Product Monograph

Including Patient Medication Information

[Pr] NITROFURANTOIN

nitrofurantoin tablets

For oral use

50 mg and 100 mg

BP

Urinary Tract Antibacterial

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Date of Authorization:
2025-07-03

Control Number: 294748

Recent Major Label Changes

Not applicable

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Health Professional Information

1 Indications

NITROFURANTOIN (Nitrofurantoin tablets) is indicated for:

- The treatment of pyelonephritis, pyelitis, and cystitis when due to susceptible organisms.

NITROFURANTOIN is not for the treatment of associated renal cortical or perinephric abscesses, nor in prostatitis.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NITROFURANTOIN and other antibacterial drugs, NITROFURANTOIN should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

1.1 Pediatrics

Pediatrics (< 1 month of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of NITROFURANTOIN in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use. See 2 Contraindications.

1.2 Geriatrics

Geriatrics (>65 years of age): Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness. See 7.1.4 Geriatrics.

2 Contraindications

NITROFURANTOIN is contraindicated in the following conditions:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6 Dosage Forms, Strengths, Composition and Packaging.

- Anuria, aliguria, or significant impairment of renal function (creatinine clearance under 40 mL/min.) are some of the contraindications of nitrofurantoin tablets causing an increased risk of toxicity because of impaired excretion of the drug. For the same reason, the drug is much less effective under these circumstances.

- Pregnant patients at term as well as in infants under 1 month of age, because of the possibility of hemolytic anemia due to immature enzyme systems (glutathione instability).

4 Dosage and Administration

4.2 Recommended Dose and Dosage Adjustment

Adults

50 to 100 mg four times a day.

Continue therapy for at least 1 week and for at least 3 days after sterility of the urine is obtained. Continued infection indicates the need for re-evaluation.

If the drug is to be used for long-term suppressive therapy, consider a dosage reduction.

4.4 Administration

To minimize gastric upset, administer the drug with food or milk.

4.5 Missed Dose

If the patient misses a dose, the patient should take the dose as soon as they remember it. If it is almost time for the next dose, the patient should skip the missed dose and continue the regular dosing schedule.

5 Overdose

Symptoms: Occasional incidents of acute overdose of nitrofurantoin have not resulted in any specific symptomatology other than vomiting.

Treatment: In case vomiting does not occur soon after an excessive dose, induction of emesis is recommended. There is no specific antidote for nitrofurantoin, but a high fluid intake should be maintained to promote urinary excretion of the drug, but only in case of overdosage.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6 Dosage Forms, Strengths, Composition and Packaging

Table 1 - Dosage Forms, Strengths, Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-medicinal Ingredients
oral	tablet 50 mg, 100 mg of nitrofurantoin	croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose

Description

NITROFURANTOIN, 50 mg tablet: yellow, round, biconvex tablet, scored on one side, other side plain. Available in bottles of 100 tablets.

NITROFURANTOIN, 100 mg tablet: yellow, round, biconvex tablet, scored on one side, other side plain. Available in bottles of 100 tablets.

7 Warnings and Precautions

Driving and Operating Machinery

Nitrofurantoin may cause dizziness and drowsiness and the patient should not drive or operate machinery if affected this way.

Hematologic

Hemolytic anemia of the primaquine-sensitivity type has been induced by nitrofurantoin. The hemolysis appears to be linked to a glucose-6-phosphate dehydrogenase deficiency in the affected patients' red blood cells. This deficiency is found in 10% of people of sub-Saharan African descent and in a small percentage of ethnic groups of Mediterranean and Near-Eastern origin. Any sign of hemolysis is an indication to discontinue the drug. Hemolysis ceases when the drug is withdrawn.

Neurologic

Predisposing conditions such as renal impairment, anemia, diabetes, electrolyte imbalance, vitamin B deficiency, and debilating disease may enhance the occurrence of peripheral neuropathy. Peripheral neuropathy may occur with nitrofurantoin therapy; this may become severe or irreversible. A fatality has been reported. If numbness or tingling occurs, discontinue the drug.

Renal

Do not administer nitrofurantoin concomitantly with drugs which may produce impaired renal function.

Sensitivity/Resistance

Development of Drug Resistant Bacteria: Prescribing NITROFURANTOIN in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria

Pseudomonas is the organism most commonly implicated in superinfections in patients with nitrofurantoin preparations.

7.1 Special Populations

7.1.1 Pregnancy

Nitrofurantoin's safety during pregnancy has not been established. It should not be used in women of childbearing potential unless the expected benefits outweigh the possible hazards. See 2 Contraindications.

7.1.2 Breastfeeding

Nitrofurantoin's safety during breastfeeding has not been established.

7.1.3 Pediatrics

Pediatrics (< 1 month of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of NITROFURANTOIN in pediatric patients has not been established; therefore, Health Canada has not authorized an indication for pediatric use. See 2 Contraindications.

7.1.4 Geriatrics

Geriatrics (>65 years of age): Evidence from clinical studies and experience suggests that use in the geriatric population is associated with differences in safety or effectiveness.

8 Adverse Reactions

8.1 Adverse Reaction Overview

Blood and lymphatic system disorders: hemolytic anemia, granulocytopenia, eosinophilia and megaloblastic anemia have occurred. Return of the blood picture to normal has followed cessation of therapy.

Gastrointestinal disorders: Nausea, emesis are the most frequent reactions; less frequently, abdominal pain and diarrhea.

General disorders and administration site conditions: Drug fever

Hepatobiliary disorders: cholestatic jaundice: rarely, hepatitis. This dose-related toxicity reaction can be minimized by reduction of dosage, especially in the female patient.

Immune system disorders: Anaphylaxis, asthmatic attack in patients with history of asthma.

Infections and Infestations: As with other antimicrobial agents, superinfections by resistant organism may occur. With nitrofurantoin, however, these are limited to the genitourinary tract because suppression of normal bacterial flora elsewhere in the body does not occur.

Metabolism and nutrition disorders: Anorexia.

Musculoskeletal and connective tissue disorders: Arthralgia

Nervous system disorders: Peripheral neuropathy, headache, dizziness, nystagmus and drowsiness.

Respiratory thoracic and mediastinal disorders: Pulmonary sensitivity reactions, which can be acute, subacute, or chronic.

Acute reaction is commonly manifested by fever, chills, cough, chest pain, dyspnea, pulmonary infiltration with consolidation or pleural effusion on X-ray, and eosinophilia. The acute reactions usually occur within the first week of treatment and resolve with cessation of the drug therapy.

Subacute or chronic pulmonary reaction is associated with prolonged therapy. Insidious onset of malaise, dyspnea on exertion, cough, altered pulmonary function, and roentgenographic and histologic findings of diffuse interstitial pneumonitis or fibrosis or both are common manifestations. Impaired pulmonary function may result even after cessation of the drug therapy.

Skin and subcutaneous tissue disorders: Maculopapular, erythematous, or eczematous eruption, pruritus, urticaria, angioedema, transient alopecia.

9 Drug Interactions

9.2 Drug Interactions Overview

Do not administer NITROFURANTOIN concomitantly with drugs which may produce impaired renal function.

9.4 Drug-Drug Interactions

Interactions with other drugs have not been established.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 Clinical Pharmacology

Information is not available.

11 Storage, Stability and Disposal

Store at temperature not exceeding 25°C. Protect from light.

Part 2: Scientific Information

13 Pharmaceutical Information

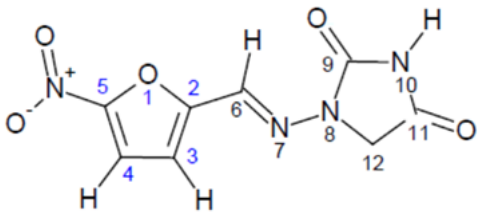
Drug Substance

Non-proprietary name of the drug substance(s): Nitrofurantoin

Chemical name: 1-[[5-Nitrofuran-2-yl)methylene]amino]imidazolidine-2,4-dione

Molecular formula and molecular mass: $C_8H_6N_4O_5$ and 238.16 g/mol

Structural formula:



Physicochemical properties: Nitrofurantoin is a synthetic antibacterial nitrofuran derivative. It occurs as lemon-yellow odourless crystals, or fine powder, and soluble in Dimethyl Formamide.
pH : Between 5 and 7 (1% suspension in water)
Melting Point: About 270°C.

Pharmaceutical standard: BP

14 Clinical Trials

The clinical trial data on which the indication was originally authorized is not available.

15 Microbiology

Information is not available.

16 Non-Clinical Toxicology

Information is not available.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]NITROFURANTOIN

nitrofurantoin tablets

This patient medication information is written for the person who will be taking **NITROFURANTOIN**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **NITROFURANTOIN**, talk to a healthcare professional.

What NITROFURANTOIN is used for:

NITROFURANTOIN is used to treat urinary tract infections caused by certain bacteria.

Antibacterial drugs like NITROFURANTOIN treat only bacterial infections. They do not treat viral infections.

How NITROFURANTOIN works:

NITROFURANTOIN works to:

- Stop growth of bacteria.
- Kill the bacteria.
- Reduce the infection in your body.

The ingredients in NITROFURANTOIN are:

Medicinal ingredients: Nitrofurantoin

Non-medicinal ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

NITROFURANTOIN comes in the following dosage form:

Tablets: 50 mg and 100 mg.

Do not use NITROFURANTOIN if:

- you are allergic (causing itching, redness of skin or difficulty breathing) to NITROFURANTOIN or any of the ingredients in NITROFURANTOIN tablets.
- you have kidney disease.

- you are pregnant.

NITROFURANTOIN should not be given to infants under 1 month old.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NITROFURANTOIN. Talk about any health conditions or problems you may have, including if you:

- have diabetes.
- have anemia (a decrease in red blood cells causing pale skin, weakness and breathlessness) or a lack of vitamin B (particularly folate) or abnormal levels of salts in your blood.
- have a condition known as glucose-6-phosphate dehydrogenase deficiency.
- have any disease of lungs, liver or nervous system.
- are planning to become pregnant.
- are breastfeeding or planning to breastfeed.

Other warnings you should know about:

- **Driving and using machines**

  NITROFURANTOIN Tablets may cause dizziness and drowsiness. You should not drive or use machinery if you are feeling dizzy and until such symptoms go away.

- **NITROFURANTOIN tablets contain lactose**

  This medicine contains lactose. If you have been told by your healthcare professional that you are intolerant to some sugars and you have to avoid them, contact your healthcare professional before taking this medicine.

- **Peripheral neuropathy**
  The following conditions may increase the chance of developing a side effect known as peripheral neuropathy. It can cause damage to the nerves, altered sense of feeling, like pins and needles:
  - anemia (a decrease in red blood cells causing pale skin, weakness and breathlessness),
  - diabetes,
  - a lack of vitamin B,
  - abnormal levels of salts in your blood,
  - you are suffering from an illness that makes you very tired.

- **Liver disease**
  NITROFURANTOIN may cause liver disease. Symptoms include nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light colored bowel motions, and dark colored urine. Your healthcare professional may want to regularly check how your liver is working. If you get liver disease while taking NITROFURANTOIN, you should immediately stop taking the medicine and talk to your healthcare professional.

How to take NITROFURANTOIN:

- Although you may feel better early in treatment, NITROFURANTOIN should be used exactly

as directed.
- Misuse or overuse of NITROFURANTOIN could lead to the growth of bacteria that will not be killed by NITROFURNATOIN (resistance). This means that NITROFURANTOIN may not work for you in the future.
- Do not share your medicine.
- NITROFURANTOIN tablets should be taken with food or milk. This will help to avoid stomach upset and also to help the absorption.

Usual dose:

Adults: 50 mg to 100 mg four times daily for at least 1 week or as directed.

Overdose:

If you think you, or a person you are caring for, have taken too much NITROFURANTOIN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you forget to take NITROFURANTOIN tablets, take the dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

Possible side effects from using NITROFURANTOIN:

These are not all the possible side effects you may have when taking NITROFURANTOIN. If you experience any side effects not listed here, tell your healthcare professional.

Side Effects may include:

- Headache
- Abdominal pain
- Loss of appetite
- Diarrhea
- Short-term unusual hair loss or thinning
- Drowsiness
- Dizziness
- Joint pain
- Fever and chills

Serious side effects and what to do about them

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Blood and lymphatic system disorders: - **Hemolytic anemia** (breakdown of red blood cells): pale skin, feeling tired or weak, dizziness, fainting, thirst, rapid breathing. - **Granulocytopenia** (decrease in white blood cells): frequent infection with fever, chills, sore throat - **Eosinophilia** (increased numbers of certain white blood cells): abdominal pain, rash, weight loss, wheezing. - **Megaloblastic anemia** (abnormally large red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness.			√
Hepatobiliary (liver, gallbladder, and bile ducts) disorders: - **Hepatitis** (Inflammation of liver): Abdominal pain, fatigue, fever, itchiness, light coloured stool, trouble thinking clearly, yellowing of the skin. - **Cholestatic jaundice:** dark urine, light-colored stools, generalized itchiness.			√
Nervous system disorders: - **Peripheral neuropathy** (damage to the nerves): altered sense of feeling, like pins and needles, numbness in arms and legs, pain, lack of coordination, muscle weakness. - **Nystagmus**: rapid repetitive uncontrolled movement of the eye.			√
Gastrointestinal (stomach) disorders: Nausea, vomiting, abdominal pain and diarrhea	√		

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Glucose-6-phosphate dehydrogenase deficiency anemia (a type of breakdown of red blood cells)**:** Pale skin, yellowing of the skin, eyes, and mouth (jaundice), dark-colored urine, fever, weakness, dizziness, confusion, trouble with physical activity, enlarged spleen and liver, increased heart rate, heart murmur			√
General disorders and administration site conditions: Drug Fever (it typically occurs after seven to ten days of treatment and usually resolves within 48 hours of discontinuing the administration)		√	
Immune system disorders: **- Angioedema and Serious Allergic Reactions (including anaphylaxis):** swelling of the face, eyes, lips, tongue or throat, trouble breathing or swallowing; sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. **- Asthmatic attack** (in patients with history of asthma).			√
Infections and Infestations: Urinary infection by germs which do no respond to treatment.			√
Metabolism and nutrition disorders: loss of the appetite for food	√		
Musculoskeletal and connective tissue disorders: pain in joints, muscle aches and pain	√		
Renal and urinary disorders: rust-yellow to brown discoloration of the urine	√		
Respiratory thoracic and mediastinal disorders:			√

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
(lung and chest problems): fever, chills, cough, chest pain, shortness of breath, pulmonary infiltration with consolidation or pleural effusion on X-ray (build up of fluids in the lungs, and eosinophilia increased numbers of certain white blood cells) which can cause abdominal pain, rash, weight loss, wheezing.			
Skin and subcutaneous tissue disorders: red, raised skin rash; itchy rash, severe itching, short-term hair loss	√		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at temperature not exceeding 25°C. Protect from light.

Keep out of reach and sight of children.

If you want more information about NITROFURANTOIN:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (Drug Product Database: Access the database); the manufacturer's website (https://www.aapharma.ca/en/); or by calling 1-877-998-9097.

This leaflet was prepared by AA Pharma Inc. 1165 Creditstone Road Unit #1, Vaughan, Ontario, L4K 4N7.

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