# Reelife®

## Chlordiazepoxide USP and Amitriptyline Hydrochloride USP Film Coated Tablet

#### DESCRIPTION

Reelife® and Reelife® DS are a combined preparation of Chlordiazepoxide USP and Amitriptyline Hydrochloride USP. Both the drugs exert their action in the central nervous system. Extensive studies with Chlordiazepoxide in many animal species suggest action in the limbic system. Recent evidence indicates that the limbic system is involved in emotional response. Taming action was observed in some species. The mechanism of action of Amitriptyline in man is not known, but the drug appears to interfere with the reuptake of norepinephrine into adrenergic nerve endings. This action may prolong the sympathetic activity of biogenic amines.

#### INDICATIONS

For the treatment of patients with moderate to severe depression associated with moderate to severe anxiety.

### **DOSAGE AND ADMINISTRATION**

Reelife®: Recommended in an initial dosage of 3 or 4 tablets daily in divided doses may be satisfactory in patients who do not tolerate higher doses. Some patients respond to smaller doses and can be maintained on 2 tablets daily.

Reelife® DS (Double Strength): Recommended in an initial dosage of 3 or 4 tablets daily in divided doses; this may be increased to 6 tablets daily as required. Some patients respond to smaller doses and can be maintained on 2 tablets daily.

#### **CONTRAINDICATIONS**

Chlordiazepoxide and Amitriptyline combination is contraindicated in patients with hypersensitivity to either benzodiazepines or tricyclic antidepressants. It should not be given concomitantly with a monoamine oxidase inhibitor. Hyperpyretic crises, severe convulsions and deaths have occurred in patients receiving a tricyclic antidepressant and a monoamine oxidase inhibitor simultaneously.

#### SIDE EFFECTS

Headache, weight gain or loss
Skin rash, urticaria
Euphoria, apprehension
Hypotension, hypertension

#### PRECAUTION AND WARNING

Close supervision is required when Chlordiazepoxide and Amitriptyline combination is given to hyperthyroid patients or those on thyroid medication. The usual precautions should be observed when treating patients with impaired renal or hepatic function. Patients with suicidal ideation should not have easy access to large quantities of the drug. The possibility of suicide in depressed patients remains until significant remission occurs.

To be dispensed only by the prescription of a registered physician.

## **USE IN PREGNANCY AND LACTATION**

Safe use of Chlordiazepoxide and Amitriptyline combination during pregnancy and lactation has not been established. It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug, since many drugs are excreted in human milk.

#### PHARMACEUTICAL PRECAUTION

Store below 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

#### **PACKAGING**

## Reelife® Tablet:

Box containing 4 strips of 14 tablets each. Each tablet contains Chlordiazepoxide USP 5 mg and Amitriptyline Hydrochloride USP equivalent to Amitriptyline 12.5 mg.

## Reelife® DS Tablet:

Box containing 3 strips of 10 tablets each. Each tablet contains Chlordiazepoxide USP 10 mg and Amitriptyline Hydrochloride USP equivalent to Amitriptyline 25 mg.



Manufactured by

# **ESKAYEF PHARMACEUTICALS LTD.**

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