AKURIT-4 TABLETS

Rifampin /Isoniazid /Pyrazinamide /Ethambutol Hydrochloride (150mg/75mg/400mg/275mg)

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What Akurit-4 is used for

Akurit-4 is used for the treatment of tuberculosis.

How Akurit-4 works

AkuriT-4 contains four different medicines called rifampin, isoniazid, pyrazinamide and ethambutol hydrochloride. They work by killing the bacteria that cause tuberculosis.

Before you use Akurit-4

- When you must not use it

Do not take this medicine if you:

- are allergic to rifampin, isoniazid, pyrazinamide, ethambutol hydrochloride or to any of the other ingredients of this medicine
- had liver injury cause by medicine or history of adverse reaction to isoniazid such as fever, chills and joint inflammation
- have eye disorder caused by inflamed optic nerve

<u>Before you start use it</u>

Ethambutol is not recommended for use in children under 13 years old.

Tell your doctor if you have one of the following condition before taking this medicine:

- Diabetes
- Eye defects
- Drink alcohol every day or you are alcoholic
- Kidney problem
- Long term liver disease

- Pregnancy and lactation

Akurit 4 may be secreted into breastmilk.

Please contact your doctor or pharmacist if you are pregnant, or planning for pregnancy or breast feeding before using any medicine. Your doctor will assess whether it is possible for you to continue with the treatment of Akurit-4.

Akurit-4 may affect the results of some blood tests like tests for folate, vitamin B12 and liver function. If you are going to have a blood test, it is important to tell your doctor that you are taking Akurit 4.

- <u>Taking other medicines</u>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines obtained without a prescription.

Tell your doctor if you take one of the following medicines:

- Medicines for irregular heartbeats such as quinidine, disopyramide, mexiletine, digitoxin and tocainide.
- Medicines for the heart or blood pressure (diltiazem, nifedipine, verapamil, enalapril, beta-blockers).

- Corticosteroids (medicine to reduce inflammation)

- Oral contraceptives including progestin
- Medicines to treat fungal infections such as fluconazole, itraconazole, ketoconazole
- Antibiotics such as dapsone, ciprofloxacin, chloramphenicol, ethionamide, cotrimoxazole
- Medicines for mental/ mood disorder such as nortriptyline, and haloperidol
- Methadone (medicine used for drug addiction or narcotic pain reliever)
- Medicine for asthma such as theophylline
- Medicine to prevent organ rejection such as cyclosporine
- Medicines to prevent blood clots such as warfarin
- Anticonvulsants such as carbamazepine, Fos phenytoin, phenytoin, primidone, valproic acid, diazepam
- Gout medicine such as probenecid
- Anesthetic such as halothane and barbiturate
- Antiretroviral medication for HIV/AIDS such as zidovudine
- Clofibrate (Medicine for cholesterol lowering)

If you are currently taking any of these medicines, ask your doctor about switching to a different medicine while you are taking Akurit-4. Often, there are other medicines you can take instead.

If you need to take a medicine for indigestion, such as an antacid, take your tablets at least one hour before the antacid.

Akurit may make oral contraceptive pills work less well. In such cases, you should take alternative contraceptive measures.

If you are taking other anti-tuberculosis medicines, please ask your doctor on how to take the medicine.

How to use Akurit-4

- How much to use

Adults – Take 3 tablets per day for an average body weight of 50 kg. This tablet can be broken into two for easy swallowing purpose. It is not for taking half tablet dosage.

- When to use it

Use as directed by your doctor or pharmacist.

During initial phase that can last 3 months, Akurit-4 is taken on a daily continuous basis. Check with your doctor or pharmacist if you are not sure.

How long to use it

Take the tablets for the duration as your doctor recommends. Even if you feel better, you should not interrupt treatment with Akurit-4 without consulting your doctor.

If you stop taking the tablets too soon, the infection may come back. Also, the bacteria may become resistant to the medicine.

Rare kidney hypersensitivity reactions has been reported when therapy was resumed with interruption of the daily dosage regimen.

<u>If you forget to use it</u>

Consult your doctor or pharmacist onwhat you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

Do not take a double dose to make up for the missed dose.

<u>If you use too much (overdose)</u>

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or

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poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, increasing lethargy, dizziness, slurring of speech, blurring of vision and visual hallucinations.

If possible, take your tablets or the box with you to show the doctor what you have taken.

While you are using it

<u>Things you must do</u>

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Akurit-4.

Tell your doctor immediately if you become pregnant while taking this medication.

<u>Things you must not do</u>

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Akurit-4 to anyone else, even if they have the same symptoms or condition as you.

Do not drink any alcohol as longs as you are taking Akurit-4.

- Things to be careful of:

- Driving and using machines

This medicine may affect your ability to drive or use machines. It may cause confusion, disorientation, hallucinations, dizziness, malaise and visual disturbances (blurred vision, red-green color blindness, loss of vision). If you experience any of the above, do not drive or use machines and contact your doctor immediately.

Akurit 4 may cause urine, feces, saliva, sputum, sweat and tears to turn red-orange in color. Soft contact lenses may be permanently stained.

Side effects

Like all medicines, Akurit-4 can cause side effects, although not everybody gets them.

If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Nervous system reactions:

Headache, drowsiness, fatigue, coordination disorder, dizziness, inability to concentrate, confusion, visual disturbances, muscle weakness, pain or tingling in extremities, generalized numbness, convulsions, nerve inflammation of the eye, memory impairment and hallucinations.

Gastrointestinal disturbances

Heartburn, epigastric distress, eating disorder, nausea, vomiting, flatulence, and diarrhea.

Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis).

Liver reactions

Jaundice and occasionally severe liver inflammation.

Kidney reactions

Kidney impairment, destruction of red blood cell, causing presence of blood in urine, inflammation of kidney, an excess of uric acid in blood.

Blood reactions

Decrease in red blood cell, white blood cell and platelet count.

Allergic and immunological reactions

Enlargement of lymph nodes, inflammation of blood vessel, itchiness, hives, rash, sore mouth or tongue, eye inflammation.

Metabolic and endocrine reactions

Vitamin B6 or B3 deficiency, excess glucose in blood, too much acid in blood, growth of male breast.

Musculoskeletal and connective tissue disorders

Disease that cause your immune system to attack your joints, skin, organs and blood vessels.

Skin and subcutaneous tissue disorders

Flushing, inflammation of skin

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website <u>npra.gov.my</u> [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Akurit-4

- <u>Storage</u>

Keep out of the reach and sight of children.

Store at temperature not exceeding 30°C.

Do not store any medicine in the bathroom, or near a sink, or on a windowsill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date. The expiry date refers to he last day of that month.

<u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

<u>What it looks like</u>

Brown colored, capsule shaped film coated tablets with break line on one side and plain on the other side.

Ingredients

Active ingredient(s): Rifampin, Isoniazid, Pyrazinamide, Ethambutol hydrochloride

Inactive ingredients:

Microcrystalline cellulose, Crospovidone, Pregelatinized starch Ascorbic acid, Gelatin, Colloidal silicon dioxide, Magnesium stearate, Opadry 80W56578 Brown

<u>MAL number:</u> MAL20051429AZ

Manufacturer

Lupin Ltd. A-28/1, M.I.D.C. Chikalthana Aurangabad -431 210 India

Product Registration Holder

Pahang Pharmacy Sdn. Bhd., Lot 5979, Jalan Teratai, 5 ½ Mile, Off Jalan Meru,41050 Klang, Selangor. Malaysia

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