Norzim

Chlordiazepoxide USP 5 mg &
Amitriptyline USP 12.5 mg

COMPOSITION
Each film coated tablet contains Chlordiazepoxide USP 5 mg & Amitriptyline Hydrochloride USP equivalent to Amitriptyline 12.5 mg.

PHARMACOLOGY
Chlordiazepoxide belongs to a class of drug known as benzodiazepine. It helps to reduce anxiety. It acts on the brain and nerves to produce a calming effect. Amitriptyline is a tricyclic antidepressant. It helps to improve mood and feelings of well-being, relieve depression and tension. It works by affecting the balance of serotonin in the brain. This combination (Chlordiazepoxide & Amitriptyline) is used to treat mental/mood disorders such as depression with symptoms of anxiety.

INDICATIONS
Norzim tablet is indicated for the treatment of patients with moderate to severe depression associated with moderate to severe anxiety, insomnia, feelings of guilt or worthlessness, agitation, psychic and somatic anxiety, suicidal ideation and anorexia.

DOSAGE AND ADMINISTRATION
The initial dosage of 3 or 4 tablets daily in divided doses is satisfactory. When a satisfactory response is obtained, dosage should be reduced to the smallest amount needed to maintain the remission. In some patients, a single dose at bedtime may be sufficient. In general, lower dosages are recommended for elderly patients.

CONTRAINDICATIONS
This 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 convulsion have occurred in patients receiving a tricyclic antidepressant and a monoamine oxidase inhibitor simultaneously.

ADVERSE REACTIONS
Drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating.

PRECAUTIONS
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.

USE IN SPECIAL GROUPS
Use in pregnancy: Safety of this combination during pregnancy has not been established.
Use in nursing mothers: It is not known whether this drug is excreted in human milk. Since many drugs are excreted in human milk, caution should be exercised when it is administered to a nursing mother.
Pediatric use: Safety and effectiveness in the pediatric patients have not been established.
Geriatric use: In elderly patients it is recommended to start at the smallest effective dose.
Hepatic Insufficiency: In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic function.
Renal Insufficiency: The components of this preparation are known to be substantially excreted by the kidney and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

DRUG INTERACTIONS
Because of its Amitriptyline component, this combination may block the antihypertensive action of guanethidine or compounds with a similar mechanism of action.

STORAGE
- Store below 30°C, keep in dry place & protect from light.
- Keep out of reach of children.

PACKING
Each box contains 50 tablets in Alu-Alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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