

PATIENT INFORMATION LEAFLET FOR PRAZIBIL 600**SCHEDULING STATUS:****S4****PRAZIBIL 600 film coated tablet****Praziquantel****PRAZIBIL 600 is sugar free****Read all of this leaflet carefully before you start taking PRAZIBIL 600**

- 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.
- **PRAZIBIL 600** 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 **PRAZIBIL 600** is and what it is used for
2. What you need to know before you take **PRAZIBIL 600**
3. How to take **PRAZIBIL 600**
4. Possible side effects
5. How to store **PRAZIBIL 600**
6. Contents of the pack and other information

1. What PRAZIBIL 600 is and what it is used for

Praziquantel is in a class of medicines called anthelmintics. It works by killing the worms. Praziquantel is used to treat schistosoma (infection with a type of worm that lives in the bloodstream) and liver fluke (infection with a type of worm that lives in or near the liver).

Applicant/PHRC: Hetero Drugs South Africa (Pty) Ltd	Product proprietary name: PRAZIBIL 600	pil
API & Dosage form and strength: Praziquantal & Film coated tablet & 600 mg		

2. What you need to know before you take PRAZIBIL 600

Do not take PRAZIBIL 600 :

- If you are hypersensitive (allergic) to praziquantel or any of the other ingredients of **PRAZIBIL 600** (listed in section 6).
- If you are in first trimester of your pregnancy.
- If you are taking rifampicin (used to treat tuberculosis).
- If you are suffering from eye infection caused by a type of tapeworm that forms cysts in the eyes.

Warnings and precautions

Take special care with PRAZIBIL 600 :

- If you suffer from liver problems.
- If you have any kidney disease.
- If you suffer from irregular heartbeat.
- If you have or have ever had seizures; cysticercosis nodules (bumps) just under your skin.
- If you experience a potential lack of efficacy of praziquantel against migrating schistosomulae. The symptoms may be indicated by a sudden inflammatory immune response, which may lead to potentially life-threatening events, e.g. respiratory failure, encephalopathy, and/or cerebral vasculitis.

If any of the above applies to you, talk to your doctor before or while taking **PRAZIBIL 600** .

Other medicines and PRAZIBIL 600

Always tell your health care provider if you are taking any other medicine. (This included all complementary or traditional medicines).

Make sure to tell your doctor if you are taking any of the following medicines, as a dose adjustment of **PRAZIBIL 600** or monitoring may be required:

- Phenytoin (used to treat epilepsy)
- Dexamethasone (used to relieve inflammation (swelling, heat, redness, and pain) and is used to treat certain forms of arthritis; skin, blood, kidney, eye, thyroid, and intestinal disorders (e.g., colitis); severe allergies; and asthma)

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- Rifampicin (an antibiotic, used to treat tuberculosis)
- Ketoconazole, itraconazole (medicines for treating fungal infection)
- Erythromycin (medicine for treating bacterial infections/antibiotic)
- Cimetidine (used to treat ulcers; gastroesophageal reflux disease (GERD), a condition in which backward flow of acid from the stomach causes heartburn and injury of the food pipe (esophagus))

PRAZIBIL 600 with food and drink

Simultaneous consumption of grapefruit juice may lead to increased PRAZIBIL 600 levels.

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 this medicine.

Driving and using machines

PRAZIBIL 600 may make you drowsy. Do not drive a car or operate machinery on the day you take **PRAZIBIL 600** and the day after you take **PRAZIBIL 600**.

3. How to take PRAZIBIL 600

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

Always take **PRAZIBIL 600** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PRAZIBIL 600 can be taken during or after a meal.

PRAZIBIL 600 is not intended for use in children below 4 years.

If you take more PRAZIBIL 600 than you should

A large dose of **PRAZIBIL 600** could make you feel dizzy. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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If you forget to take PRAZIBIL 600

If you have missed your dose by only a few hours, take the missed dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and take **PRAZIBIL 600** at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking PRAZIBIL 600

If you think that the effect of **PRAZIBIL 600** is too strong or too weak, talk to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

PRAZIBIL 600 can have side effects.

Not all side effects reported for **PRAZIBIL 600** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PRAZIBIL 600**, please consult your health care provider for advice.

If any of the following happens, stop taking PRAZIBIL 600 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and 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 reaction to **PRAZIBIL 600**. 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:

- Aching muscles, muscle tenderness or weakness, not caused by exercise

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- Polyserositis (inflammation of several serous membranes)
- Increase in some white blood cells
- Fits or convulsions
- Irregular heartbeats

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Headache
- Dizziness
- Spinning sensation
- Sleepiness
- Drowsiness
- Stomach pain
- Nausea (feeling sick)
- Vomiting
- Loss of appetite
- Diarrhoea
- Bloody Diarrhoea
- Rash
- Unusual tiredness, fatigue or weakness
- Feeling unwell

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. 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>. or to the Holder of certificate of registration through the mail:

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pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **PRAZIBIL 600**.

5. How to store PRAZIBIL 600

- Store at or below 25 °C.
- Protect from light and moisture.
- Store the tablets in the original container until required for use.
- Store all medicines out of reach of children.
- There are no special storage instructions for **PRAZIBIL 600**.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- 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 PRAZIBIL 600 contains

- The active substance is praziquantel.
- The other ingredients are magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulphate, purified water and Opadry white 03F580079 (consists of HPMC 2910/hypromellose, titanium dioxide, macrogol/PEG).

What PRAZIBIL 600 looks like and contents of the pack

White to orange tinged, oblong, film-coated tablets with three scores on one side and two scores on the other side. The tablet is debossed with “P8” on the one side and “H” on the other side.

Contents of the pack

HDPE bottle:

Tablets are pack in a white opaque high density polyethylene container (HDPE) container with white

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opaque polypropylene, ribbed, child resistant plastic cap with pulp liner.

Pack size: 6's, 100's, 500's and 1000's

Bulk pack:

Tablets are pack in a clear transparent polyethylene (poly bag), plain triple laminated bag with open mouth and heat-sealed bottom containing 5 grams of silica gel sachet.

Pack size: 500's

Blister strips:

Blister strips of PVC/Aluminium/OPA forming film and plain aluminium lidding foil, containing 10 tablets per blister.

Pack sizes: 10 tablets per blister. 10's x 10 blisters packed in a box.

HDPE bottle and blister strips are enclosed in an outer carton box.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd.

Waterfall Corporate Campus

Building No. 2, First floor

74 Waterfall Drive

Midrand

2066

This leaflet was last revised in

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Access to the corresponding Professional Information

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