

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

QUANTIMAK 600

Praziquantel 600 mg

Sugar free

Read all of this leaflet carefully before you start taking QUANTIMAK 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.
- **QUANTIMAK 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 **QUANTIMAK 600** is and what it is used for
2. What you need to know before you take **QUANTIMAK 600**
3. How to take **QUANTIMAK 600**
4. Possible side effects
5. How to store **QUANTIMAK 600**
6. Contents of the pack and other information

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

QUANTIMAK 600 contains praziquantel.

It is used to treat infections caused by schistosoma worms, which enter the body through skin that has come into contact with contaminated water.

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

Do not take QUANTIMAK 600:

- If you are allergic to praziquantel or any of the other ingredients of this medicine.
- If you are pregnant or breastfeeding.
- If you have a parasitic infection in your eye.
- If you concomitantly take medicines whose active ingredient lowers the blood levels of praziquantel such as rifampicin which is used as an antibiotic to treat tuberculosis or leprosy.

Warnings and precautions

Talk to your doctor before taking **QUANTIMAK 600**

- If you have seizures or epilepsy.
- If you have liver disease.
- If you have heart disease.

Use in children and adolescents

The use of **QUANTIMAK 600** in children (below the age of 1 year) is not recommended.

Other medicines and QUANTIMAK 600

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

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

- Rifampin (used to treat tuberculosis)

- Ketoconazole, itraconazole (used to treat fungal infections), erythromycin (used to treat bacterial infections)
- Chloroquine (used to treat malaria)

QUANTIMAK 600 with food and drink:

QUANTIMAK 600 must be taken with or after a meal.

Grapefruit juice may interact with praziquantel. Avoid the use of grapefruit products.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **QUANTIMAK 600**.

Do not take **QUANTIMAK 600** if you are pregnant.

Driving and using machines

Your ability to drive or operate machinery may be temporarily impaired. You should not drive or use any tools or machines on the day of treatment and for 24 hours thereafter. Dizziness, vertigo and drowsiness may occur with **[PRODUCT NAME]** and this may affect your ability to drive or operate machinery.

It is not always possible to predict to what extent **[PRODUCT NAME]** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **[PRODUCT NAME]** affects them.

3. How to take QUANTIMAK 600

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

Always take **QUANTIMAK 600** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Swallow your tablets whole with a drink of water, preferably during or after meals.

- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

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

If you take more QUANTIMAK 600 than you should

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

If you forget to take QUANTIMAK 600

It is important to take your **QUANTIMAK 600** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking QUANTIMAK 600

If **QUANTIMAK 600** is stopped earlier than your doctor has prescribed, your symptoms may return or worsen. Always take **QUANTIMAK 600** for as long as your doctor has prescribed.

4. Possible side effects

QUANTIMAK 600 can have side effects.

Not all side effects reported for **QUANTIMAK 600** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **QUANTIMAK 600**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Allergic reactions – the signs may include: hives, difficulty breathing, swelling of your lips and face, tongue or throat.

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

- Fever, chills, sore throat, headaches, body aches, tiredness, not feeling well.
- Slow or irregular heartbeats.
- Stomach cramps, bloating, diarrhoea, constipation, nausea, bloody diarrhoea
- A seizure
- Trouble concentrating or
- Cold sweats, skin irritation

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

Tell your doctor if you notice any of the following:

Frequent

- General ill feeling
- Headache, dizziness
- Nausea, stomach discomfort
- fever
- rash

Less frequent:

- Hypersensitivity (includes allergic reactions)
- Seizures (fits)
- Itchy skin

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

Should your general health worsen or if you experience any untoward effects while taking **QUANTIMAK 600**, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com By reporting side effects, you can help provide more information on the safety of **QUANTIMAK 600**.

5. How to store QUANTIMAK 600

Store below 30 °C in a dry place.

Protect from light.

Store in the original package / container.

Do not store in a refrigerator.

KEEP OUT OF THE REACH OF CHILDREN.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister / 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 pack and other information

What QUANTIMAK 600 contains

The active ingredient is praziquantel.

Sugar free

The other ingredients are:

Tablet core contains:

Magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium lauryl sulphate.

Coating material contains:

Hypromellose, polyethylene glycol, titanium dioxide.

What QUANTIMAK 600 looks like and contents of the pack

White to off-white, capsule shaped, film coated tablets with breakline on both side.

Contents of the pack:

HDPE container pack

Tablets are packed in a round white opaque HDPE container closed with continuous thread closure with pulp and heat seal liner.

Pack size include 500 tablets.

Blister pack

Tablets are packed in PVC/PVdC as forming material and aluminium foil as lidding material.

Pack size include 4 tablets or 10 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

MACLEODS PHARMACEUTICALS SA (PTY) LTD

GROUND FLOOR, BLOCK 1,

BASSONIA ESTATE OFFICE PARK (EAST),

1 CUSSONIA DRIVE,
BASSONIA ROCK EXT 12
ALBERTON
GAUTENG

This leaflet was last revised in

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Registration numbers

QUANTIMAK 600: 56/12/1162

Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://www.macleodspharma.com> or email macleodsrta@macleodspharma.com or contact 011 682 1169