

MEDICINES CONTROL COUNCIL APPROVED MINIMUM PARAMETERS THAT THE VETERINARIAN SHOULD COMPLY WITH FOR LYSODREN (MITOTANE) SECTION 21 APPLICATIONS

PURPOSE

To request the South African Veterinary Council (SAVC) to inform the practising veterinarians of the Medicines Control Council (MCC) resolution and approval of minimum parameters that the veterinarian should comply with for Lysodren (Mitotane) Section 21 applications.

REQUEST

The MCC, in its meeting of 18 March 2010 resolved that Lysodren Section 21 requests will be considered on merit basis, taking into consideration approval of minimum parameters that the veterinarian should comply with for diagnosis of Cushing's disease.

An authorisation to use Lysodren should be restricted for use on cases that qualify on the following grounds:

1. A convincing clinical presentation (appetite good, weight gain/ obesity/ pendulous abdomen, skin/hair coat abnormalities);
2. A dog in the appropriate age group (over 5 years of age);
3. A laboratory work-up that includes:
 - a. ALT (L-alanine aminotransferase) elevated; and/or
 - b. ALP (alanine aminophosphatase) elevated;
 - c. Urine Specific Gravity is low (less than 1.015) (especially if polyuria/ polydypsia is undocumented or not convincingly reported);
4. One of the dynamic adrenal function tests (ACTH stim test or LDDST (Low Dose Dexamethasone stimulation test) is diagnostic;
5. Adrenal ultrasonography by an appropriately experienced / qualified ultrasonographer showing bilateral adrenomegaly or unilateral adrenomegaly;
6. Sudden Acquired Retinal Degeneration Syndrome (SARDS) and Diabetes Mellitus have been ruled out.