Relaxo

Dantrolene Sodium USP

Composition
Relaxo 25 mg Capsule : Each capsule contains 25 mg of Dantrolene Sodium USP.
Relaxo 50 mg Capsule : Each capsule contains 50 mg of Dantrolene Sodium USP.

Pharmacology
Relaxo produce relaxation by affecting the contractile response of the skeletal muscle at a site beyond the myoneural junction, directly on the muscle itself. In skeletal muscle, **Relaxo** dissociates the excitation-contraction coupling, probably by interfering with the release of Ca++ from the sarcoplasmic reticulum.

Indications
In Chronic Spasticity: Relaxo is indicated in controlling the manifestations of clinical spasticity resulting from upper motor neuronal disorders (e.g., spinal cord injury, stroke, cerebral palsy, or multiple sclerosis). It is of particular benefit to the patients whose functional rehabilitation has been retarded by the sequelae of spasticity. Such patients must have presumably reversible spasticity where relief of spasticity will aid in restoring residual function.
Relaxo is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.
Occasionally, subtle but meaningful improvement in spasticity may occur with **Relaxo** therapy. In such instances, information regarding improvement should be solicited from the patient.
Brief withdrawal of **Relaxo** for a period of 2 to 4 days will frequently demonstrate exacerbation of the manifestations of spasticity and may serve to confirm a clinical impression.
A decision to continue the administration of **Relaxo** on a long-term basis is justified if introduction of the drug into the patient's regimen:
-produces a significant reduction in painful and/or disabling spasticity such as clonus, or
-permits a significant reduction in the intensity and/or degree of nursing care required, or
-rids the patient of any annoying manifestation of spasticity considered important by the patient himself.
In Malignant Hyperthermia: Oral **Relaxo** is also indicated preoperatively to prevent or attenuate the development of signs of malignant hyperthermia in known, or strongly suspect, malignant hyperthermia susceptible patients who require anesthesia and/or surgery. Oral **Relaxo** should be administered following a malignant hyperthermic crisis to prevent recurrence of the signs of malignant hyperthermia.

Dosage and administration
For Use in Chronic Spasticity: Adults: The following gradual titration schedule is suggested. Some patients will not respond until higher daily dosage is achieved. Each dosage level should be maintained for seven days to determine the patient's response. If no further benefit is observed at the next higher dose, dosage should be decreased to the previous lower dose.
Starting dose is 25 mg twice per day and it can be increased to 25-50 mg per day per week. Maximum accepted dosage is 400 mg per day.
Paediatric Patients: The following gradual titration schedule is suggested. Some patients will not respond until higher daily dosage is achieved. Each dosage level should be maintained for seven days to determine the patient's response. If no further benefit is observed at the next higher dose, dosage should be decreased to the previous lower dose.
0.5 mg/kg once daily for seven days, then 0.5 mg/kg 3 times for 7 days, 1 mg/kg 3 times for 7 days, 2 mg/kg 3 times a day, Therapy with a dose 4 times daily may be necessary for some individuals.

For Malignant Hyperthermia
Preoperatively: Administer 4 to 8 mg/kg/day of oral **Relaxo** in 3 or 4 divided doses for one or two days prior to surgery, with the last dose being given approximately 3 to 4 hours before scheduled surgery with a minimum of water.
Post Crisis Follow-up: Oral **Relaxo** should also be administered following a malignant hyperthermia crisis, in doses of 4 to 8 mg/kg per day in four divided doses, for a one to three day period to prevent recurrence of the manifestations of malignant hyperthermia.

Warnings
In view of the potential for liver damage in long-term **Relaxo** use, therapy should be stopped if benefits are not evident within 45 days.
Information for Patients: Patients should be cautioned against driving a motor vehicle or participating in hazardous occupations while taking **Relaxo**. Caution should be exercised in the concomitant administration of tranquilizing agents. **Relaxo** might possibly evoke a photosensitivity reaction; patients should be cautioned about exposure to sunlight while taking it. It is important to recognize that fatal and non-fatal liver disorders of an idiosyncratic or hypersensitivity type may occur with **Relaxo** therapy. At the start of **Relaxo** therapy, it is desirable to do liver function studies (SGOT, SGPT, alkaline phosphatase, total bilirubin) for a baseline or to establish whether there is pre-existing liver disease. Liver function studies (e.g., SGOT or SGPT) should be performed at appropriate intervals during **Relaxo** therapy. Some patients have revealed a return to normal laboratory values in the face of continued therapy while others have not. If symptoms compatible with hepatitis, accompanied by abnormalities in liver function tests or jaundice appear, **Relaxo** should be discontinued. If caused by **Relaxo** and detected early, the abnormalities in liver function characteristically have reverted to normal when the drug was discontinued. **Relaxo** therapy has been reinstituted in a few patients who have developed clinical and/ or laboratory evidence of hepatocellular injury. If such reinstitution of therapy is done, it should be attempted only in patients who clearly need **Relaxo** and only after previous symptoms and laboratory abnormalities have cleared. The patient should be hospitalized and the drug should be restarted in very small and gradually increasing doses. Laboratory monitoring should be frequent and the drug should be withdrawn immediately if there is any indication of recurrent liver involvement. **Relaxo** should be used with particular caution in females and in patients over 35 years of age in view of apparent greater likelihood of drug-induced, potentially fatal, hepatocellular disease in these groups.

Contraindications
Active hepatic disease, such as hepatitis and cirrhosis.

Precautions
Relaxo should be used with caution in patients with impaired pulmonary function, and in patients with severely impaired cardiac function due to myocardial disease. It should be used with caution in patients with a history of previous liver disease or dysfunction.

Adverse Reactions
The most frequently occurring side effects of **Relaxo** have been drowsiness, dizziness, weakness, general malaise, fatigue, and diarrhea. These are generally transient, occurring early in treatment, and can often be obviated by beginning with a low dose and increasing dosage gradually until an optimal regimen is established. Diarrhea may be severe and may necessitate temporary withdrawal of **Relaxo** therapy. If diarrhea recurs upon readministration of **Relaxo**, therapy should probably be withdrawn permanently.

Pregnancy: Pregnancy Category C: Relaxo capsules should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Nursing Mothers: Relaxo should not be used in nursing mothers.
Usage in Paediatric Patients: The long-term safety of **Relaxo** in paediatric patients under the age of 5 years has not been established. Because of the possibility that adverse effects of the drug could become apparent only after many years, a benefit-risk consideration of the long-term use of **Relaxo** is particularly important in pediatric patients.

Drug Interactions
Drowsiness may occur with **Relaxo** therapy, and the concomitant administration of CNS depressants such as sedatives and tranquilizing agents may result in further drowsiness.
Hepatotoxicity has occurred more often in women over 35 years of age receiving concomitant estrogen therapy.

Storage
Store in a cool & dry place, protected from light

Packaging:
Relaxo 25 mg Capsule : Each carton contains 3 x 10's capsules in blister strips.
Relaxo 50 mg Capsule : Each carton contains 3 x 8's capsules in blister strips.

Manufactured by

ZISKA PHARMA

Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh