PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NIAROQ 300 tablets

Isoniazid

Contains sugar (sucrose).

Each tablet contains 150 mg sucrose.

Read all of this leaflet carefully before you start taking NIAROQ.

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

1. What NIAROQ is and what it is used for

NIAROQ is an antibiotic, which kills bacteria that cause tuberculosis (also known as TB). NIAROQ is used to prevent tuberculosis, and it is also used in combination with other antibiotic (or antituberculosis) medicines to prevent and treat tuberculosis.

2. What you need to know before you take NIAROQ

Do not take NIAROQ if:

- You know you are hypersensitive (allergic) to isoniazid or any of the other ingredients of NIAROQ tablets (listed in section 6), or to medicines such as ethionamide or pyrazinamide (also used to treat tuberculosis) and niacin (also known as vitamin B3). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue (see section 4).
- if you suffer from alcoholism.
- if you have serious liver function problems after taking any medicine.
- if you have serious kidney failure.
- if you have epilepsy or have ever had convulsions (fits).
- if you are pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking NIAROQ, if:

- you are alcohol dependent or drink excessively. You may be more likely to suffer from fits, mental disturbances or liver problems if you regularly drink alcohol whilst taking NIAROQ.
- you have liver problems, including hepatitis.
- you have kidney problems.

- you have been told by your doctor that you have a slow acetylator status. Your doctor may wish to change your dose or monitor you closely.
- you have epilepsy or have ever had convulsions (fits) (NIAROQ can increase the likelihood of fits).
- you have a mental illness (psychosis).
- you suffer from porphyria, you should report any symptoms of porphyria to your doctor immediately (a change in the colour of your urine; your skin may become sensitive, inflamed or begin to blister).
- you are diabetic (have high blood sugar), under-weight or malnourished, alcoholic, pregnant, elderly, have kidney problems, or suffer from human immunodeficiency virus (HIV) infection. You may be at risk to develop peripheral neuropathy (weakness, numbness and pain, usually in your hands and feet, but also in other areas of your body). Your doctor may advise that you use pyridoxine (vitamin B_6) to prevent or treat this.
- you have a bleeding tendency.
- you are aged 65 years or older.

Take special care with:

Tell your doctor immediately if you develop:

- any eye problems, as regular eye examinations are advised while being treated with NIAROQ.
- yellowing of your skin, gums or eyes (jaundice), or tiredness, weakness, general feeling of illness (malaise), loss of appetite, nausea or vomiting. These could be symptoms of liver problems such as hepatitis (inflamed liver);
- blistering of the skin, mouth, eyes and genital area, red/purple rash, fever, headache, cough and joint pain (Stevens-Johnson syndrome), severe extensive skin damage, e.g. separation of the epidermis and superficial

mucous membranes (known as toxic epidermal necrolysis);

- fever, unexplained tiredness or shortness of breath, cough, swollen lymph nodes, muscle pains, diarrhoea, a full feeling quickly while eating or a rash or itching. These may be symptoms of 'DRESS syndrome', a medicine hypersensitivity reaction which affects your internal organs and increases the white cells in your blood (also see section 4).

While taking NIAROQ you must visit your doctor at least once a month. Tell your doctor if you experience any problems with your treatment.

***Blood tests**:* Your doctor will need to check your blood before you take NIAROQ. This will help your doctor know if any changes happen to your blood after you start taking NIAROQ. You may also need to have regular blood tests to check how your liver is working especially if you are older than 35 years of age, suffer from chronic liver disease or drink alcohol regularly.

Other medicines and NIAROQ

Always tell your doctor, pharmacist or health care provider if you are taking any other medicine (this includes all complimentary or traditional medicine). This is because NIAROQ can affect the way some other medicines work. Also, some medicines can affect the way NIAROQ work.

The following medicines can make NIAROQ work less well:

- Antacids used for indigestion. Take NIAROQ at least 1 hour before taking antacids.

Tell your doctor if you are taking any of the following medicines:

- phenytoin, carbamazepine or ethosuximide, and primidone (used to treat epilepsy or seizures)
- diazepam (used to treat conditions including anxiety and sleep problems)

- triazolam (usually used as a sedative to treat severe sleep problems)
- oral anticoagulant medicines (used to thin the blood) such as warfarin
- theophylline (used in asthma or bronchitis to relieve wheezing or difficulty in breathing)
- alfentanil (used for pain)
- rifampicin, cylcoserine and para-aminosalicylic acid (antibiotics used to treat infections, including tuberculosis)
- paracetamol (used for pain and fever)
  (used in some syrups and cough mixtures)
- prednisolone (used in a wide range of inflammatory and auto-immune conditions)
- disulfiram (used in alcohol dependence)
- ketoconazole and miconazole (used to treat fungal infections).

Treatment with higher doses of NIAROQ can cause deficiency of pyridoxine (vitamin B_6) in your body and therefore increased occurrence of some undesirable effects. Therefore, concurrent use of pyridoxine is recommended. Ask your doctor or pharmacist for advice.

Laboratory tests: NIAROQ may interfere with the copper sulphate urine glucose tests, resulting in a false positive test. If you are going to have a blood test, it is important to tell your doctor that you are taking NIAROQ.

NIAROQ with food, drink and alcohol

NIAROQ tablets should be taken preferably on an empty stomach, i.e. at least 30 minutes before a meal or 2 hours after a meal. Tablets must be swallowed whole and not chewed.

While you are being treated with NIAROQ, do not have cheese, red wine or some fish (e.g. skipjack tuna, mackerel, salmon, or other tropical fish) as this may lead to symptoms such as itching of your skin, rapid or pounding heartbeat, sweating, flushing, headache and low blood pressure (fainting).
Using alcohol while you are being treated with NIAROQ can increase your risk of developing liver disease or problems.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking NIAROQ.
The safety of NIAROQ in pregnant and breastfeeding women has not been established. You should not take NIAROQ if you are pregnant or breastfeeding.

Driving and using machines

NIAROQ can cause dizziness, balance problems (vertigo) and optic neuritis (inflammation of the optic nerve that may cause loss of vision), or other side effects that could affect your ability to drive while taking NIAROQ. If this happens, do not drive or use any tools or machines.

NIAROQ contains sucrose

NIAROQ contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NIAROQ.

3. How to take NIAROQ

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

Your doctor will decide what dose of NIAROQ you need. NIAROQ may be given alone to prevent tuberculosis (TB) or will be given with other effective antituberculosis medicines to treat your TB. Always take NIAROQ and other medicines exactly as your doctor has instructed you take. You should check with your doctor or pharmacist if you are unsure.

Do not stop taking your medicine unless your doctor has instructed you to do so.

Recommended dose: 3 to 5 mg per kg body mass in single or divided doses up to a maximum of 300 mg daily.
If aluminium-containing antacids are taken, they must be taken at least one hour after NIAROQ.

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

If you take more NIAROQ than you should

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

If you forget to take NIAROQ

If you forget a dose, take it as soon as you remember it.
However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten tablets.

If you stop taking NIAROQ

You must take NIAROQ for the whole time the doctor has told you to take the tablets.

Do not stop and start taking the tablets at any time. This may cause NIAROQ to be less effective and your infection will not be treated properly.

4. Possible side effects

NIAROQ can have side effects.

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

If any of the following happens, stop taking NIAROQ and tell your doctor or pharmacist immediately or go to the nearest hospital:

Frequency unknown:

- you have signs of a serious allergic reaction which can include swelling of your lips, face, throat or tongue, hands, feet, ankles, or throat which may cause difficulty in swallowing or breathing or collapse;
- severe extensive skin damage, e.g. peeling or separation of the skin and superficial mucous membranes (known as toxic epidermal necrolysis);
- skin blistering, red/purple rash, fever, headache, cough and joint pain (Stevens-Johnson syndrome);
- a medicine reaction that causes rash, fever, inflammation of internal organs, abnormalities in the blood and systemic illness (DRESS syndrome).

These are all very serious side effects. If you have them, you may have had a serious reaction to NIAROQ. 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:

Less frequent:

- blotchy red skin rash (erythema multiforme);
- immune system problems with symptoms that include tiredness, joint pain and skin rashes (called lupus-like syndrome);
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis).

Frequency unknown:

- yellowing of your skin or whites of the eyes (jaundice), fever, dark urine and pale stools, tiredness, feel weak or generally unwell, loss of appetite (anorexia), feeling sick (nausea) or vomiting. These may be early signs of liver problems (hepatitis);
- your fits get worse or you start to have fits;
- vision problems such as loss of sight, blurred vision and reduced vision;
- blood disorders which are determined by blood tests. These include thrombocytopenia (signs may include bruising more easily than usual);
- blood disorders (e.g. low or abnormal number of white blood cells) which are determined by blood tests. Signs may include getting infections more easily than normal, fever, sore throat, mouth ulcers or tiredness;
- blood disorders which are determined by blood tests. Signs may include chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark coloured urine (haemolytic anaemia), or weight loss, night sweats and

fever (eosinophilia);

- blistering, peeling, bleeding, scaling or fluid filled patches on any part of your skin. This includes your lips, eyes, mouth, nose, genitals, hands or feet. You may have a serious skin problem;
- high blood sugar levels, signs of which include increased hunger, increased thirst and going to the toilet more often;
- mental health problems, signs of which may include hallucinations (seeing things that are not there), delusions, confusion, disturbed thoughts and a lack of self-awareness;
- rapid and shallow breathing, confusion, fatigue, headache, sleepiness, lack of appetite, yellowing of the skin or increased heart rate (these could be symptoms of metabolic acidosis).

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

Tell your doctor if you notice any of the following:

Frequency unknown:

- inflammation in your blood vessels
- headache
- dizziness
- nerve problems which can cause memory loss, movement problems (muscle weakness) or the loss of full control of bodily movements and may affect your manner of walking (ataxia), tingling and loss of feeling (this can be prevented with the use of pyridoxine)
- unusual skin sensations such as feeling numb, tingling, pricking, burning or creeping on the skin (paraesthesia)
- eye problems such as visual disturbances and eye pain
- vertigo (feeling off balance or as if your head is spinning)

- feeling sick (nausea) or being sick (vomiting)
- dry mouth
- constipation
- chronic or recurrent stomach pain.
- memory problems, diarrhoea, scaly skin rash this may be due to niacin deficiency (pellagra)
- loss of appetite (anorexia)
- skin conditions, including acne, lumpy red rash, red/purple skin discolouration (purpura), itching and skin scaling
- hair loss
- decreased flow of urine
- breast enlargement in men
- fever

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, pharmacist, or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store NIAROQ

Store at or below 25 °C.

Store in well closed containers. Protect from light.

Store all medicines out of reach of children.

Do not use your tablets after the expiry date shown on the container.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What NIAROQ contains

The active substance of NIAROQ 300 ~~mg~~ tablets is 300 mg isoniazid.

Other ingredients in the tablets are:

Icing sugar (sucrose), magnesium stearate, maize starch, gelatin and colour Quinoline Yellow.

What NIAROQ looks like and contents of the pack

Light yellow, flat, scored tablet with bevelled edges.

28, 84, 100* tablets packed with a leaflet in:

- labelled opaque white polypropylene securitainers with opaque white snap-on polyethylene caps or
- clear PVC – aluminium blister pack in a carton or
- clear PVC/PVDC – aluminium blister pack in a carton.

*Pack size of 100’s only available in blister packs.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

https://www.pharmaq.co.za