

Approved Patient Information Leaflet for Medicines for Human Use:

MIRPOLYZ 100 mg and MIRPOLYZ 300 mg

SCHEDULING STATUS: S3

MIRPOLYZ 100 mg tablets

MIRPOLYZ 300 mg tablets

Allopurinol

Contains sugar (lactose monohydrate):

Each MIRPOLYZ 100 mg tablet contains: 52,03 mg lactose monohydrate.

Each MIRPOLYZ 300 mg tablet contains: 153,60 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking MIRPOLYZ

- 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.
- MIRPOLYZ 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 MIRPOLYZ is and what it is used for
2. What you need to know before you take MIRPOLYZ
3. How to take MIRPOLYZ
4. Possible side effects
5. How to store MIRPOLYZ
6. Contents of the pack and other information

1. What MIRPOLYZ is and what it is used for

The active substance is allopurinol.

MIRPOLYZ 100: Each tablet contains 100 mg allopurinol.

MIRPOLYZ 300: Each tablet contains 300 mg allopurinol.

Pharmacotherapeutic group: Preparations inhibiting uric acid production

It contains a medicine called allopurinol. It is used to reduce urate concentrations in body fluids and/or urine to prevent or reverse the deposition of urate/uric acid.

MIRPOLYZ is indicated in:

- the management of the main clinical manifestations of urate deposition which are: gouty arthritis, skin tophi, idiopathic gout, uric acid lithiasis and acute uric acid nephropathy.
- the management of patients with neoplastic (abnormal mass of tissue that forms when cells grow and divide more than they should or do not die when they should) and myeloproliferative (a type of disease in which the bone marrow makes too many red blood cells, platelets, or certain white blood cells) disease with high cell turnover rates which cause elevations of serum and urinary levels. These include leukaemia, lymphomas, or other malignancies, especially when cytotoxic therapy has been initiated.
- the management of patients with recurrent mixed calcium oxalate renal (kidney) stones in the presence of hyperuricosuria when fluid, dietary and similar measures have failed.

2. What you need to know before you take MIRPOLYZ

Do not take MIRPOLYZ

- if you are hypersensitive (allergic) to allopurinol or any of the other ingredients of MIRPOLYZ (see the section explaining what MIRPOLYZ contains)
- if you are currently having an acute attack of gout

- if you have a severe kidney or liver problem
- if you are breastfeeding your baby

MIRPOLYZ is not indicated for children, except those diagnosed with a certain type of cancer.

If you are uncertain whether any of these apply to you, please discuss this with your doctor or pharmacist before taking MIRPOLYZ.

Warnings and precautions

Take special care with MIRPOLYZ

Talk to your doctor before taking or whilst taking MIRPOLYZ:

- if you have a kidney problem as your doctor may reduce your dose of MIRPOLYZ
- if you are currently having an attack of gout
- if you are taking a medication called azathioprine or mercaptopurine (these are medications used after organ transplantation and for the treatment of cancer and some immune diseases)
- if you have a liver problem
- whilst taking MIRPOLYZ, ensure that you drink sufficient amounts of water, your doctor will advise you on how much water you should drink daily
- children with Lesch-Nyhan syndrome, a type of juvenile gout, may develop kidney stones. This can be minimised by increasing daily fluid intake and alkalinisation of the urine. Your doctor will advise you on what to give to your child.

Serious skin rashes (hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis) can occur whilst taking MIRPOLYZ. Before these rashes develop, you may have “flu-like” symptoms such as fever (high temperature), headache, and body ache. The rash may progress to blistering and peeling of the skin of the entire body. If you develop a rash or these skin symptoms while taking MIRPOLYZ, stop taking MIRPOLYZ and contact your doctor immediately.

Other medicines and MIRPOLYZ

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

If you are taking any medicines containing the following:

- mercaptopurine, ciclosporin or azathioprine (these are medications used after organ transplantation and/ or for the treatment of cancer and some immune diseases)
- cyclophosphamide or other treatments for cancer such as doxorubicin, bleomycin, procarbazine and mechloroethamine
- theophylline (medicine for asthma and found in some cough mixtures)
- chlorpropamide (this is a medication used to treat diabetes)
- probenecid (medicine used to treat gout) or salicylates (medicine used to treat pain)
- medicines, used to treat high blood pressure and other heart conditions, such as ACE inhibitors (e.g. captopril) and diuretics “water tablets”
- warfarin (medicine used to “thin” your blood)
- amoxicillin or ampicillin (medicines used to treat bacterial infections)
- vidarabine (medicine used to treat viral infections)
- didanosine (medicine used in the treatment of HIV)
- phenytoin (medicine used in the treatment of epilepsy “fits”).

Consult your doctor, pharmacist or other healthcare provider as these medicines may interact with MIRPOLYZ.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking MIRPOLYZ.

The safety of MIRPOLYZ in pregnant women is not known and it should not be taken in pregnancy unless advised by your doctor.

If you are breastfeeding or about to start breastfeeding, talk to your doctor. MIRPOLYZ is not recommended for use by mothers who are breastfeeding.

Driving and using machines

MIRPOLYZ may cause headaches and make you feel drowsy or dizzy. If you are feeling this way, do not drive or operate machinery.

MIRPOLYZ contains lactose monohydrate which is a sugar. Talk to your doctor or pharmacist, if you have an intolerance to some sugars before taking this medication.

3. How to take MIRPOLYZ

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

Always take MIRPOLYZ tablets exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Duration of administration

Your doctor will tell you how long your treatment with MIRPOLYZ will last. Do not stop treatment early. If you have the impression that the effect of MIRPOLYZ is too strong or too weak, tell your doctor or pharmacist.

Method of administration

Adults

The usual starting dose is 100 mg and this may be increased by your doctor depending on how severe your condition is.

In children under 15 years:

The dose of MIRPOLYZ is usually determined by weight in children.

If you have a serious kidney problem:

Your dose will be adjusted according to the results of your kidney function tests. If you are unsure as to whether your dose should be adjusted, contact your doctor or pharmacist.

Do not stop taking MIRPOLYZ without discussing it with your doctor.

If you take more MIRPOLYZ than you should:

- If you have taken too much MIRPOLYZ you may experience nausea, vomiting, diarrhoea and dizziness.
- In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take MIRPOLYZ:

- Take your dose of MIRPOLYZ as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose.
- Do not take a double dose to make up for the forgotten tablet.

If you stop taking MIRPOLYZ:

- Do not stop taking MIRPOLYZ unless your doctor instructs you to stop treatment.
- If you stop taking MIRPOLYZ, your original symptoms may come back.

4. Possible side effects

MIRPOLYZ can have side effects. Check with your doctor, pharmacist or healthcare professional if any of these side effects persist or become bothersome.

Not all side-effects reported for MIRPOLYZ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MIRPOLYZ, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking MIRPOLYZ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a rash, that develops quickly, with itching and peeling or flaking of your skin and possibly blistering of the mouth and the genital and anal regions. Your eyes may also be affected and may be red and swollen
- fever (high temperature) and chills, flu-like symptoms such as pain in the joints.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to MIRPOLYZ. You may need urgent medical attention or hospitalisation.

Contact a doctor as soon as possible:

Frequent:

- any skin rash

Less frequent:

- dark urine, yellowing of your skin or the whites of your eyes. These may be signs of a problem with your liver
- feeling unable to move your body (paralysis), having a “fit” (epilepsy), loss of consciousness
- pain in your chest.

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

Tell your doctor if you notice any of the following:

Less frequent:

- a decrease in your white blood cells. In such a case you will notice tiredness, fever or an infection

- peripheral neuritis (a tingling or numbness usually in the tips of your fingers “pins and needles”)
- feeling drowsy or sleepy, feeling unbalanced and unable to control your movements, headache
- cataract formation or change in your ability to see
- vertigo (feeling dizzy or experiencing a spinning sensation while standing still)
- increase in blood pressure
- fluid build-up causing swelling of parts of the body such as the ankles and feet
- slow heart beat
- feeling in a sad mood for long periods of time (depression)
- feeling sick (nausea) and being sick (vomiting)
- enlargement of the breasts
- male infertility, impotence (being unable to have or to maintain an erection)
- hair loss, change in the colour of your hair
- noticing blood in your urine
- joint pain
- increase in blood sugar: you may feel thirsty and tired- your doctor may do a blood test to check your blood sugar levels
- increase in cholesterol levels (noticeable on a blood test)
- infection of the skin “boils”
- change in taste or feeling “unwell” (malaise).

Frequency unknown:

- pain in the abdomen (stomach area/ “midsection”)
- gastric irritation (you will notice a burning sensation in your stomach)
- diarrhoea.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction 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 MIRPOLYZ.

5. How to store MIRPOLYZ

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 25 °C.
- Store in the original packaging. Keep blister packs in the carton until required for use.
- Do not store your medicine in the bathroom.
- Do not use MIRPOLYZ after the expiry date printed on the label, container or blister.
- Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MIRPOLYZ contains

- The active substance is allopurinol
 - The other ingredients are lactose monohydrate, maize starch, povidone, sodium starch glycollate, dried maize starch and micronized stearic acid.
- MIRPOLYZ 300 mg tablets also contain a colourant: sunset yellow FCF aluminium lake (E110).

What MIRPOLYZ looks like and contents of the pack

Tablets are packed in clear PVDC coated PVC/Aluminium foil blister strips of 7 or 10, which are further packed in printed cartons, in pack sizes of 28, 30 or 100 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Dezzo Trading 392 (Pty) Ltd., 570017-8, MIRPOLYZ, Tablets, 100 /300 mg

Dezzo Trading 392 (Pty) Ltd

Cnr. Jespan Centre, Corner Garrick

& Flagtail Street, Extension 8,

Lenasia, 1821 South Africa

Tel: +27 87 405 9660

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