

# BCCA Protocol Summary for Treatment of Adrenal Cortical Cancer with Mitotane

**Protocol Code:** ENMITO

**Tumour Group:** Endocrine

**Contact Physician:** Dr. Joseph Connors

## ELIGIBILITY:

- Adjuvant treatment or treatment for local recurrence or metastases of primary adrenal cortical tumours
- ECOG 0, 1, 2

## TESTS:

- Baseline: CBC & diff, lytes, LFT's, and DHEAS, 24 hour urinary cortisol or serum cortisol
- CBC & diff, lytes, creatinine, AST, alk phos, bilirubin every 4-6 weeks while adjusting doses, then every 1 to 3 months during treatment
- DHEAS or 24 hour urinary cortisol or serum cortisol, if appropriate for patients with functioning tumours, to be measured after on stable tolerated dose for four weeks, then every 3-4 months along with other tumour measures and imaging.

## PREMEDICATIONS:

- none

## TREATMENT:

Drug	Dose	BCCA Administration Guidelines
Mitotane	Starting dose is 2 gm daily in 4 divided doses; then escalate by 1 gm per day once every 1-2 weeks to maximum tolerated dose. Usual dose limiting toxicity is anorexia and nausea.	PO
Cortisone acetate	25 mg every morning and 12.5 mg every evening. Omit if patient has increased levels of serum cortisol	PO
Fludrocortisone acetate	0.1 mg every morning Omit if patient has increased levels of serum cortisol	PO

- Continue treatment as long as there is a clinical benefit and no excessive toxicity
- An adequate trial is three months at the maximum tolerated dose

**DOSE MODIFICATIONS:**

- Contact Dr. Joseph Connors or Dr. Meg Knowing for more information.

**PRECAUTIONS:**

**Hypoadrenalism:** Mitotane will cause potentially permanent **hypoadrenalism**. Patients must take cortisone acetate and fludrocortisone acetate as above and continue them even after mitotane is discontinued. In the event of physiologic stress, glucocorticoid supplementation should be given. Occasional patients will require lifelong replacement even after mitotane is stopped, so it should not be discontinued without evaluation for adequate adrenal function. Patients with functioning tumours produce excessive cortisol. Replacement with gluco- and mineralocorticoid should not be started until cortisol levels have been documented to fall to normal or below.

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

Date Activated: N/A

Date revised: 01 May 2009 (unsafe abbreviations and symbols replaced)

**References:**

1. Cancer: principles & practice of oncology. 5<sup>th</sup> ed. DeVita VT, Hellman S, Rosenberg SA, eds. Philadelphia: Lippincott-Raven, 1997.
2. Harrison's principles of internal medicine. 14<sup>th</sup> ed. AS Fauci et al. eds. New York: McGraw-Hill, 1998.
3. Van Slooten H, Moolenaar AJ, Seters AP, Smeenk D. The treatment of adrenocortical carcinoma with o,p'-DDD prognostic simplifications of serum level monitoring. Eur J Cancer Clin Oncol 1984;20:47-53.