Buspirone hydrochloride tablets are indicated for the management of anxiety disorders associated with the stress of everyday life usually does not require treatment with an anxiolytic. However, the efficacy of buspirone hydrochloride has been demonstrated in controlled clinical trials of out-patients whose diagnosis roughly corresponds to Generalized Anxiety Disorder (GAD). Most of the patients in these studies had a diagnosis of GAD. The effectiveness of buspirone hydrochloride in treating these disorders is predictable from its known pharmacology, the mechanism of action of which is not well understood. Buspirone differs from typical benzodiazepine anxiolytics in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines. In vitro preclinical studies have shown that buspirone has a high selectivity for 5-HT1A over 5-HT1B, 5-HT2A, and 5-HT2C receptors. However, buspirone does not appear to exert any clinically significant sedative effects or other benzodiazepine-like effects. The mechanism of action of buspirone remains unknown. Buspirone is not a typical benzodiazepine anxiolytic in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines.

**CLINICAL PHARMACOLOGY**

Buspirone differs from the mechanism of action of a typical benzodiazepine. Buspirone differs from typical benzodiazepine anxiolytics in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines. In vitro preclinical studies have shown that buspirone has a high selectivity for 5-HT1A over 5-HT1B, 5-HT2A, and 5-HT2C receptors. However, buspirone does not appear to exert any clinically significant sedative effects or other benzodiazepine-like effects. The mechanism of action of buspirone is not well understood. Buspirone differs from typical benzodiazepine anxiolytics in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines. In vitro preclinical studies have shown that buspirone has a high selectivity for 5-HT1A over 5-HT1B, 5-HT2A, and 5-HT2C receptors. However, buspirone does not appear to exert any clinically significant sedative effects or other benzodiazepine-like effects. The mechanism of action of buspirone remains unknown. Buspirone is not a typical benzodiazepine anxiolytic in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines.

**DESCRIPTION**

Buspirone hydrochloride is a white crystalline, water soluble compound with a molecular formula of C17H15ClN2O and a molecular weight of 288.72. Buspirone hydrochloride is available as white, round, scored tablets for oral administration containing 5 mg and 10 mg of buspirone hydrochloride. The tablets are scored with 3 tablets of 10 mg each. Buspirone hydrochloride tablets are formulated with the following inactive ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium starch glycolate.

**WARNINGS**

The administration of buspirone hydrochloride to a patient taking a monoamine oxidase inhibitor (MAOI) may pose a hazard. There have been reports of life-threatening reactions in patients taking MAOIs. When buspirone is administered concomitantly with a monoamine oxidase inhibitor, the possibility of serious, sometimes fatal, reactions must be considered. Because buspirone hydrochloride has no established antipsychotic activity, it should not be used in any situation for which an antipsychotic drug is indicated. If buspirone is used in this way, there is a risk of serious, sometimes fatal, reactions.

**PRECAUTIONS**

**Potential for Withdrawal Reactions in Sedative/Hypnotic/Antianxiety Drug Users**

Buspirone hydrochloride does not cross-react with benzodiazepines. However, buspirone hydrochloride may cause withdrawal reactions in patients who have become dependent on benzodiazepines. The symptoms of withdrawal may include anxiety, irritability, and agitation. The duration of withdrawal symptoms may range from several days to several weeks. In a study of healthy volunteers, withdrawal symptoms began within 12 hours of the last dose and lasted up to 10 days. The symptoms included restlessness, agitation, insomnia, and anxiety. The symptoms were generally manageable with supportive care, including reassurance, and the use of benzodiazepines if necessary.

**Interference with Cognitive and Motor Performance**

Buspirone hydrochloride tablets are indicated for the management of anxiety disorders associated with the stress of everyday life usually does not require treatment with an anxiolytic. However, the efficacy of buspirone hydrochloride has been demonstrated in controlled clinical trials of out-patients whose diagnosis roughly corresponds to Generalized Anxiety Disorder (GAD). Most of the patients in these studies had a diagnosis of GAD. The effectiveness of buspirone hydrochloride in treating these disorders is predictable from its known pharmacology, the mechanism of action of which is not well understood. Buspirone differs from typical benzodiazepine anxiolytics in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines. In vitro preclinical studies have shown that buspirone has a high selectivity for 5-HT1A over 5-HT1B, 5-HT2A, and 5-HT2C receptors. However, buspirone does not appear to exert any clinically significant sedative effects or other benzodiazepine-like effects. The mechanism of action of buspirone remains unknown. Buspirone is not a typical benzodiazepine anxiolytic in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines.

**CONTRAINDICATIONS**

Buspirone hydrochloride is contraindicated in patients hypersensitive to buspirone hydrochloride.

**Drug Interactions**

Several antidepressants and a pharmacologically active compound (nefazodone hydrochloride, fluoxetine hydrochloride, paroxetine hydrochloride, and sertraline hydrochloride) have demonstrated in vivo and in vitro potentiation of the effects of buspirone. These drugs are known to selectively suppress or induce various isoforms of cytochrome P450. Buspirone is not a significant substrate for CYP2C19, CYP2C9, or CYP3A4. However, buspirone is a weak inhibitor of CYP1A2, CYP2C19, CYP2C9, and CYP3A4. Therefore, the use of buspirone in patients receiving these drugs should be avoided, unless the benefits of the combination outweigh the risks.

**Interactions with Other Psychotropics**

Buspirone hydrochloride tablets are indicated for the management of anxiety disorders associated with the stress of everyday life usually does not require treatment with an anxiolytic. However, the efficacy of buspirone hydrochloride has been demonstrated in controlled clinical trials of out-patients whose diagnosis roughly corresponds to Generalized Anxiety Disorder (GAD). Most of the patients in these studies had a diagnosis of GAD. The effectiveness of buspirone hydrochloride in treating these disorders is predictable from its known pharmacology, the mechanism of action of which is not well understood. Buspirone differs from typical benzodiazepine anxiolytics in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines. In vitro preclinical studies have shown that buspirone has a high selectivity for 5-HT1A over 5-HT1B, 5-HT2A, and 5-HT2C receptors. However, buspirone does not appear to exert any clinically significant sedative effects or other benzodiazepine-like effects. The mechanism of action of buspirone remains unknown. Buspirone is not a typical benzodiazepine anxiolytic in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines.

**Other Drugs**

Buspirone hydrochloride tablets are indicated for the management of anxiety disorders associated with the stress of everyday life usually does not require treatment with an anxiolytic. However, the efficacy of buspirone hydrochloride has been demonstrated in controlled clinical trials of out-patients whose diagnosis roughly corresponds to Generalized Anxiety Disorder (GAD). Most of the patients in these studies had a diagnosis of GAD. The effectiveness of buspirone hydrochloride in treating these disorders is predictable from its known pharmacology, the mechanism of action of which is not well understood. Buspirone differs from typical benzodiazepine anxiolytics in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines. In vitro preclinical studies have shown that buspirone has a high selectivity for 5-HT1A over 5-HT1B, 5-HT2A, and 5-HT2C receptors. However, buspirone does not appear to exert any clinically significant sedative effects or other benzodiazepine-like effects. The mechanism of action of buspirone remains unknown. Buspirone is not a typical benzodiazepine anxiolytic in that it does not exert anticonvulsant or muscle relaxant effects and it also does not produce sedative effect that is associated with typical benzodiazepines.
Drug/Laboratory Test Interactions  
Buspirone hydrochloride may interfere with the urinary excretion of catecholamines. Its use in patients with uncontrolled hypertension or pheochromocytoma should be avoided. When administered in vitro, buspirone hydrochloride may displace less firmly bound drugs like digoxin, the clinical significance of this property is unknown. The drug should be used during pregnancy only if clearly needed.  

Laboratory Tests  
The effect of buspirone hydrochloride on labor and delivery in women is unknown. No adverse effects were noted in reproduction studies in rats.  

Nursing Mothers  
The use of buspirone in nursing mothers is not known. Buspirone hydrochloride administration to nursing women should be avoided if clinically feasible.  

Pediatric Use  
The safety and effectiveness of buspirone were evaluated in two placebo-controlled 6-week trials involving a total of 551 pediatric patients (ranging from 6 to 17 years of age). In addition, 279 patients (ranging from 6 to 17 years of age) were treated with buspirone hydrochloride for 9 to 16 weeks in a multiple-dose, parallel-group, double-blind study. Frequent adverse events occurring in approximately 10% of subjects from the group who took multiple doses of buspirone hydrochloride in the range of 10 to 30 mg daily were: anxiety, for which the maximum recommended dose is 10 mg/day; headache, for which the maximum recommended dose is 30 mg/day. In the study, no adverse events were reported in children younger than 12 years of age. No unexpected safety findings were associated with buspirone hydrochloride therapy in children. There are no long-term safety or efficacy data in this population.  

In one study of 632 patients who received buspirone hydrochloride tablets for the treatment of 55 days and 41 were 17-75 years old. The safety and efficacy profiles for these 62B elderly patients (mean age 77.8 years) were similar to those in younger populations.  

Other Events During the Entire Premarketing Evaluation of Buspirone Hydrochloride  
During its premarketing assessment, buspirone hydrochloride was evaluated in over 3,000 subjects. The following frequency of adverse events occurring in approximately 300 subjects from the group who took multiple doses of buspirone hydrochloride in the range of 10 to 30 mg daily were: anxiety, for which the maximum recommended dose is 10 mg/day; headache, for which the maximum recommended dose is 30 mg/day. In the study, no adverse events were reported in children younger than 12 years of age. No unexpected safety findings were associated with buspirone hydrochloride therapy in children. There are no long-term safety or efficacy data in this population.  

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Eotaxin  
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