PRESCRIBING INFORMATION

NITROFURANTOIN

Nitrofurantoin Tablets BP

50 mg and 100 mg

Urinary Antibacterial

AA PHARMA INC.
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Control Number: 216071

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THERAPEUTIC CLASSIFICATION

Urinary Antibacterial

INDICATIONS

The treatment of pyelonephritis, pyelitis, and cystitis when due to susceptible organisms. Not indicated for the treatment of associated renal cortical or perinephric absecesses, 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."

CONTRAINDICATIONS

Anuria, aliguria, or significant impairment of renal function (creatinine clearance under 40 ml/min.) are some of the contraindications of nitrofurantoin 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.

Nitrofurantoin is contraindicated in 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).

Known hypersensitivity to nitrofurantoin.

PRECAUTIONS

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 Hemolysis ceases when the drug is withdrawn.

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

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.

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

Susceptibility/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 resistant organisms.

ADVERSE EFFECTS

Gastrointestinal: Anorexia, nausea, emesis are the most frequent reactions; less frequently, abdominal pain and diarrhea: rarely, hepatitis. This dose-related toxicity reaction can be minimized by reduction of dosage, especially in the female patient.

Hypersensitivity: 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.

Dermatologic: maculopapular, erythematous, or eczematous eruption, pruritus, urticaria, angioedema.

Other sensitivity reactions: anaphylaxis, asthmatic attack in patients with history of asthma, cholestatic jaundice, drug fever, arthralgia.

Hematologic: hemolytic anemia, granulocytopenia, eosinophilia, magaloblastic anemia. Return of the blood picture to normal has followed cessation of therapy. Neurological: peripheral neuropathy, headache, dizziness, nystagmus, and drowsiness.

Miscellaneous: transient alopecia. 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.

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

OVERDOSAGE

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.

DOSAGE

To minimize gastric upset, administer the drug with food or milk. Adults: 50 to 100 mg 4 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 reevaluation.

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

AVAILABILITY OF DOSAGE FORMS

Each scored tablet, contains: nitrofurantoin 50 mg or 100 mg.

In addition to nitrofurantoin each tablet contains non-medicinal ingredients like crosscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

Storage:
Store at temperature not exceeding 25ºC. Protect from light.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

NITROFURANTOIN

Nitrofurantoin Tablets BP

Read this carefully before you start taking NITROFURANTOIN and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about NITROFURANTOIN.

What is NITROFURATOIN used for?

NITROFURANTOIN is used to treat infections that are caused by certain bacteria.

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

How does NITROFURANTOIN work?

NITROFURANTOIN works to:
- Stop growth of bacteria.
- Kill the bacteria.
- Reduce the infection in your body.

What are the ingredients in NITROFURANTOIN?
In addition to nitrofurantoin each tablet contains non-medicinal ingredients like crosscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

NITROFURATOIN comes in the following dosage forms:
Nitrofurantoin 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 anaemia (a decrease in red blood cells causing pale skin, weakness and breathlessness) or a lack of vit**a**min 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.

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 doctor that you are intolerant to some sugars and you have to avoid them, contact your doctor before taking this medicine.

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 adult dose:

50 mg – 100 mg four times daily for at least 1 week or as directed.

Overdose:

If you think you have taken too much **NITROFURATOIN**, contact your healthcare professional, hospital emergency department or regional poison control center immediately, even if there are no 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.

What are possible side effects from using NITROFURATOIN?

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

Side Effects Include:
- Headache
- Abdominal pain
- Loss of appetite
- Diarrhea
- Short-term unusual hair loss or thinning
- Drowsiness
- Dizziness
- Joint pain

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Skin			
Rash: red, raised skin rash; itchy rash			√
Allergic			
Pulmonary sensitivity reactions: fever, chills, cough, chest pain, shortness of breath, generally feeling unwell			√
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)			√
Neurological			
Numbness or weakness of the arms and legs		√	
Rapid, uncontrollable movements of the eyes		√	
Liver			
Hepatitis (a liver disease) **(Rarely):** nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine			√
Jaundice: yellowing of the skin and/or eyes			√
Miscellaneous			
Urinary infection by germs which are not sensitive		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health 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 25ºC. Protect from light.

If you want more information about NITROFURATOIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this patient medication information by visiting the Health Canada website (https://www.canada.ca/en/health-canada.html); the manufacturer's website http://www.aapharma.ca/products, or by calling 1-800-667-4708.

This leaflet was prepared by AA Pharma Inc.

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