Front Side

230 mm

335 mm

QUANTIMAK 600
PM04338118

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 **QUANTIMAK 600** and this may affect your ability to drive or operate machinery.
It is not always possible to predict to what extent **QUANTIMAK 600** 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 **QUANTIMAK 600** 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 of 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

Blister pack: Store at or below 25°C in a dry place.
Container pack: Store at or 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
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa

This leaflet was last revised in
17 September 2024

Registration numbers
QUANTIMAK 600: 56/12/1162

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169

Back Side

230 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

QUANTIMAK 600
Prasikwantel 600 mg
Suikervry

Lees hierdie hele inligtingstuk noukeurig deur voordat jy QUANTIMAK 600 begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **QUANTIMAK 600** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **QUANTIMAK 600** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **QUANTIMAK 600** neem
3. Hoe om **QUANTIMAK 600** te neem
4. Moontlike newe-effekte
5. Hoe om **QUANTIMAK 600** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat QUANTIMAK 600 is en waarvoor dit gebruik word

QUANTIMAK 600 bevat prasikwantel.

Dit word gebruik om infeksies te behandel wat veroorsaak word deur skistosoma wurms, wat die liggaam binnedring deur die vel wat met besmette water in aanraking gekom het.

2. Wat jy behoort te weet voordat jy QUANTIMAK 600 neem

Moet nie QUANTIMAK 600 neem nie:
- Indien jy allergies is vir prasikwantel of enige van die ander bestanddele van hierdie medisyne.
- Indien jy swanger is of borsvoed.
- Indien jy 'n parasitiese infeksie in jou oog het.
- Indien jy gelyktydig medisyne neem waarvan die aktiewe bestanddeel die bloedvlakke van prasikwantel verlaag, soos rifampisien wat gebruik word as 'n antibiotika om tuberkulose of melaatsheid te behandel.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **QUANTIMAK 600** neem
- Indien jy aanvalle of epilepsie het.
- Indien jy lewersiekte het.
- Indien jy hartsiekte het.

Gebruik in kinders en adolessente
Die gebruik van **QUANTIMAK 600** in kinders (onder die ouderdom van 1 jaar) word nie aanbeveel nie.

Ander medisyne en QUANTIMAK 600
Vertel altyd jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy enige van die volgende medisyne neem:
- Rifampisien (gebruik om tuberkulose te behandel)
- Ketokonasool, itrakonasool (gebruik om swambesmettings te behandel), eritromisien (gebruik om bakteriële infeksies te behandel)
- Chlorokien (gebruik om malaria te behandel)

QUANTIMAK 600 met kos en vloeistowwe:
QUANTIMAK 600 moet saam met, of na 'n ete geneem word.
Pomelosap kan interaksie met prasikwantel hê. Vermy die gebruik van pomelo produkte.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **QUANTIMAK 600** neem.

Moet nie **QUANTIMAK 600** neem indien jy swanger is nie.

Bestuur en gebruik van masjinerie
Jou vermoë om te bestuur of masjinerie te hanteer kan tydelik ingekort word. Jy moet nie bestuur of enige gereedskap of masjinerie gebruik op die dag van behandeling en vir 24 uur daarna nie. Duiseligheid, vertigo en lomerigheid kan voorkom met **QUANTIMAK 600** en dit kan jou vermoë om te bestuur of masjinerie te hanteer, beïnvloed.
Dit is nie altyd moontlik om te voorspel tot watter mate **QUANTIMAK 600** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie by bogenoemde aktiwiteite betrokke raak totdat hulle is bewus van die mate waartoe **QUANTIMAK 600** hulle affekteer nie.

3. Hoe om QUANTIMAK 600 te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **QUANTIMAK 600** presies soos wat jou dokter vir jou opdrag gegee het. Jy behoort met jou dokter of apteker te bevestig indien jy nie seker is nie.

Sluk jou tablette heel, met 'n glas water, verkieslik tydens of na etes.
- Jou dokter sal jou inlig oor hoeveel tablette om te neem en vir hoe lank om dit te neem. Dit sal afhang van jou toestand.
- Indien jy hierdie medisyne vir 'n lang tydperk gebruik, sal jou dokter jou wil monitor.

Indien jy die indruk kry dat die effek van **QUANTIMAK 600** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer QUANTIMAK 600 neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om QUANTIMAK 600 te neem
Dit is belangrik om jou **QUANTIMAK 600** gereeld op dieselfde tyd, elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse op dieselfde tyd neem, om op te maak vir 'n vergete dosis nie.

Indien jy ophou om QUANTIMAK 600 te neem
Indien **QUANTIMAK 600** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **QUANTIMAK 600** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

QUANTIMAK 600 kan newe-effekte hê.
Nie alle newe-effekte wat vir **QUANTIMAK 600** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **QUANTIMAK 600** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om QUANTIMAK 600 te neem en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Allergiese reaksie - die tekens kan die volgende insluit: galbulte , moeilike asemhaling, swelling van jou lippe en gesig, tong of keel.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **QUANTIMAK 600** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

Vertel jou dokter onmiddellik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- Koors, koue rillings, seer keel, hoofpyne, lyfseer, moegheid, voel nie goed nie.
- Stadige of onreëlmatige hartklop.
- Maagkrampe, opgeblasenheid, diarree, hardlywigheid, naarheid, bloederige diarree
- 'n Aanval
- Probleme om te konsentreer of
- Koue sweet, velirritasie

Hierdie is alles ernstige newe-effekte. Jy sal moontlik dringend mediese aandag nodig hê.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereeld
- Algemene siek gevoel
- Hoofpyn, duiseligheid
- Naarheid, omgekrapte maag
- koors
- uitslag

Minder gereeld:
- Hipersensitiwiteit (sluit allergiese reaksies in)
- Aanvalle (stuipe)
- Jeukende vel

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis. Indien jou algemene gesondheid verswak of indien jy enige ongewenste effekte ervaar terwyl jy **QUANTIMAK 600** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word, of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **QUANTIMAK 600.**

5. Hoe om QUANTIMAK 600 te bewaar

Stulpstrook verpakking: Bewaar benede 25°C in 'n droë plek.
Houer verpakking: Bewaar benede 30°C in 'n droë plek.
Beskerm teen lig.
Bewaar in die oorspronklike verpakking / houer.
Moet nie in 'n yskas bêre nie.
HOU BUITE DIE BEREIK VAN KINDERS.
Hou die stulpstroke in die karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulpstrook / etiket / karton / bottel aangedui word nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat QUANTIMAK 600 bevat
Die aktiewe bestanddeel is prasikwantel.
Suikervry
Die ander bestanddele is:
Tabletkern bevat:
Magnesiumstearaat, mikrokristallyne sellulose, povidoon, voorafgelatineerde stysel, natriumlaurielsulfaat.
Bedekkingsmateriaal bevat:
Hipromellose, poliëtileenglikol, titaandioksied.

Hoe QUANTIMAK 600 lyk en inhoud van die pak
Wit tot naaswit, kapsuulvormige, filmbedekte tablette met breeklyn aan beide kante.

Inhoud van die pak:
HDPE houer verpakking
Tablette word verpak in 'n ronde wit ondeursigtige HDPE-houer wat toegemaak is met deurlopende draadsluiting met pulp en hitteseëlvoering.
Verpakkingsgrootte sluit 500 tablette in.

Stulpstrook verpakking
Tablette word verpak in PVC/PVdC as vormingsmateriaal en aluminiumfoelie as dekmateriaal.
Verpakkingsgrootte sluit 4 tablette of 10 tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van Sertifikaat van Registrasie
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was laas hersien in
17 September 2024

Registrasienommers
QUANTIMAK 600: 56/12/1162

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@ macleodspharma.com of kontak 011 682 1169

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: Quantimak 600 (Praziquantel Tablets 600 mg)					
2. Country: South Africa		**3. Packaging component: Patient Information Leaflet**			
4. No. of Colours: 1 Colour		**5. Pantone Shade No.: Black**			
6. Specification: 40 gsm bible paper					
7. Machine Layout No.: NA		**8. Dimensions: 335 (L) x 230 (W) mm**			
9. Design / Style: Booklet		**10. Item code No.: PM04338118**			
11. Artwork has been made: Actual Size		**12. Pharma code No.: 34870 mini**			
13. Barcode/NDC no: NA		**14. Supersedes Item code No: NA**			
15. Revision No: 00		**16. A/W File name:X:\PRAZIQUANTEL TABLETS 600MG\Quantimak 600mg PIL - PM04338118.cdr**			
Approved By:		**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**RAD**	**QC**	**PRODN**	**QA**
	08/04/2025				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM04338118		