

Package leaflet: information for the user
Nitrofurantoin Activase 50 mg hard capsules
Nitrofurantoin Activase 100 mg hard capsules
nitrofurantoin

Read carefully the entire leaflet before you this medicine are going to use, because there is important information in for you.

- Keep this leaflet. Maybe you have you later again need.
- Do you any questions? Then contact your doctor or pharmacist.
- Do not give this medicine to others others, because it is only for you prescribed. It can be harmful to others ,even if they have the same symptoms as you. u.
- Do you suffer from one of the side effects listed in section 4 ? Ordo you experience a side effect that is not in this leaflet state? Then contact your doctor or pharmacist.

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1. Nitrofurantoin Activase and what is it used for for what is this medicine used?

Nitrofurantoin is the active ingredient in this medicine. Nitrofurantoin is a medicine against infections by a bacteria (antibiotic). It is used for the treatment of infections of your urinary tract and bladder . Itis also also used to ensure that you do not get these infections ..

you feel during or after the treatment not not better? Or do you feel you feel worse? Then contact your doctor.

2. When should you not use this medicine or must you be extra careful with are?

When may you this medicine not use?

You are allergic to nitrofurantoin or to one of the substances in this medicine. These substances can you find in section 6 of this leaflet.

You are allergic to other nitrofurans.

Your doctor has you told that your kidneys not functioning work minute).You are in the

final stage of your pregnancy pregnancy (the delivery).

You may this medicine not use in babies younger than three months.

You lack an enzyme that glucose-6-phosphate dehydrogenase hot. This can your red blood cells more easily damage. This occurs more often in black people and people of Mediterranean Mediterranean, Middle-Eastern or Asian descent. Your doctor will know this.

You have a disease called porphyria ,, a group blood diseases that your nervous system, skin or both damaged.

You have symptoms in your lungs, liver or nerves had (peripheral neuropathy) after taking nitrofurantoin or other nitrofurans . Are you unsure.

any of the above points ?? Tell the to your doctor.

When should you be extra careful with this medicine ?Contact your doctor or pharmacist before before you this medicine take if:

you diabetes have (diabetes).

you problems with your kidneys have. You must then possibly extra become checked by your doctor during the treatment.

you suffer from no feeling or a weak feeling in in your arms and legs (peripheral neuropathy).

you anemia have. This causes less red blood cells, pale skin, a weak feeling and short of breath are. Or if you too little vitamin B or an abnormal amount salt in your blood has. Your doctor can you advice give.

you previously allergic reactions had ..

above points can can the chance increase of a side effect that causes damage to your nerves . This can cause things to feel different feel of cause for tingling.

you a disease in your lungs, liver or nervous system have.

must you this medicine before one couple months use? Then your doctor may regularly check how well your lungs and liver work. Especially if you older are.

this medicine can also cause a lung disease in patients who do not previous damage to the lungs have had. Lung disease can occur in patients who a short or long treatment receive.

you diarrhea have that is caused by a bacterium called clostridium difficile is called. you other medications against bacteria use.

you suffer from fatigue being ,, yellow color of your skin or eyes, itching, skin rash, joint pain, complaints in your abdomen, nauseous are, vomiting, no appetite, dark urine and pale or gray stool. These can symptoms be of a disease in your liver.

this medicine can affect have on the result of tests of glucose in your urine. The result can therefore false-positive be.

Some black people and people of Mediterranean, Oriental or Asian descent may during the treatment develop anemia .. Do you belong to this group? And do you experience during the treatment symptoms of fatigue, dizziness and shortness of breath ? Then stoptaking it of this medicine. Take also contact with your doctor.

Do you any other medications?

Do you besides Nitrofurantoin Activase any other medications, have you that recently done or are you this perhaps soon do ?Tell that then then your doctor or pharmacist. Do you use a one of the following medications together with Nitrofurantoin Activase? Then these medications can change effect work. Of can Nitrofurantoin Activase otherwise go work:

Magnesium trisilicate. This is a antacid. This medicine is used as it digest of food in your body not well goes.

Medications against an inflammation in a joint with pain (gout). For example probenecid of sulfipyrazone.

Medicines that ensure that food remains in your stomach longer. For example atropine or hyoscine.

Medicines against a type cataract (glaucoma). As carbonic anhydrase inhibitors. For example acetazolamide.

Medications that make your urine less acidic make (urine-alkalizing agents). For example a potassium citrate mixture.
Medicines against infections (quinolones).
Typhoid vaccine if it is taken orally is taken.

What should you pay attention with food and drink?

This medicine must with food or milk be taken. This helps to ensure that you do not experience stomach complaints gets. The will also help with the absorption of this medicine.

Pregnancy and breastfeeding

Are you pregnant, think you pregnant to be, do you want to become pregnant or are you breastfeeding ? Then contact your doctor? Then contact pharmacist before you use this medicine . used.

Pregnancy

As far as known this medicine can be used during pregnancy . It shouldnot be used during labor the delivery. Use of this medicine during the delivery can affect have on your baby (see the section 'When are you this medicine not use?' above).

Breastfeeding

Do you want to breastfeed give? Then first first contact your your doctor. This medicine enters into the breast milk. This can be dangerous for babies younger than 3 months. It can also be dangerous for babies who lack a type of enzyme do not have.

Driving ability and the use of machines

This medicine can cause that you feel dizzy and sleepy . Drive. Drive no car and operate no machines if you here suffer from have. Wait until these symptoms go away are.

This medicine contains lactose and sodium

Has your doctor told that you some sugars cannot tolerate? Then contact your doctor before you this medicine take.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, which means that it is in essence ' sodium-free'.3.

3. do you take this medicine in?

Use this medicine always exactly as your doctor or pharmacist you that has told. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Follow very carefully the instructions of your doctor. Complete the treatment course . Evenif you feel better better feels.

Recommended dose

Adults and children older than 10 years:

The usual dosage depends on the type infection that you have. The instructions for use must be written on the label that your pharmacist gives you. Contact your doctor or pharmacist if these instructions for use not clear are.

The normal dosages are:

For the treatment of infections: 1 capsule of 50 mg 4 times per day before 7 days

For the treatment of severe infections that do not go away and keep recurring: 1 capsule of 100 mg 4 times per day for 7 days

To ensure that you do not get other infections receives before bedtime the To

ensure that you do not get infections infections gets during a surgery: 1 capsule of 50 mg 4 times per day on the day of the surgery and for 3 days afterwards.

Use in children and babies older than 3 months:

The dosage depends on the weight of the child. Your doctor determines the dosage. Follow very carefully the instructions of your doctor.

The use of this medicine (a capsule) may possibly not well at younger children. Other forms of this medicine may be better. Like a liquid. Are you unsure? Then contact your doctor or pharmacist.

Use in children younger than 3 months:

Children younger than 3 months may not use this medicine.

Method of administration

This medicine must always with food or milk be taken. The medicine works then better.

Capsules must whole become swallowed. Forget your medicine not in to take.

Medical checks

Your doctor will very carefully monitor for possible influences on your liver, lungs, blood or nervous system. This medicine can affect the results of some tests examinations of glucose in your urine.

Have you too much of this medicine taken?

Contact immediately your doctor or pharmacist . Or goto to the emergency department of the hospital nearby ..

always always still have left . Takealso the packaging and the label label with you. This way knows the medical staff what you have taken.

Did you forget to take this medicine in totake

? Do you remember later in the to? Then take the dose of that day as usual. Did you miss a dose for the whole day? Then take the usual dose the next day in. Do not take any double dose to make up for a missed dose in order to catch up. Are you unsure? Then contact your doctor or pharmacist.

If you stop taking the medication of this medicine

Your doctor will tell you how long you this medicine must take . Stop. Stop not earlier than you are told. Also not if you feel better ..

you have any other questions about the use of this medicine? Then contact your doctor, pharmacist or nurse.

4. Possible side effects

Like any medicine can also this medicine side effects have. Not everyone gets them to deal.

The most side effects are mild. They go away again if you stop with the use of this medicine.

All medicines can cause allergic reactions. But severe allergic reactions occur almost never for. Do you suddenly have a wheezing breath, problems with breathing, swelling of your eyelids, face or lips, skin rash or itching (especially over your whole body)? Stop taking this medicine. Also, go immediately to one doctor.

Do you experience any of the one of the following side effects? Then stop using the use of this medicine. Also contact your doctor. A

group group blood diseases that your nervous system, skin, or both damaged (acute porphyria).

Your lungs may react to nitrofurantoin. This can quickly, within a week after the start of the treatment occur. It can also very slowly develop. Especially in older patients. This can cause fever, chills, coughing, shortness of breath, fainting or a blue color of blue color from your skin. There can scars develop due to damage of the tissue in your lungs.

Jaundice (inflammation of the liver that a yellow color of your skin or whites of the eyes caused). Your liver may also less well begin to function (liver failure). This may fatal are.

The nerves outside your spinal cord can damage. This can cause for changes in the sensation and the use of your muscles. The treatment must be stopped at the first symptoms of a tingling sensation or no sensation in your hands or feet. You may also experience headaches, extreme changes in mood or mental health, being confused, confused are, one weak feeling and blurred vision. These complaints can be very severe. In some cases they never go away.

Higher pressure in your skull. This causes severe headache ..

or purple color of your skin due to too little little oxygen in your blood. This disease is called cyanosis.

Symptoms of fever, flu, abdominal pain, diarrhea, blood in your stool and a weak feeling. This can be symptoms of a disease called cutaneous vasculitis ..

Complaints of jaundice, fatigue, abdominal pain, joint pain and swelling. This can be symptoms of a disease that is auto- disease the carautoimmune hepatitis hot.

Keep in mind that your urine dark yellow or brown may become during use of this medication. This is very normal. This is not a reason to stop using the medication. Other side effects may.

: Rarely (occur:

Rare (come for at less than 1 in 1000 users)

Damage of your bone marrow. Hereby receives you tea little red blood cells (anemia).

Not known (can with the available data not be determined)

In some patients the blood cells are damaged. This can cause for bruising, slower clotting of the blood, sore throat, fever, anemia and more quickly catch a cold or or a cold have that not away goes.

Nauseous be

Diarrhea (loose stool)

No appetite, abdominal pain and vomiting

Some patients experienced suffered from various types of skin rash or skin issues. There are also cases reported of a severe inflammation of the skin and other parts of the body due to an allergy to a medicine (DRESS syndrome). You may experience peeling of scales on your skin, red skin rash or fever together with a rapid heartbeat and severe skin rash with blisters. Other symptoms may include: inflammation of salivary glands (which facial pain cause), inflammation of your pancreas (which severe abdominal pain causes) and joint pain.

The nerves outside your spinal cord can damage. This can cause changes in the sensation and the use of your muscles .. Additionally can you experience suffer from headache, extreme changes in mood or mental health (psychosis), be confused be, a weak feeling, movements with your eyes make without that you that yourself want (causing your eye quickly back and forth, up and down or in a circle can move and you blurry can see). These symptoms can very be. In some cases go they never again away.

Tired are, cold chills and fever due to medications

Rapid loss of hair

Infection of your urinary tract by pathogens that not sensitive are to nitrofurantoin.

Inflammation of the walls of small blood vessels. This causes damage to your skin.

Inflammation of your liver because your immune system attacks your liver cells.

Inflammation of tissue around the tubes in your kidneys. As a result, your kidneys function less effectively ..

medicine can affect the function of the results of some studies of glucose in your urine.

The reporting of side effects

Do you experience side effects, contact your doctor, pharmacist or nurse nurse. This applies also to side effects that are not in this leaflet . You can report side effects also via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By Centrum Lareb, website: www.lareb.nl. By side effects to report, helps you us to gain information about the safety of this medicine ..

5. How store you this medicine?

Keep out of sight and reach of children keep.

Do not use this medicine after the expiry date expiry date. You find it on the box and the blister pack after EXP. There is a month and a year. The last day of the month is the expiry date.

Store below 25 °C.

Do not flush medicines not down the sink or the toilet and throw them away in the trash can. Ask your pharmacist what to do with medications you should do that you no longer use. If you medications in the right way dispose of be they on a correct way destroyed and enter they not into the environment end up.

6. Contents of the package and other information

Which substances are in this medicine?

The active ingredient in this medicine is nitrofurantoin.

Nitrofurantoin Activase 50 mg hard capsules: Each hard capsule contains 50 mg nitrofurantoin.

Nitrofurantoin Activase 100 mg hard capsules: Each hard capsule contains 100 mg nitrofurantoin.

The other substances in this medicine are talc, corn starch and lactose monohydrate. The shell of the capsule contains gelatin, titanium dioxide (E 171) and yellow iron oxide (E 172).

How does Nitrofurantoin look like and what is in a package?

Nitrofurantoin 50 mg hard capsules have a yellow cap and ivory-yellow body. The capsules contain yellow to yellow-white powder.

Nitrofurantoin 100 mg hard capsules have an ivory-yellow cap and body. The capsules contain yellow to yellow-white powder.

Nitrofurantoin is available in blister packs with 14, 15, 20, 28, 30, 56, 60, 84 or 90 hard capsules.

It is possible that not all pack sizes in the market are brought.

Holder of the license for the placing on the market bringing and manufacturer

License holder:

Activase Pharmaceuticals Limited
11 Boumpoulinas,
P.C. 1060, Nicosia
Cyprus

Manufacturer:

Elara Pharmservices Europe Limited
Regus Block 1, Blanchardstown Corporate Park,
Ballycoolin Road, Blanchardstown, Dublin 15,
D15 AKK1
Ireland

Registered under number

Nitrofurantoin Activase 50 mg hard capsules: RVG 131639

Nitrofurantoin Activase 100 mg hard capsules: RVG 131640

This medicine is registered in member states of the European Economic Area under the following names:

Ireland	Nitrofurantoin 50 mg hard capsules en Nitrofurantoin 100 mg hard capsules
Netherlands	Nitrofurantoin Activase 50 mg hard capsules & Nitrofurantoin Activase 100 mg hard capsules
Belgium	Nitrofurantoin Activase 50 mg capsule & Nitrofurantoin Activase 100 mg capsule
Portugal	Nitrofurantoin 50 mg Capsule & Nitrofurantoin 100 mg Capsule
Slovenia	Nitrofurantoin Activase 50 mg capsule & Nitrofurantoin Activase 100 mg capsule

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