

MITOTANE (Lysodren)

INDICATION (ICD10) C74

1. Inoperable metastatic adrenal cortical carcinoma of both functional and non-functional types
2. Adjuvant high risk adrenocortical carcinoma

REGIMEN

MITOTANE start at 2-6g, increased incrementally to 9-10g per day in 2 or 3 divided doses

CYCLE FREQUENCY AND NUMBER OF CYCLES

Continuously as long as clinical benefits are observed.

If after 3 months at the maximum tolerated dose no clinical benefits are observed, the case would generally be considered a clinical failure

ADMINISTRATION

Available as 500mg tablets

Swallowed whole with water with fat-rich meal

ANTI-EMETICS

Minimal emetic risk

CONCURRENT MEDICATION REQUIRED

Mitotane	Hydrocortisone 20-30mg daily in divided doses
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EXTRAVASATION AND TYPE OF LINE / FILTERS

Not applicable

INVESTIGATIONS

Blood results required before SACT administration

FBC, U&E and LFTs every cycle

Neutrophils x $10^9/L$ ≥ 1.5

Platelets x $10^9/L$ ≥ 100

Mitotane levels

Baseline weight and every cycle

Blood pressure every cycle

Thyroid function baseline then every 3 cycles

MAIN TOXICITIES AND ADVERSE REACTIONS

Mitotane	Gastrointestinal disturbances - anorexia, nausea or vomiting, diarrhoea. Central Nervous System – depression, lethargy and somnolence, dizziness or vertigo. Skin toxicity - transient skin rashes this side effect subsided while the patients were maintained on the drug without a change of dose. Visual blurring, diplopia, lens opacity, toxic retinopathy). Haematuria, hemorrhagic cystitis, and albuminuria Hypertension, orthostatic hypotension, and flushing
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INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS

(not exhaustive list check SPC/BNF/Stockleys)

Mitotane	Many interactions check carefully
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DOSE MODIFICATIONS

If severe side effects appear, the dose should be reduced until the maximum tolerated dose is achieved.

If the patient can tolerate higher doses and improved clinical response appears possible, the dose should be increased until adverse reactions interfere. Experience has shown that the maximum tolerated dose will vary from 2 to 16g per day, but has usually been 9 to 10g per day. The highest doses used in the studies to date were 18 to 19g per day.

REFERENCES

1. Fassnacht, M et al; NEJM 2012; 366 (23): 2189–2197