220mm

Pralzo® Tablets

(Alprazolam)

DESCRIPTION:

Pralzo® tablets contain alprazolam which is a triazolo analog of the 1, 4 benzodiazepine class of central nervous system active compounds

COMPOSITION:

Pralzo® 0.5mg Tablets
Each tablet contains:
Alprazolam USP.....0.5mg

PHARMACOLOGY:

Mechanism of Action

The exact mechanism of action of alprazolam is unknown. Benzodiazepines bind to gamma amino butyric acid (GABA) receptors in the brain and enhances GABA-mediated synaptic inhibition; such actions may be responsible for the efficacy of alprazolam in anxiety disorder and panic disorder

PHARMACOKINETICS:

Absorption

Following oral administration, alprazolam is readily absorbed. Peak concentrations in the plasma occur in 1 to 2 hours following administration. The mean plasma elimination half-life of alprazolam has been found to be about 11.2 hours (range: 6.3–26.9 hours) in healthy adults

Distribution

Alprazolam is 80% bound to human serum protein. Serum albumin accounts for the majority of the binding

Metabolism

Alprazolam is metabolized mainly in liver. The predominant metabolites are α-hydroxyalprazolam and benzophenone derived from Alprazolam. Plasma levels of these metabolites are very low. The biological activity of α-hydroxyalprazolam is approximately one half that of parent compound

Excretion

Alprazolam and its metabolites are excreted primarily in the urine

INDICATIONS:

Pralzo® (Alprazolam) is indicated for the treatment of:

Anxiety disorders or the short-term relief of symptoms of anxiety

- Anxiety states (anxiety neurosis)
- Mixed anxiety- depression

Panic disorders

Pralzo® (Alprazolam) is indicated for the management of panic disorders with or without agoraphobia

DOSAGE AND ADMINISTRATION:

The optimum dosage of alprazolam should be individualized for maximum beneficial effect. The usual daily doses will meet the needs of most patients. In patients who require higher doses, dosage should be increased cautiously to avoid adverse effects. When higher dosage is required, the evening dose should be increased before daytime doses. In general, patients who have not previously been treated with minor tranquilizers, anti-depressants, or those with history of chronic alcoholism, it is recommended that the general principle of using the lowest effective dosage be followed in elderly or debilitated patients to preclude the development of over sedation or ataxia. Patient should be periodically re-assessed and dosage adjustments made, as appropriate

Indications	Usual Starting Dosage	Maximum Dosage
Anxiety	0.25 to 0.5mg given three times daily	Dose can progressively be increased at 3-4 days interval to a maximum of 4mg a day in divided doses
Panic related disorders	0.5mg given three times daily	Doses can be increased every 3-4 days but not more than 1mg. The maximum daily dose is up to 10mg

If side effects occur, the dose should be lowered

OR

As directed by the physician

DISCONTINUATION THERAPY:

Dosage should be reduced gradually in keeping with good medical practice. It is suggested that the daily dosage of **Pralzo®** (Alprazolam) be decreased by no more than 0.5mg every three days. Some patients may require an even slower dosage reduction

CONTRAINDICATION:

Alprazolam is contraindicated in patients:

- with known hypersensitivity to this drug or other benzodiazepines
- with acute narrow angle glaucoma

PRECAUTIONS:

Usage has not been established in depression with psychiatric features in bipolar disorders or in "endogenous" depression (i.e. severely depressed inpatient). Habituation and emotional /physical dependence may occur with benzodiazepines, including alprazolam. Caution should be particularly used when prescribing benzodiazepines, to patients who are prone to abuse drugs (e.g. alcoholics and drug addicts) because of their predisposition to habituation and dependence. Withdrawal symptoms have occurred following rapid decrease or abrupt discontinuance of benzodiazepines including alprazolam. These can range from mild dysphoria and insomnia to major syndrome which may include abdominal and muscle cramps, vomiting, sweating, tremors and convulsions. The signs and symptoms, especially the more serious ones, are generally more common in those patients who have received excessive doses over an extended period of time. However withdrawal symptoms have also been reported following abrupt discontinuation of benzodiazepines taken at therapeutic levels

Consequently, abrupt discontinuation should be avoided and a gradual tapering in dosage followed (see Discontinuation Therapy). When therapy is discontinued in patients with panic related disorders, the symptoms associated with recurrence of panic attacks often mimic those of withdrawal Administration to severely depressed or suicidal patients should be done with appropriate precaution and appropriate size of prescription; panic related disorders have been associated with the primary and secondary major depressive disorders and increased reports of suicide among untreated patients Therefore, the same precaution must be exercised when using the higher doses of alprazolam in treating patients with panic-related disorders as is exercised with the use of any psychotropic drug in treating depressed patients or those in whom there is reason to expect concealed suicidal ideation or plans. The usual precaution for treating patients with impaired renal or hepatic function should be observed

Pregnancy: Category D

There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks

Nursing mothers

Benzodiazepines are known to be excreted in human milk. It should be assumed that alprazolam is as well. Nursing should not be undertaken by mothers who must use alprazolam

Paediatric use

Safety and effectiveness of alprazolam in individuals below 18 years of age have not been established

ADVERSE REACTION:

Anxiety Disorder

Common

Drowsiness, light-headedness

Less common

Blurred vision, headache, depression, insomnia, nervousness/anxiety, tremor, change in weight, memory impairment/amnesia, co-ordination disorders, various gastrointestinal disturbance, and autonomic manifestations

In addition the following adverse events have been reported in association with the use of anxiolytic benzodiazepines including alprazolam

Dystonia, irritability, hostility, concentration difficulties, hallucination, anorexia, transient amnesia or memory impairment, loss of co-ordination, fatigue, seizures, sedation, slurred speech, jaundice, musculoskeletal weakness, pruritus, diplopia, dysarthria, changes in libido, menstrual irregularities, incontinence and urinary retention

Panic Disorder

Common

Sedation / drowsiness, fatigue, ataxia/impaired co-ordination and slurred speech

Less common

Altered mood, gastrointestinal symptoms, dermatitis, memory problem, sexual dysfunction, intellectual impairment and confusion

DRUG INTERACTIONS:

CNS depressants and other antipsychotics

Benzodiazepines, including alprazolam, produce additive CNS depressant effects when co-administered with other psychotropic medications, anticonvulsants, antihistamines, alcohol and other drugs which themselves produce CNS depression

CYP3A4 inhibitor

Compounds that inhibit certain hepatic enzymes (particularly cytochrome P450 3A4) may increase the concentration of alprazolam and enhance its activity

- Co-administration of alprazolam with ketoconazole, itraconazole or other azole type antifungals is not recommended
- Caution and consideration of dose reduction is recommended when alprazolam is co-administered with nefazodone, fluvoxamine and cimetidine
- Caution is recommended when alprazolam is co-administered with fluoxetine, propoxyphene, oral contraceptives, and sertraline, diltiazem or macrolide antibiotics such as erythromycin, clarithromycin and troleandomycin

OVERDOSAGE:

Manifestation of alprazolam overdosage includes somnolence, confusion, impaired coordination, diminished reflexes and coma. As in all cases of drug overdosage, respiration, pulse rate and blood pressure should be monitored. General supportive measures should be employed, along with immediate gastric lavage. Intravenous fluids should be administered and an adequate airway maintained. If hypotension occurs, it may be combated by the use of vasopressors. Dialysis is of limited value. As with the management of intentional overdosing with any drug. It should be borne in mind that multiple agents may have been ingested

STABILITY:

See expiry on the pack

PRESENTATION:

Pralzo® 0.5mg tablets in a pack of 30's

INSTRUCTIONS:

Keep out of reach of children
Avoid exposure to heat, light and humidity
Store between 15 to 30°C
Improper storage may deteriorate the medicine

پرالزو® ٹیبلٹ

(الپرازولم)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

R.N-02/HA/04/18

220mm

71mm

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