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type drug name here...

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[Home](#) / [Buspirone Hydrochloride Tablets, USP \(5 mg, 10 mg, 15 mg, 30 mg\) Drug Information](#) / [Drug Summary](#)

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# Buspirone Hydrochloride Tablets, USP (5 mg, 10 mg, 15 mg, 30 mg) (buspirone hydrochloride) - Drug Summary

Teva Pharmaceuticals USA Inc

## Jump to Section

[COMMON BRAND NAMES](#)

[THERAPEUTIC CLASS](#)

[DEA CLASS](#)

[ADULT DOSAGE & INDICATIONS](#)

[DOSING CONSIDERATIONS](#)

[▼ View All Sections...](#)

## Related Drug Information ▼

**Buspirone**  
(buspirone hydrochloride)

### COMMON BRAND NAMES

Buspar (Discontinued), Buspirone

### THERAPEUTIC CLASS

Atypical anxiolytic

### DEA CLASS

RX

### ADULT DOSAGE & INDICATIONS

#### Anxiety Disorders

#### Management of Disorders or Short-Term Relief of Symptoms:

**Initial:** 7.5mg bid

**Titrate:** May increase by 5mg/day at intervals of 2-3 days, prn

**Usual:** 20-30mg/day in divided doses

**Max:** 60mg/day

Periodically reassess usefulness of drug if used for extended periods

### DOSING CONSIDERATIONS

#### Renal Impairment

**Severe:** Not recommended

#### Hepatic Impairment

**Severe:** Not recommended

### ADMINISTRATION

Oral route

Take in a consistent manner w/ regard to the timing of dosing; either always w/ or always w/o food

### HOW SUPPLIED

Tab: 5mg\*, 7.5mg\*, 10mg\*, 15mg\*, 30mg\* \*scored

### WARNINGS/PRECAUTIONS

May impair mental/physical abilities. Does not exhibit cross-tolerance with benzodiazepines and other common sedatives/hypnotics; before starting therapy, withdraw gradually from prior treatment, especially in patients using a CNS depressant chronically. May cause acute and chronic changes in dopamine-mediated neurological function; syndrome of restlessness, appearing shortly after initiation, reported. May interfere with urinary metanephrine/catecholamine assay; d/c therapy for at least 48 hrs prior to undergoing urine collection for catecholamines. Not recommended with severe hepatic/renal impairment.

### ADVERSE REACTIONS

Dizziness, nausea, headache, nervousness, lightheadedness, excitement, drowsiness, fatigue, insomnia, dry

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mouth.

## DRUG INTERACTIONS

See Dosage. Elevated BP reported with MAOI; avoid concomitant use. Avoid with alcohol. Dizziness, headache, nausea, and increased nordiazepam reported with diazepam. May increase serum concentrations of haloperidol. ALT elevations reported with trazodone. Caution with CNS-active drugs. CYP3A4 inhibitors (eg, diltiazem, ketoconazole, ritonavir) may increase concentrations; may require dose adjustment. CYP3A4 inducers (eg, dexamethasone, phenytoin, rifampin), including potent inducers, may decrease concentrations; may require dose adjustment of buspirone. Avoid with large amounts of grapefruit juice. Nefazodone may decrease concentrations of metabolite 1-pyrimidinylpiperazine (1-PP). May increase levels of nefazodone. Cimetidine may increase  $C_{max}$  and  $T_{max}$ . Prolonged PT reported with warfarin. May displace less firmly bound drugs like digoxin.

## PREGNANCY AND LACTATION

Category B, not for use in nursing.

## MECHANISM OF ACTION

Atypical anxiolytic; has not been established. Has a high affinity to 5-HT<sub>1A</sub> receptors and moderate affinity for brain D<sub>2</sub>-dopamine receptors; may have indirect effects on other neurotransmitter systems.

## PHARMACOKINETICS

**Absorption:** Rapid. (20mg, single dose)  $C_{max}$ =1-6ng/mL;  $T_{max}$ =40-90 min. **Distribution:** Plasma protein binding (86%). **Metabolism:** Liver (extensive 1st-pass), primarily by oxidation via CYP3A4, and by hydroxylation; 1-PP (active metabolite). **Elimination:** Urine (29-63%), feces (18-38%); (10-40mg, single dose)  $T_{1/2}$ =2-3 hrs.

## ASSESSMENT

Assess for hypersensitivity to drug, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions.

## MONITORING

Monitor for CNS effects, syndrome of restlessness, and other adverse reactions. Periodically reassess usefulness of drug if used for extended periods.

## PATIENT COUNSELING

Instruct to inform physician about any medications, prescription or nonprescription, alcohol, or drugs patient is taking or planning to take, and if patient is pregnant/breastfeeding, becomes pregnant, or is planning to become pregnant. Advise not to drive a car or operate potentially dangerous machinery until effects have been determined. Instruct to avoid drinking large amounts of grapefruit juice.

## STORAGE

(5mg, 10mg, 15mg, 30mg) 20-25°C (68-77°F). (7.5mg) 25°C (77°F); excursions permitted between 15-30°C (59-86°F).

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