

---

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

S4

AKURIT KID 75/50 ODT, dispersible tablets

Rifampicin and Isoniazid

AKURIT KID 75/50 ODT dispersible tablets are sugar free. Contains sweetener, aspartame 2,0 mg and saccharin sodium 2,0 mg.

**Read all of this leaflet carefully before you start taking AKURIT KID 75/50 ODT**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your healthcare provider or your pharmacist.
- AKURIT KID 75/50 ODT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What AKURIT KID 75/50 ODT is and what it is used for
2. What you need to know before your child use AKURIT KID 75/50 ODT
3. How to use AKURIT KID 75/50 ODT

---



4. Possible side effects
5. How to store AKURIT KID 75/50 ODT
6. Contents of the pack and other information

**1. What AKURIT KID 75/50 ODT is and what it is used for**

AKURIT KID 75/50 ODT contains rifampicin and isoniazid, one of a group of medicines called Tuberculostatics.

AKURIT KID 75/50 ODT is indicated for tuberculosis of the lungs in children.

**2. What you need to know before your child takes AKURIT KID 75/50 ODT**

**Your child should not take AKURIT KID 75/50 ODT:**

- if he/she is hypersensitive (allergic) or has a history of being hypersensitive to rifampicin, other rifampicins, isoniazid or any of the other ingredients of AKURIT KID 75/50 ODT (see section 6)
- if he/she has yellowing of the skin or liver problems
- if he/she has moderate to severe kidney or liver problems, diabetes, history of gout, suffering from fits and a rare hereditary disease called porphyria, with symptoms like severe abdominal pain, constipation or diarrhoea, nausea and vomiting, red or brown urine
- if you are taking medicine for HIV/AIDS called nevirapine and the combination saquinavir/ritonavir
- if you are pregnant or breastfeeding.

---



## **Warnings and precautions**

### **Take special care with AKURIT KID 75/50 ODT:**

If your child has kidney or liver problems, he/she should not be given AKURIT KID 75/50 ODT. If it is the only treatment option available, your doctor or healthcare provider will monitor his/her liver function via blood tests every two to four weeks.

AKURIT KID 75/50 ODT dispersible tablets may cause liver problems. You should be attentive to symptoms of liver damage, such as unexplained loss of appetite, nausea, vomiting, dark urine, yellow discolouration of the skin (jaundice), persistent fatigue of greater than 3 days duration and abdominal pain and tenderness in your child. If these occur, you should immediately report this to your child's healthcare provider.

Your child's urine, stool, saliva, sweat and tears may change colour, and soft contact lenses may be stained as a result of taking AKURIT KID 75/50 ODT.


If you develop kidney problems or a blood disorder, where your red blood cells are destroyed faster than they can be made, your child should discontinue the treatment.

AKURIT KID 75/50 ODT may enhance the functioning of certain hormones and vitamin D.

Your healthcare provider will monitor your child closely as there is a possibility that he/she may develop an allergic reaction towards AKURIT KID 75/50 ODT. For this reason, do not interrupt the treatment if not advised by your healthcare provider.

If your child gets flu-like symptoms such as fever, headache, muscle aches etc. you should report this to your child's healthcare provider, since AKURIT KID 75/50 ODT dispersible tablets may be the cause.

---



Your healthcare provider will monitor your child's blood counts during treatment, as he/she may develop certain blood disorders.

AKURIT KID 75/50 ODT may reduce the functioning of certain medicine like antiretrovirals (used to treat HIV/AIDS), medicine for epilepsy (fits/seizures), immunosuppressants (medicine used to lower the functioning of the immune system) and warfarin (medicine used to treat blood clots).

If your child is allergic to ethionamide (used to treat TB), pyrazinamide (used to treat TB) or niacin (vitamin B<sub>3</sub>), you should inform your child's healthcare provider, because your child may also be allergic to AKURIT KID 75/50 ODT.

Tingling in the hands and feet (peripheral neuropathy) is the most common side effect of isoniazid, one of the active ingredients in AKURIT KID 75/50 ODT, particularly in HIV-positive and malnourished children being treated for TB. You should report any such symptoms to your child's healthcare provider. A certain vitamin, pyridoxine, should be administered routinely at doses of 5-10 mg per day during treatment with AKURIT KID 75/50 ODT dispersible tablets, as it reduces the risk of developing a nerve called neuropathy.

If your child has diabetes, he/she should be closely monitored

If your child has epilepsy or a history of psychiatric disease, you should report this to your child's healthcare provider, as these conditions may affect his/her ability to tolerate AKURIT KID 75/50 ODT.

---



If your child is taking cortisone or any cortisone-like medicine, you should report this to your child's healthcare provider, as the cortisone dose may have to be increased whilst taking AKURIT KID 75/50 ODT.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **Other medicines and AKURIT KID 75/50 ODT**

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Taking any other medicines may affect how AKURIT KID 75/50 ODT works, or AKURIT KID 75/50 ODT may affect how the other medicines work.

Your child should not take AKURIT KID 75/50 ODT with any of the following:

- nevirapine (used to treat HIV infection)
- saquinavir/ritonavir combination (used to treat HIV infection)
- inhalation anaesthetics (used during surgery)
- ketoconazole (a medicine used to treat fungal infections)
- aluminium hydroxide (medicine used to treat diseases related to the gastric acid)
- disulfiram (medicine used for the treatment of chronic alcoholism).

---



AKURIT KID 75/50 ODT may reduce the activity of the following medicines:

- azathioprine, ciclosporin (used to lower the functioning of the immune system)
- chloramphenicol, doxycycline (antibiotic)
- cimetidine (used to treat stomach ulcer)
- clofibrate (treats high cholesterol)
- corticosteroid (lowers inflammation in the body)
- dapsone (used to treat leprosy)
- diazepam (used to treat anxiety and fits)
- fluconazole, itraconazole, ketoconazole (used to treat fungus infections)
- haloperidol (used to treat mood disorders)
- hexobarbitone (sedative)
- methadone (pain medication)
- oral hypoglycaemic medicines (used to treat diabetes)
- phenytoin (used to treat fits/seizures)
- quinine (used to treat malaria)
- sulfasalazine (used to treat arthritis)
- thyroid hormones
- theophylline (used to treat asthma)
- zidovine, delavirdine, efavirenz (used to treat HIV)
- beta-adrenoceptor blocking medicine (used to treat abnormal heart rhythms i.e. acebutolol and atenolol)

---



- digoxin (used to treat various heart conditions)
- disopyramide, lorcainide, mexiletine, propafenone, quinidine, tocainide, verapamil (used to treat abnormal heart rhythm)
- calcium-channel blocking medicines (used to treat high blood pressure i.e. amlodipine, nifedipine)
- oral contraceptives
- narcotics
- analgesics (pain medication)
- barbiturates (used to treat anxiety and fits/seizures).

AKURIT KID 75/50 ODT may enhance the effects of some medicine:

- phenytoin (used to treat fits/seizures)
- primidone (used to treat seizures and tremors)
- carbamazepine (used to treat fits/seizures)
- ethosuximide (used to treat absence seizures)
- benzodiazepines (tranquilizers i.e. diazepam, triazolam)
- warfarin (used to treat blood clots)
- theophylline (used to treat respiratory problems).

---



Take special care when giving AKURIT KID 75/50 ODT with the following medicines:

- cycloserine (used to treat TB) as side effects may be worse
- disulfiram (used to treat alcoholism) as side effects may be worse
- alcohol may affect the effect of AKURIT KID 75/50 ODT
- alfentanil (pain medication during surgery) may affect the effect of AKURIT KID 75/50 ODT
- aminosalicylic acid (antibiotic used to treat TB) may affect the effect of AKURIT KID 75/50 ODT
- large doses of pyridoxine (Vitamin B6) may affect the effect of AKURIT KID 75/50 ODT
- antacids may reduce the absorption of AKURIT KID 75/50 ODT and reduce the effect
- concurrent use of chronically used paracetamol, alcohol and other medicine which may cause liver toxicity, may increase the possibility of AKURIT KID 75/50 ODT causing liver toxicity.
- ARV's like stavudine and zalcitubine can cause a nerve disease called peripheral neuropathy (symptoms include tingling of the hands and feet).

The active ingredients in AKURIT KID 75/50 ODT may also interact with a number of other medicines, including the following:

- medicines used to treat HIV infection (e.g. tenofovir alafenamide, emtricitabine, efavirenz, tenofovir DF, abacavir, nevirapine, etravirine, dolutegravir, maraviroc)
- medicines to treat fungal infections (e.g. voriconazole)
- certain antibiotics (e.g. clarithromycin, chloramphenicol, ethionamide)

---





- medicines to treat malaria (e.g. quinine, chloroquine, mefloquine, lumefantrine, amiodaquine, artemisinin)
- immunosuppressant medicines (e.g. ciclosporin, tacrolimus)
- medicines to treat heart conditions (e.g. verapamil, digoxin, atenolol, lidocaine, amlodipine, enalapril)
- medicines to treat cholesterol (e.g. simvastatin, atorvastatin)
- some medicines to treat diabetes (e.g. glibenclamide)
- medicines to treat epileptic seizures (e.g. carbamazepine, valproic acid, phenobarbitone, lamotrigine)
- medicines used to help you sleep (benzodiazepines, e.g. flurazepam, triazolam, midazolam, zolpidem)
- medicines for the treatment of certain psychiatric conditions (neuroleptics, e.g. chlorpromazine, haloperidol, amitriptyline)
- medicines used during surgery (narcotics, e.g. enflurane)
- levothyroxine (use to treat thyroid conditions)
- pain killers, e.g. morphine, codeine
- praziquantel (used to treat worm infections).

Taking any of these medicines together with AKURIT KID 75/50 ODT may either be unsuitable or require dose adjustment.

### **AKURIT KID 75/50 ODT with food, drink and alcohol**

AKURIT KID 75/50 ODT should be dispersed in as little as 5 mL of water, or chewed, taken on an empty stomach as a single dose, orally.

---



AKURIT KID 75/50 ODT should be taken at least 1 hour before aluminium containing antacids are used (see section 4.5).

Patients should not drink alcohol while taking AKURIT KID 75/50 ODT as this increases the risk of liver damage.

When taken with cheese or fish (histamine- or tyramine-rich food) AKURIT KID 75/50 ODT may cause redness/itching of the skin, hot feeling, rapid or pounding heartbeat, sweating, chills or clammy feeling, headache, and/or light-headedness. If your child experiences these side effects, he/she should avoid eating cheese and fish while taking this medicine.

### **Pregnancy and breastfeeding**


If you are pregnant or breastfeeding your baby, please consult your healthcare provider, pharmacist or other healthcare professional for advice before using AKURIT KID 75/50 ODT.

### **Driving and using machines:**

AKURIT KID 75/50 ODT may cause dizziness, impaired concentration, and drowsiness.

It is not always possible to predict to what extent AKURIT KID 75/50 ODT may interfere with your daily activities. You should ensure that your child does not engage in the above activities until they are aware of the measure to which AKURIT KID 75/50 ODT affects them.

---



**AKURIT KID 75/50 ODT contains aspartame**

AKURIT KID 75/50 ODT contains aspartame, a source of phenylalanine, which may be harmful to people with phenylketonuria.

**3. How to take AKURIT KID 75/50 ODT**

Do not share medicines prescribed for you with any other person.

Always give AKURIT KID 75/50 ODT exactly as your healthcare provider has instructed you. You should check with your healthcare provider or pharmacist if you are unsure.


*For the continuation phase of TB treatment:*

The dose of AKURIT KID 75/50 ODT dispersible tablets is decided on the basis of your child's body weight.

The usual dose is:

Weight Band	Number of dispersible tablets
4 – 7 Kg	1
8 – 11 Kg	2
12 – 15 Kg	3
16 – 24 Kg	4
25 Kg +	Adult dosages recommended

For children weighing 25 kg and above, adult dosages are recommended.



Your healthcare provider will tell you how long your child's treatment with AKURIT KID 75/50 ODT will last. Do not stop treatment early because your child's infection may come back.

If you have the impression that the effect of AKURIT KID 75/50 ODT is too strong or too weak, tell your healthcare provider or pharmacist.

**If you give your child more AKURIT KID 75/50 ODT than you should:**

In the event of overdose, consult your healthcare provider or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- your child may also get a reddish-orange discolouration of the skin and mucous membranes, facial swelling and itching
- high blood glucose levels, vomiting, gastrointestinal disturbances, slurring of speech, fits/seizures, coma, hallucinations, difficulty breathing, central nervous system depression, fatalities.

**If you forget to give your child AKURIT KID 75/50 ODT:**

Give AKURIT KID 75/50 ODT as soon as you remember, then continue to give AKURIT KID 75/50 ODT at the usual times. Do not take a double dose to make up for forgotten individual doses.

---



### **If you stop giving AKURIT KID 75/50 ODT to your child**

You should not stop giving this medicine to your child without checking with your child's healthcare provider. Stopping tablets too early may no longer protect your child from the infection or cause it to come back.

#### **4. Possible side effects**

AKURIT KID 75/50 ODT can have side effects.

Not all side effects reported for AKURIT KID 75/50 ODT are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using AKURIT KID 75/50 ODT, please consult your healthcare provider, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop using AKURIT KID 75/50 ODT and tell your healthcare provider immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AKURIT KID 75/50 ODT. You may need urgent medical attention or hospitalisation.

---



Tell your healthcare provider immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- diarrhoea that is serious, lasts a long time or has blood in it with stomach pain or fever as this can be a sign of serious bowel inflammation
- hepatitis (swelling and inflammation of the liver, characterised by symptoms such as, abdominal pain or distension, dark urine and pale or clay-coloured stools, fatigue, fever, general itching, yellowing of the skin or eyes, loss of appetite, nausea and vomiting), jaundice
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
- Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters)
- muscle weakness, involuntary twitching, poor decision making or concentration, trembling, difficulty speaking (toxic encephalopathy)
- renal failure
- sudden increase in blood pressure (hyperreflexia), bleeding in the brain
- toxic exfoliative dermatitis (a severe inflammation of the entire skin surface).

These are all serious side effects. You may need urgent medical attention.

Tell your healthcare provider if you notice any of the following:

Frequent side effects:

- weakness, numbness and pain from nerve damage, usually in the hands and feet

---



- redness of eyes, discoloration of soft contact lenses
- diarrhoea, abdominal pain, nausea, loss of appetite, vomiting
- elevated liver activity blood test results
- disturbances of menstrual cycle
- flushing, reddish discoloration of body fluids like urine, tears, saliva and sweat, lower blood pressure, shock
- skin reactions which consist of redness and itching, with or without a rash
- muscle weakness and muscle disease
- constipation, dry mouth.

Less frequent side effects:

- worsening of porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin)
- impaired memory
- medicine induces psychosis
- headache, lack of energy, impaired balance or coordination, difficulty concentration, dizziness, seizures/fits
- pink eye
- stomach inflammation, swelling or inflammation of the large intestine
- sun allergy, redness and peeling of the skin over large areas of the body, skin condition called pemphigoid (symptoms include itching skin, large blisters), a rash of purple spots due to small blood vessels leaking blood into the skin, joints, intestines or organ

---



- inflammation of the kidney
- several blood disorders
- confusion, generalised numbness
- blurred vision, eye irritation
- loss of hearing
- hypersensitivity skin reactions, an inflammation of the blood vessels that causes changes in the blood vessel walls, medicine-induced hypersensitivity reaction that presents with skin rash, involvement of internal organs like liver, lung, or kidney
- flu syndrome, a fever reaction with flu-like symptoms, fungal overgrowth i.e. sore mouth or tongue
- swollen lymph nodes, reactions which is similar to a disease called Lupus (an inflammatory disease caused when the immune system attacks its own tissues)
- a condition in which too much acid accumulates in the body
- psychotic reactions (characterised by delusions, hallucinations and confusion), memory impairment
- nerve condition associated with pins and needles, loss of tendon reflexes, increase in frequency of fits in epileptic patients
- blurred vision or loss of vision, with or without eye pain
- vertigo
- pellagra (a disease caused by a lack of the vitamin niacin (vitamin B<sub>3</sub>). Symptoms include inflamed skin, diarrhoea, dementia, and sores in the mouth),  
acne

---





- urinary retention
- male breast enlargements.

The following side effects have been reported but the frequency for them to occur is not known:

- bleeding into the skin, bruising and slow blood clotting after an injury (thrombocytopenia)
- shortage of white blood cells, accompanied by sudden high fever, severe sore throat and ulcers in the mouth (agranulocytosis)
- hallucinations (strange visions or sounds)
- tremors, sleeplessness
- vision problems due to death or inflammation of cells in your eye
- flatulence, constipation
- joint pain
- a lung disease that occurs when lung tissue becomes damaged and scarred, inflammation of lung tissue, shortness of breath, wheezing
- ulcerative colitis (chronic, inflammatory bowel disease that causes inflammation in the digestive tract), gastrointestinal bleeding
- swelling of the face, arms and legs
- hair loss, hives
- rheumatic syndrome (autoimmune and inflammatory diseases that cause your immune system to attack your joints, muscles, bones and organs).

---



If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your healthcare provider or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of AKURIT KID 75/50 ODT.

### **5. How to store AKURIT KID 75/50 ODT**

Store all medicines out of reach of children.

Store at or below 30 °C in original container.

Protect from moisture and light.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What AKURIT KID 75/50 ODT contains**

The active substances are rifampicin and isoniazid.

Each dispersible tablet contains 75 mg rifampicin and 50 mg isoniazid.

---



**The other ingredients are:**

Ascorbic acid, aspartame (sweetener) 2,0 mg, colloidal silicon dioxide, colour ponceau 4R Supra LD, crospovidone, dry flavour trusil raspberry special LD, dry flavour trusil strawberry select LD, magnesium stearate, microcrystalline cellulose, pregelatinized starch, saccharin sodium (sweetener) 2,0 mg.

**What AKURIT KID 75/50 ODT looks like and contents of the pack**

AKURIT KID 75/50 ODT dispersible tablets are brick red coloured, flat faced bevelled edged, mottled, circular tablet plain on both sides with characteristic flavour.

*Aluminium Strip pack:*


10 dispersible tablets shall be packed per strip using plain strip aluminium foil 0,03 mm as a base material and plain strip aluminium strip pack 0,03 mm aluminium foil as a lidding material. 10 strip packs will be packed into a printed outer carton.

6 dispersible tablets shall be packed per strip using plain strip aluminium foil 0,03 mm as a base material and plain strip aluminium strip pack 0,03 mm aluminium foil as a lidding material. 14 strip packs will be packed into a printed outer carton.

*Aluminium Blister pack:*

5 dispersible tablets shall be packed per blister using plain aluminium foil 25 micron as a lidding material and cold forming lu-Alu foil base material. 18 blisters shall be packed into a printed outer carton.

---



**Holder of Certificate of Registration**

Pharma Dynamics (Pty) Ltd

1<sup>st</sup> Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

**This leaflet was last revised in**

14 December 2021

**Registration number**

A54/20.2.3/0648

---

