



Furazolidone (Oral-Local)

VA CLASSIFICATION

Primary: AM600

Secondary: AP109

Commonly used brand name(s): *Furoxone; Furoxone Liquid.*

Note: For a listing of dosage forms and brand names by country availability, see *Dosage Forms* section(s).

[†]Not commercially available in Canada.

Category:

Antibacterial (oral-local)—

antiprotozoal—

Note: Furazolidone is a broad-spectrum anti-infective that is effective against most gastrointestinal tract pathogens. ^{01}

Indications

Accepted

Cholera (treatment)—Furazolidone is indicated as a secondary agent in the treatment of cholera caused by *Vibrio cholerae* (*V. comma*) . ^{{01} {02} {03} {04} {05} {07} {09} {15} {18} {19}}

Diarrhea, bacterial (treatment)—Furazolidone is indicated as a secondary agent in the treatment of bacterial diarrhea caused by susceptible organisms. Furazolidone is active *in vitro* against *Campylobacter jejuni*, *Enterobacter aerogenes*, *Escherichia coli*, *Proteus* species, *Salmonella* species, *Shigella* species, and staphylococci. However, clinical studies on the effectiveness of furazolidone in some types of bacterial diarrhea have been inconclusive or conflicting. ^{{01} {02} {25} {26}}

Giardiasis (treatment)—Furazolidone is indicated as a secondary agent in the treatment of giardiasis caused by *Giardia lamblia*. {01} {02} {03} {04} {05} {06} {07} {08} {09} {13} {14} {16}

—Not all species or strains of a particular organism may be susceptible to furazolidone.

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Molecular weight—
225.16 {10}

Mechanism of action/Effect:

Microbicidal. Furazolidone interferes with several bacterial enzyme systems. It neither significantly alters normal bowel flora nor results in fungal overgrowth. {01} {03}

Other actions/effects:

Furazolidone also acts as a monoamine oxidase inhibitor (MAOI). MAOIs prevent the inactivation of tyramine by hepatic and gastrointestinal monoamine oxidase. Tyramine in the bloodstream releases norepinephrine from the sympathetic nerve terminals and produces a sudden increase in blood pressure. {18}

Absorption:

Radiolabeled drug studies indicate that furazolidone is well absorbed following oral administration. {28}

Distribution:

Limited pharmacokinetic information is available in humans; however, recent data have reported that variable plasma concentrations were measured in subjects given therapeutic doses. One study of 8 meningitis patients showed that cerebral spinal fluid (CSF) concentrations reached levels comparable to serum concentrations. Also, significant concentrations have been measured in the bile of rats. {28}

Biotransformation:

Furazolidone is rapidly and extensively metabolized; the primary metabolic pathway identified begins with nitro-reduction to the aminofuran derivative. {28}

Elimination:

Radiolabeled drug studies showed that more than 65% of an oral dose was recovered in the

urine of humans and animals. Also found in feces. {28}

Precautions to Consider

Cross-sensitivity and/or related problems

Patients hypersensitive to other nitrofurans may be hypersensitive to this medication also.

Carcinogenicity/Tumorigenicity

Several studies in rodents, given chronic, high-dose furazolidone orally, have shown that this medication is tumorigenic. Furazolidone has been shown to cause mammary neoplasia in two strains of rats. In addition, furazolidone has been shown to cause pulmonary tumors in mice. {01} {08} {16} {17}

Pregnancy/Reproduction

Pregnancy—

Studies in humans have not been done. However, teratogenic effects on the human fetus or newborn infants have not been reported.

Studies in animals have not shown that furazolidone, given in doses far exceeding recommended human doses for long periods of time, causes adverse effects on the fetus. {01}

Breast-feeding

It is not known whether furazolidone is distributed into breast milk. However, breast-feeding is not recommended in nursing infants up to 1 month of age because of the possibility of hemolytic anemia due to glutathione instability in the early neonatal period. {29}

Pediatrics

Use of furazolidone is not recommended in infants up to 1 month of age because of the possibility of hemolytic anemia due to immature enzyme systems (glutathione instability) in the early neonatal period. {01} {03}

Geriatrics

No information is available on the relationship of age to the effects of furazolidone in geriatric patients.

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

» Alcohol (concurrent use of alcohol with furazolidone may rarely result in a disulfiram-like reaction, characterized by facial flushing, difficult breathing, slight fever, and tightness of the chest; these effects usually subside spontaneously within 24 hours with no lasting ill effects; patients should be advised not to drink alcoholic beverages while taking furazolidone and for 4 days after discontinuing it {01} {02} {03} {04} {05} {07} {08} {12} {16} {20} {24} {25})

» Antidepressants, tricyclic or

» Monoamine oxidase (MAO) inhibitors, other or

» Sympathomimetics, direct- or indirect-acting, such as amphetamines, ephedrine, or phenylephrine or

» Tyramine- or other high pressor amine-containing foods and beverages, such as aged cheese; beer; reduced-alcohol and alcohol-free beer and wine; red and white wine; sherry; liqueurs; yeast or protein extracts; fava or broad bean pods; smoked or pickled meat, poultry, or fish; fermented sausage (bologna, pepperoni, salami, summer sausage) or other fermented meat; and any overripe fruit (concurrent use of these medications, foods, and beverages with furazolidone may theoretically precipitate sudden and severe hypertensive reactions due to furazolidone's MAO inhibitory properties; a dose of 400 mg daily for 5 days was required to experimentally enhance tyramine and amphetamine sensitivity by 2- to 3-fold; this dose does not usually cause an undue risk of hypertensive crises in adults due to MAO inhibition, and no clinical reports of this interaction have been reported; however, if furazolidone is given in larger-than-recommended doses or for more than 5 days, there may be an increased risk of hypertensive crises due to accumulation of monoamine oxidase {01} {24} {25})

(because of furazolidone's MAO inhibitory properties, dietary restrictions must be continued for at least 2 weeks after the medication is discontinued; other tyramine- or high pressor amine-containing foods, such as yogurt, sour cream, cream cheese, cottage cheese, chocolate, and soy sauce, if eaten when fresh and in moderation, are considered unlikely to cause serious problems {01} {03} {04} {12} {21} {22} {23})

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance).

Risk-benefit should be considered when the following medical problems exist

Glucose-6-phosphate dehydrogenase (G6PD) deficiency (mild, reversible, hemolytic anemia may occur in G6PD-deficient patients; it is recommended that furazolidone be discontinued if hemolytic anemia occurs in patients with G6PD deficiency {01} {03} {04} {05} {08} {14} {16} {17})

Hypersensitivity to furazolidone or other nitrofurans^{01}

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; » = major clinical significance):

Glucose-6-phosphate dehydrogenase (G6PD) determinations (recommended prior to treatment in Caucasians of Mediterranean and Near Eastern origin, Orientals, and blacks; if a deficiency is found, furazolidone should be given with caution since hemolytic effects may be exacerbated in these patients; dosage adjustments and/or discontinuation of the medication may be required {01} {27})

For giardiasis

» Stool examinations (3 stool examinations, taken several days apart, beginning 3 to 4 weeks following treatment are recommended if symptoms persist; however, in some successfully treated patients, the lactose intolerance brought on by infection may persist for a period of some weeks or months, mimicking the symptoms of giardiasis; in cases of treatment failure, alternate medications may be used {08})

Side/Adverse Effects

Note: Furazolidone may cause mild, reversible hemolytic anemia in G6PD-deficient patients. Furazolidone should be discontinued if hemolytic anemia occurs in these patients. {01} {03} {04} {16}

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)—not necessarily inclusive:

Those indicating need for medical attention

Incidence rare

Hypersensitivity reactions (fever; itching; joint pain; skin rash or redness)—incidence approximately 0.6%{01}{02}{03}{04}{05}{07}{08}{16}{17}{24}

leukopenia (sore throat and fever)—incidence approximately 0.2%^{24}

Those indicating need for medical attention only if they continue or are bothersome
Incidence less frequent

Gastrointestinal disturbances (abdominal pain, diarrhea, nausea, or vomiting)^{{01}{03}{04}{05}{07}{08}{16}{17}}

headache^{{01}{04}{07}{08}}

Those not indicating need for medical attention
Incidence more frequent

Dark yellow to brown discoloration of urine^{{01}{02}{03}{16}}

Patient Consultation

As an aid to patient consultation, refer to *Advice for the Patient, Furazolidone (Oral)*.

In providing consultation, consider emphasizing the following selected information (» = major clinical significance):

Before using this medication

» Conditions affecting use, especially:
Sensitivity to furazolidone or other nitrofurans

Breast-feeding—Not recommended in infants up to 1 month of age because of possibility of hemolytic anemia

Use in children—Not recommended in infants up to 1 month of age because of possibility of hemolytic anemia

Other medications, especially direct-acting and indirect-acting sympathomimetics, other MAO inhibitors, or tricyclic antidepressants

Proper use of this medication

» Not giving to infants up to 1 month of age; may cause hemolytic anemia

May be taken with food to reduce gastrointestinal irritation {27}

Proper administration technique for oral suspension: Using a specially marked measuring spoon or other device

» Compliance with full course of therapy

» Proper dosing

Missed dose: Taking as soon as possible; not taking if almost time for next dose; not doubling doses

» Proper storage

Precautions while using this medication

Regular visits to physician to check progress

Checking with physician if no improvement within a week

» Avoiding alcoholic beverages or other alcohol-containing preparations while taking, and for 4 days after discontinuing, furazolidone

» Avoiding tyramine- and other high pressor amine-containing foods and beverages, OTC appetite suppressants, cough and cold medications, and other medications unless prescribed by physician; also avoiding these products for at least 2 weeks after discontinuing furazolidone; asking health care professional to provide list of products that may or may not cause serious problems with furazolidone

Side/adverse effects

Signs of potential side effects, especially hypersensitivity reactions and leukopenia

Dark yellow to brown discoloration of urine may be alarming to patient, although medically insignificant

General Dosing Information

Furazolidone has been used as adjunctive therapy with other antibacterial agents or bismuth salts with no problems reported. {01}

Diet/Nutrition

Gastrointestinal intolerance may be decreased if furazolidone is taken with food or if the dose is reduced. {01} {24}

After discontinuation of furazolidone, the MAO inhibiting effects may persist for at least 2 weeks. During this time, food, beverage, and medication precautions must be observed by patients receiving larger-than-recommended doses or prolonged therapy (See **Drug interactions and/or related problems**). {01} {03} {04} {12} {21} {22} {23}

For treatment of adverse effects

Recommended treatment consists of the following {01} {03}

- Administering direct-acting vasopressor agents (e.g., norepinephrine) to counteract hypotensive episodes. Avoiding indirect-acting vasopressor agents.
- Administering phentolamine or parenteral chlorpromazine to counteract hypertensive crises.

Oral Dosage Forms

FURAZOLIDONE ORAL SUSPENSION USP

Usual adult and adolescent dose

Cholera or

Diarrhea, bacterial

Oral, 100 mg four times a day for five to seven {27} days. {01} {03} {04} {05} {15} {17}

Note: Some medical experts recommend shorter courses of treatment (e.g., two to five days) for the above-listed infections. {27}

Giardiasis

Oral, 100 mg four times a day for seven to ten days. {01} {02} {03} {04} {05} {07} {08} {13} {14} {16} {17} {27}

Usual pediatric dose

Cholera or

Diarrhea, bacterial

Infants up to 1 month of age: Use is not recommended because of the possibility of hemolytic anemia due to immature enzyme systems (glutathione instability) in these infants. {01} {03}

Infants and children 1 month of age and over: Oral, 1.25 mg per kg of body weight four times a

day for five to seven {27} days. {01} {03} {15} {17}

Giardiasis

Infants up to 1 month of age: Use is not recommended because of the possibility of hemolytic anemia due to immature enzyme systems (glutathione instability) in these infants. {01} {03}

Infants and children 1 month of age and over: Oral, 1.25 to 2 mg per kg of body weight four times a day for seven to ten days. {01} {03} {05} {08} {16} {17} {27}

Note: The maximum dose for children should not exceed 8.8 mg per kg of body weight daily because of the possibility of nausea or vomiting. {01} {03}

Strength(s) usually available

U.S.—

50 mg per 15 mL (Rx) [*Furoxone Liquid* (methyparaben) (propylparaben)]^{18}

Canada—

Not commercially available.

Packaging and storage:

Store below 40 °C (104 °F) in a tight, light-resistant container. Protect from freezing.

Auxiliary labeling:

- Shake well.
- Avoid alcoholic beverages.
- Continue medication for full time of treatment.
- May discolor urine.

FURAZOLIDONE TABLETS USP

Usual adult and adolescent dose

See *Furazolidone Oral Suspension USP*.

Usual pediatric dose

See *Furazolidone Oral Suspension USP*.

Strength(s) usually available

U.S.—

100 mg (Rx) [*Furoxone* (scored) (sucrose)]^{18}

Canada—

Not commercially available.

Packaging and storage:

Store below 40 °C (104 °F) in a tight, light-resistant container.

Preparation of dosage form:

For patients who cannot take oral solids—Furazolidone tablets may be crushed and given in a teaspoonful of corn syrup. ^{01}

Auxiliary labeling:

- Avoid alcoholic beverages.
- Continue medication for full time of treatment.
- May discolor urine.

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References

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Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer