ANXO - 0.25 Tablets

www.greencrossindia.com

Each uncoated tablet contains:
Alprazolam IP.....0.25 mg

ANXO - 0.50 Tablets

Each uncoated tablet contains:
Alprazolam IP .....0.5 mg

INDICATIONS

Anxiety Disorders

ANXO Tablets are indicated for the management of anxiety disorder (a condition corresponding most closely to the American Psychiatric Association [APA] Diagnostic and Statistical Manual [DSM III-R] diagnosis of generalized anxiety disorder) or the short-term relief of symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic.

[Generalized anxiety disorder is characterized by unrealistic or excessive anxiety and worry (apprehensive expectation) about two or more life circumstances, for a period of 6 months or longer, during which the person has been bothered more days than not by these concerns. At least 6 of the following 18 symptoms are often present in these patients: ***Motor tension*** *(trembling, twitching, or feeling shaky; muscle tension, aches, or soreness; restlessness; easy fatigability);****Autonomic hyperactivity*** *(shortness of breath or smothering sensations; palpitations or accelerated heart rate; sweating, or cold clammy hands; dry mouth; dizziness or light-headedness; nausea, diarrhoea, or other abdominal distress; flushes or chills; frequent urination; trouble swallowing or "lump in the throat");* ***Vigilance and scanning*** *(feeling keyed up or on edge; exaggerated startle response; difficulty concentrating or "mind going blank" because of anxiety; trouble falling or staying asleep; irritability). These symptoms must not be secondary to another psychiatric disorder or caused by some organic factor. Anxiety associated with depression is responsive to alprazolam.]*

Panic Disorder

ANXO Tablets are also indicated for the treatment of panic disorder, with or without agoraphobia.*[Panic disorder* (DSM-IV) is *characterized by the occurrence of recurrent, unexpected panic attacks, i.e. a discrete period of intense fear or discomfort, in which four (or more) of the following symptoms develop abruptly and reach a peak within 10 minutes: 1) Palpitations, pounding heart or accelerated heart rate; 2) Sweating; 3) Trembling or shaking; 4) Sensations of shortness of breath or smothering; 5) Feeling of choking; 6) Chest pain or discomfort; 7) Nausea or abdominal distress; 8) Feeling dizzy, unsteady, lightheaded or faint; 9) De-realization (feelings of unreality) or depersonalization (being detached from oneself); 10) Fear of losing control; 11) Fear of dying; 12) Paraesthesias (numbness or tingling sensations); and 13) Chills or hot flushes. It is also associated with concern about having additional attacks, worry about the implications or consequences of the attacks, and/or a significant change in behaviour related to the attacks.]*

DOSAGE AND ADMINISTRATION

Dosage should be individualized for maximum beneficial effect. While the usual daily dosages given below will meet the needs of most patients, there will be some who require doses greater than 4 mg/day. In such cases, dosage should be increased cautiously to avoid adverse effects.

Anxiety Disorders

Initiation and Maintenance

Treatment for patients with anxiety should be initiated with a dose of 0.25-0.5 mg given three times daily. The dose may be increased to achieve a maximum therapeutic effect, at intervals of 3 to 4 days, to a maximum daily dose of 4 mg, given in divided doses. The lowest possible effective dose should be employed and the need for continued treatment reassessed frequently. The risk of dependence may increase with dose and duration of treatment.

Discontinuation

In all patients, dosage should be reduced gradually when discontinuing therapy or when decreasing the daily dosage. Although there are no systematically collected data to support a specific discontinuation schedule, it is suggested that the daily dosage be decreased by no more than 0.5 mg every 3 days. Some patients may require an even slower dosage reduction.

Panic Disorder

The successful treatment of many panic disorder patients has required the use of alprazolam at doses greater than 4 mg daily. In controlled trials conducted to establish the efficacy of alprazolam in panic disorder, doses in the range of 1 to 10 mg daily were used. The mean dosage employed was approximately 5-6 mg daily. Among the approximately 1,700 patients participating in the panic disorder development programme, about 300 received alprazolam in dosages of greater than 7 mg/day, including

approximately 100 patients who received maximum dosages of greater than 9 mg/day. Occasional patients required as much as 10 mg a day to achieve a successful response.

Dose Titration

Treatment may be initiated with a dose of 0.5 mg three times daily. Depending on the response, the dose may be increased at intervals of 3 to 4 days in increments of no more than 1 mg per day. Slower titration to the dose levels greater than 4 mg/day may be advisable to allow full expression of the pharmacodynamic effect of alprazolam. To lessen the possibility of interdose symptoms, the times of administration should be distributed as evenly as possible throughout the waking hours, i.e. on a three or four times per day-schedule. Generally, therapy should be initiated at a low dose to minimize the risk of adverse responses in patients especially sensitive to the drug. Dose should be advanced until an acceptable therapeutic response (i.e. a substantial reduction in or total elimination of panic attacks) is achieved, intolerance occurs, or the maximum recommended dose is attained.

Dose Maintenance

For patients receiving doses greater than 4 mg/day, periodic reassessment and consideration of dosage reduction is advised. In a controlled post-marketing dose-response study, patients treated with doses of alprazolam greater than 4 mg/day for 3 months were able to taper to 50% of their total maintenance dose without apparent loss of clinical benefit. Because of the danger of withdrawal, abrupt discontinuation of treatment should be avoided.

The necessary duration of treatment for panic disorder patients responding to alprazolam is unknown. After a period of extended freedom from attacks, a carefully supervised tapered discontinuation may be attempted, but there is evidence that this may often be difficult to accomplish without recurrence of symptoms and/or the manifestation of withdrawal phenomena.

Dose Reduction

Because of the danger of withdrawal phenomena, abrupt discontinuation of treatment should be avoided. In all patients, dosage should be reduced gradually when discontinuing therapy or when decreasing the daily dosage. Although there are no systematically collected data to support a specific discontinuation schedule, it is suggested that the daily dosage be decreased by no more than 0.5 mg every 3 days. Some patients may require an even slower dosage reduction.

In any case, reduction of dose must be undertaken under close supervision and must be gradual. If significant withdrawal symptoms develop, the previous dosing schedule should be reinstituted and, only after stabilization, should a less rapid schedule of discontinuation be attempted. In a controlled post-marketing discontinuation study of panic disorder patients, which compared the recommended taper schedule with a slower taper schedule, no difference was observed between the groups in the proportion of patients who tapered to zero dose; however, the slower schedule was associated with a reduction in symptoms associated with a withdrawal syndrome. It is suggested that the dose be reduced by no more than 0.5 mg every 3 days, with the understanding that some patients may benefit from an even more gradual discontinuation. Some patients may prove resistant to all discontinuation regimens. If side effects occur, the dose should be lowered. It is advisable to review treatment regularly and to discontinue use as soon as possible. Should long-term treatment be necessary, then intermittent treatment may be considered to minimize the risk of dependence.

If side-effects occur, the dose should be lowered. It is advisable to review treatment regularly and to discontinue use as soon as possible. Should longer term treatment be necessary, then intermittent treatment may be considered to minimize the risk of dependence.

Special Populations

Hepatic Impairment

In elderly patients, in patients with advanced liver disease or in patients with debilitating disease, the usual starting dose is 0.25 mg, given two or three times daily. This may be gradually increased if needed and tolerated.

Geriatric Use

The elderly may be especially sensitive to the effects of benzodiazepines. If side effects occur at the recommended starting dose, the dose may be lowered.

CONTRAINDICATIONS

ANXO Tablets are contraindicated in the following:

- Patients with a known sensitivity to this drug or other benzodiazepines.
- Patients with acute narrow-angle glaucoma. (***ANXO Tablets*** *may be used in patients with open-angle glaucoma who are receiving appropriate therapy*).
- Patients with ketoconazole and itraconazole, since these medications significantly impair the oxidative metabolism mediated by CYP3A4.
- Patients with severe respiratory insufficiency, sleep apnoea syndrome and severe hepatic impairment.

PACKAGING INFORMATION

ANXO-0.25 Tablets ..... Blister pack of 10 tablets
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