

APPROVED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

UKUZID 300 mg tablets

Isoniazid 300 mg

UKUZID 300 mg is sugar free.

Read all of this leaflet carefully before you start taking UKUZID

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- UKUZID 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 UKUZID is and what it is used for
2. What you need to know before you use UKUZID
3. How to use UKUZID
4. Possible side effects
5. How to store UKUZID
6. Contents of the pack and other information



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1. What UKUZID is and what it is used for

UKUZID belongs to a group of medicines called antibacterials. Isoniazid as in UKUZID works by killing bacteria that cause tuberculosis (also known as TB).

UKUZID is used to prevent and treat tuberculosis. Your doctor will prescribe UKUZID with other anti-tuberculous medicines.

TB is a serious infectious disease that can be passed on to other people. If left untreated it can spread through your body and may be fatal. It is important that you receive effective treatment for this condition.

2. What you need to know before you take UKUZID

Do not take UKUZID:

- if you are hypersensitive (allergic) to isoniazid, or to any of the ingredients of UKUZID
- if you are allergic to other TB medicines such as ethionamide, pyrazinamide or niacin
- if you drink a lot of alcohol regularly
- if you have serious liver problems
- if you have severe kidney failure
- if you have epilepsy or have ever had convulsions (fits)
- if you are using other TB medicines with UKUZID to treat TB, as this may cause inflammation or damage to the nerve in your eye(s) (also known as optic neuritis)
- if you are pregnant or breastfeeding.



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Warnings and precautions

Take special care with UKUZID:

- if you have or have had liver disease
- if you are elderly or female
- if you are malnourished (severely underfed)
- if you have HIV infection
- if you have extra-pulmonary TB (outside the lungs)
- if you present with symptoms of hepatitis such as a general feeling of discomfort or illness (malaise), tiredness, anorexia and nausea
- if you develop signs and symptoms of conditions called Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN). This may include an increasing skin rash often with blisters or mouth ulcers
- if you develop hypersensitivity symptoms such as fever, rash, swollen lymph nodes or liver abnormalities. This condition is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)
- if you have epilepsy or have ever had convulsions (fits)
- if you have been diagnosed with diabetes (high blood sugar levels)
- if you suffer or have suffered from psychosis (mental disturbances with hallucinations or delusions)
- if you have or have had kidney disease
- if you suffer with chronic alcoholism



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- if you develop any eye problems as regular eye examinations are advised while being treated with UKUZID.

Other medicines and UKUZID

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

Tell your healthcare provider if you are taking any of the following:

- any medicine for the treatment of epilepsy such as carbamazepine, phenytoin, primidone or ethosuximide
- benzodiazepines such as diazepam, triazolam or chlorzoxazone (for the treatment of anxiety)
- warfarin (to thin the blood and prevent clotting)
- theophylline (used to prevent and treat wheezing, shortness of breath, and chest tightness caused by asthma, chronic bronchitis, emphysema, and other lung diseases)
- rifampicin, paraminosalicylic acid or any other medicine used to treat TB
- cycloserine (used to treat active tuberculosis and urinary tract infections)
- disulfiram (for the treatment of alcoholism)
- prednisolone (corticosteroid) - used to treat certain types of allergies and inflammatory conditions
- certain antacids
- levodopa (for the treatment of Parkinson's disease)
- itraconazole or ketaconazole (for the treatment of fungal infections)



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- zalcitabine and stavudine (used for the treatment of HIV).

UKUZID with food and drink

UKUZID should be taken on an empty stomach, so take it at least 30 minutes before a meal or 2 hours after a meal. This helps your body absorb UKUZID more easily.

UKUZID may interact with foods containing histamine or tyramine (e.g. matured cheeses, cured meat, some fish like tuna, salmon and mackerel, wine and beer), causing symptoms including headache, sweating, flushing, fast, uneven or forceful heartbeat (palpitations), dizziness, feel lightheaded or faint (due to low blood pressure). These foods should be avoided if you are receiving UKUZID.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before taking UKUZID.

UKUZID should not be taken during pregnancy (see Do not take UKUZID). Pyridoxine supplementation is recommended.

UKUZID passes into breastmilk and therefore should not be taken if you are breastfeeding your baby (see Do not take UKUZID).

Driving and using machines:

UKUZID may affect your ability to drive or use machinery.



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Convulsions (fits) have been reported as an adverse reaction when taking UKUZID. You should ensure that you do not engage in the above activities until you are aware of the measure to which UKUZID affects you.

3. How to take UKUZID

Do not share medicines prescribed for you with any other person. Always take UKUZID exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Your doctor will choose the dose that is right for you.

Adults and adolescents:

Prophylaxis (prevention): 5 mg/kg (maximum 300 mg (one tablet)) once daily.

Treatment: 5 -15 mg/kg, once daily or in divided doses (maximum 900 mg (3 tablets) per day), based on the type of tuberculosis and sensitivity pattern. Your doctor will prescribe UKUZID in combination with other anti-tuberculosis medicines.

Children:

Prophylaxis (prevention): 10 mg per kg of body weight up to 300 mg (1 tablet), once a day.

Treatment: 10 - 20 mg/kg, once daily or in divided doses (maximum 300 mg (1 tablet) per day), based on the type of tuberculosis and sensitivity pattern. Your doctor will prescribe UKUZID in combination with other anti-tuberculosis medicines.



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Your doctor will tell you how long your treatment with UKUZID will last. Do not stop treatment early without talking to your doctor.

If you have the impression that the effect of UKUZID is too strong or too weak, tell your doctor or pharmacist.

If you take more UKUZID than you should:

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

Taking too much isoniazid may cause; slurred speech, acidosis (upset of the acid balance in the body), high blood glucose levels, hallucinations (seeing things), fits and/or coma. These effects may require emergency treatment in hospital.

If you forget to take UKUZID:

If you forget to take UKUZID, take as soon as you remember. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking UKUZID

Do not stop taking UKUZID without first talking to your doctor. It is important you take the full course of this medicine, as directed by your doctor, in order to clear the infection that causes tuberculosis.

4. Possible side effects



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UKUZID can have side effects.

Not all side effects reported for UKUZID are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using UKUZID, please consult your healthcare provider for advice.

If any of the following happens, stop using UKUZID and tell your doctor 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 UKUZID. You may need urgent medical attention or hospitalisation.

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

- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
- serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening)



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- inflammation of blood vessels, known as vasculitis (signs could be red spots on your skin, usually on your lower legs or effects like joint pain)
- urinating less than usual or not at all
- yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems (signs of hepatitis, jaundice, liver problems or liver failure)
- seizure (convulsions), mental disturbances including psychotic reactions such as hallucinations and delusions

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- peripheral neuritis or neuropathy, a result of damage to the nerves outside of the brain and spinal cord (peripheral nerves), often causes weakness, numbness and pain, usually in your hands and feet
- hepatitis prodromal symptoms (loss of appetite, nausea or vomiting, unusual tiredness or weakness).

Less frequent side effects:

- blood disorders which may make you more likely to get infections, get tired very easily, or bruise very frequently
- neurotoxicity - damage to brain or peripheral nervous system (this can alter the activity of the nervous system in ways that can disrupt or kill nerves)



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

- anaemia, low number of special white blood cells (leukocytes, neutrophils) low number of platelets in the blood
- high or low blood sugar levels, acidosis (upset of the acid balance in the body) which may make you feel or be sick, be drowsy or have breath that smells of “pear drops”
- mental disturbances including psychotic reactions such as hallucinations and delusions, elevated mood
- convulsions (fits), overactive reflexes
- numbness and pain, usually in the hands and feet, twitching, stiff neck, pins and needles sensation
- pain with eye movement and temporary vision loss in one eye (optic neuritis)
- loss of hearing, ringing in your ears, loss of balance, dizziness or feeling if the room is spinning round (vertigo)
- inflammation of the blood vessels (vasculitis)
- a disorder which causes progressive scarring of the lung tissue, which can cause you to struggle to breathe
- stomach issues including nausea, constipation, dry mouth, upset stomach, and vomiting
- nicotinic acid deficiency (pellagra), a disease caused by a lack of the vitamin niacin (vitamin b3). Symptoms include inflamed skin, diarrhoea, dementia, and sores in the mouth, constipation, dry mouth
- inflammation of the pancreas



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- connective tissue disorders such as Lupus syndrome which can affect the skin and kidneys (symptoms may include a butterfly -shaped rash over the cheeks and nose, tiredness, a high temperature, feeling or being sick, joint pain and weight loss)
- rheumatic diseases are characterized by inflammation that affects the connecting or supporting structures of the body - most commonly the joints, but also sometimes the tendons, ligaments, bones, and muscles
- discomfort or burning with urination
- gynaecomastia (increased size of breasts in men)
- fever
- abnormal liver test results.

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

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: <https://www.sahpra.org.za/Publications/Index/8>.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

By reporting side effects, you can help provide more information on the safety of UKUZID.

5. How to store UKUZID

Store all medicines out of reach of children.



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Store at a temperature below 30 °C. Protected from light and moisture.

Keep blisters in carton until required for use.

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 UKUZID contains

Each tablet contains 300 mg isoniazid.

The other ingredients are:

Colloidal silicon dioxide, copovidone, crospovidone, microcrystalline cellulose, polyethylene glycol 6000, povidone and stearic acid.

What UKUZID looks like and contents of the pack

White to off white, circular flat faced beveled edged uncoated tablet with score line on one side and plain on other side.

UKUZID tablets are available in:

Amber PVC/PVDC blister strips of 10 tablets. 10 or 28 blister strips per printed outer carton.

Not all packs may be marketed.



UKUZID 300 mg Tablets
Pharma Dynamics (Pty) Ltd
Current approved: 18 April 2023

Each tablet contains 300 mg isoniazid

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Holder of Certificate of Registration

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