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Leaflet

Package leaflet: Information for the user

AGOTOIN

(Nitrofurantoin Tablets BP 100 mg)

Read all of this leaflet carefully before taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptom are the same as yours.
- If you get any side effect, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet.

What is in this leaflet?

- What Agotoin Tablets are and what they are used for?
- What do you need to know before you take Agotoin Tablets?
- How to take Agotoin Tablets?
- Possible Side Effects
- How to store Agotoin Tablets?
- Further information

1. What Agotoin Tablets are and what they are used for?
Agotoin tablets contain the active substance Nitrofurantoin. Nitrofurantoin is an antibiotic medication of the nitrofuran class. It is used to treat urinary tract infections. It work by killing bacteria in the urinary tract by damaging or blocking proteins the bacteria need to survive.
Agotoin tablets are used:

- To treat urinary tract infections
- To treat cystitis

2. What you need to know before you take Agotoin Tablets?
Do not take this medicine if,

- You are allergic (hypersensitive) to Nitrofurantoin.
- You have bacterial pyelonephritis.
- You have anuria, oliguria, or significant impairment of renal function.
- You have Prostatitis in men.

Take special care with Agotoin Tablets
if you have

- Kidney disease, liver disease or lung diseases
- Certain genetic condition (G-6-PD deficiency)
- Anemia
- Peripheral neuropathy
- Optic neuritis
- Diabetes
- Immunizations/vaccinations

Taking with other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.
Tell your doctor if you are taking any of these following medicines:

- Magnesium containing antacids
- Sulphinpyrazone (used to treat gout)
- Probenecid (used to treat gout)
- Methotrexate (used to treat rheumatoid arthritis)
- Darolutamide (used to treat non-metastatic castration-resistant prostate cancer in men)
- Lasmiditan (used to treat migraines)
- Pexidartinib (used to treat tenosynovial giant cell tumors)
- Pretomanid (used in combination to treat active multi-drug-resistant tuberculosis)
- Selinexor (used in combination to treat multiple myeloma in adults)

Taking Agotoin Tablets with food and drink
Do not consume alcohol while you are on a medication of Nitrofurantoin as it cause irritation of the bladder.

Pregnancy and breast-feeding
Nitrofurantoin is actively transported into breast milk in low concentration. Talk to your doctor or pharmacist before taking this medicine if you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby.

Driving and using machine
Do not drive or use any tools or machines because Nitrofurantoin can cause dizziness and drowsiness.

3. How to take Agotoin Tablets?
Always take this medicine exactly as your doctor or health care provider has told you. You should check with your doctor or health care provider if you are not sure.
Unless otherwise prescribed by the doctor, the recommended doses are:
For treatment of urinary tract infections:
Adult: 100 gm 4 times a day
Children 1 month of age and older: Dose is based on body weight and must be determined by your doctor.
Children younger than 1 month of age: Use is not recommended.
For Cystitis:
Adult: 100 mg orally 4 times a day for 1 week or for at least 3 days after urine sterility is obtained.
Children 1 month of age or older: 5 to 7 mg/kg/day (up to 400 mg/day) orally in 4 divided doses.
If you take more Agotoin Tablets than you should
If you have accidentally taken more tablets in one day than your doctor has told you to, contact your doctor or pharmacist.
If you forget to take Agotoin Tablets
Do not take a double dose to make up for a forgotten dose if you forget to take these tablets.
If you stop taking Agotoin Tablets
Do not stop taking your tablets, even if you feel better. It is important to take the tablets as long as the doctor has told you to, otherwise your medicine might not work properly.
If you have any further questions on the use of this product, ask your doctor or health care provider.

Agotoin Tablet contains Lactose
Lactose is a type of sugar. If you have been told by a doctor that you cannot tolerate sugar, talk to your doctor or healthcare provider before taking this medicine.

4. Possible side effect:
Like all medicines, Agotoin tablets can cause side effects, although not everybody gets them.
More common side effects: Changes in facial skin color, swelling of the face, mouth, hands, or feet, itching, skin rash, chest pain, fever.
Less common side effects: Black, tarry stools, dizziness, drowsiness, sore throat, weakness.
Rare side effects: Stomach pain, blindness, mood swings, eye pain, loss of appetite.
If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or health care provider.

5. How to store Agotoin Tablets?
Store below 30°C in a cool, dry and dark place. Protect from light.
Keep out of the reach and sight of children.
Store in the original carton.
Do not use this medicine after the expiry date stated on the carton (MM/YYYY)

6. Further information
What Agotoin Tablets contains:
Each uncoated tablet contains:
Nitrofurantoin BP 100 mg
Excipients q.s.
This product contains "Lactose".
What Agotoin Tablets looks like and contents of the pack.
Yellow coloured, circular, flat uncoated tablets having embossed 'AGOG' on one side and a breakline on other side of each tablet.
Shelf life: 36 months
Presentation: Bulk pack of 1000 Tablets
Blister pack of 5 X 10 Tablets
Blister pack of 10 X 10 Tablets
Distribution Category: Prescription Only Medicine **POM**

 **Marketing Authorisation Holder and Manufacturer**
AGOG PHARMA LTD.
Plot No. 33, Sector-II, The Vasai Taluka Indl. Co-op. Estate Ltd., Vasai (E), Dist. Thane, INDIA.

H0370301

110 mm

70 mm