-Small Cell Lung Cancer (NSCLC) With Pemetrexed

Protocol Code:

LUAVPMTN

Tumour Group:

Lung

Contact Physician:

Dr. Barb Melosky

ELIGIBILITY:

- Advanced non-small cell lung cancer
 - Restricted to disease of *non-squamous cell* histology
- No disease progression after 4-6 cycles of platinum-based doublet with or without pemetrexed
- Maintenance pemetrexed is to be started 21 to 42 days after the final cycle of the platinum-based doublet
- ECOG performance status 0-1 at start of maintenance

EXCLUSIONS:

- ECOG 2-4

TESTS:

- Baseline: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH
- Before each treatment: CBC & Diff, alkaline phosphatase, ALT, total bilirubin, LDH
- If clinically indicated: creatinine

PREMEDICATIONS:

- **Vitamin supplementation mandatory** starting at least 7 days prior to the first cycle, and to continue while on treatment until 21 days after last Pemetrexed dose:
 - folic Acid 0.4 mg PO daily
 - vitamin B12 1000 mcg IM every 9 weeks
- Prophylaxis for skin rash: dexamethasone 4 mg PO BID for 3 days, beginning the day before chemotherapy. (May proceed with chemotherapy even if patient has not taken the pre-treatment dexamethasone doses. Instruct patient to begin immediately.)

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
pemetrexed	500 mg/m ²	IV in 100 mL NS over 10 minutes

- Repeat every 21 days until disease progression or unacceptable toxicity

DOSE MODIFICATIONS:**1. HEMATOLOGY**

Based on day 1 counts

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
Greater than or equal to 1.5	and	Greater than or equal to 100	100%
Less than 1.5	or	Less than 100	Delay

2. RENAL DYSFUNCTION

Creatinine Clearance (mL/min)	Dose
Greater than or equal to 45	100%
Less than 45	Delay

3. MUCOSITIS

For next cycle

Mucositis Grade	Dose
0-2	100%
3-4	50% previous dose*
*Discontinue treatment after two dose reductions	

4. OTHER TOXICITIES

For any other grade 3 or higher toxicity, delay treatment until toxicity resolves, then resume with 25% dose decrease if considered appropriate to resume by attending oncologist

PRECAUTIONS:

1. **Vitamin supplements:** Appropriate prescription of folic Acid and vitamin B12 is essential. The incidence of adverse events such as febrile neutropenia related to pemetrexed is higher without vitamin supplementation.
2. **NSAIDs:** Concurrent nonsteroidal anti-inflammatory agents should be avoided as they may decrease the renal clearance of pemetrexed.
3. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.

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

REFERENCES:

1. Ciuleanu T, Brodowicz T, Zielinski C, et al. Maintenance pemetrexed plus best supportive care versus placebo plus best supportive care for non-small-cell lung cancer: a randomised, double-blind, phase 3 study. *Lancet* 2009;374:1432-40.
2. Paz-Ares L, de Marinis F, Dediu M, et al. Maintenance therapy with pemetrexed plus best supportive care versus placebo plus best supportive care after induction therapy with pemetrexed plus cisplatin for advanced non-squamous non-small-cell lung cancer (PARAMOUNT): a double-blind, phase 3, randomised controlled trial. *Lancet Oncol* 2012;13:247–55.