

<i>Applicant/PHCR:</i>	Macleods Pharmaceuticals SA (Pty) Ltd
<i>Product Name:</i>	Primaquine Phosphate 15 mg tablets
<i>Active Ingredient:</i>	Primaquine Phosphate
<i>Dosage Form:</i>	Film-coated tablets
<i>Date:</i>	22 July 2026

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APPROVED PATIENT INFORMATION LEAFLET JULY 2026

SCHEDULING STATUS: **S4**

PRILARIA 15 (film coated tablets)

Primaquine Phosphate

Contains sugar – lactose monohydrate

PRILARIA 15 mg: contains 60 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking PRILARIA 15

- 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.
- **PRILARIA 15** 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 **PRILARIA 15** is and what it is used for
2. What you need to know before you take **PRILARIA 15**
3. How to take **PRILARIA 15**
4. Possible side effects
5. How to store **PRILARIA 15**
6. Contents of the pack and other information

1. What PRILARIA 15 is and what it is used for

PRILARIA 15 contain Primaquine Phosphate

PRILARIA 15 is used to eliminate certain forms of malaria (specifically Plasmodium vivax malaria)

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and help prevent it from coming back.

PRILARIA 15 mg belongs to a group of drugs called the antimalarials.

It is used to treat malaria in an infected person. PRILARIA 15 mg affects the parasite that causes malaria, causing it to die. This stops the infection from continuing.

2. What you need to know before you take PRILARIA 15 mg

Do not take PRILARIA 15

- If you are allergic to primaquine or any of the other ingredients of this medicine, listed in section 6.
- If you suffer from a medical condition such as rheumatoid arthritis or lupus erythematosus and if you are acutely ill with systemic disease.
- If you are taking or have recently taken quinacrine (another antimalarial medicine)
- If you are taking medicines that may damage blood cells or their formation (such as cephalosporins, levodopa, methyldopa, nitrofurantoin)
- If you have a disease called severe G6PD deficiency (also known as favism)
- If you are pregnant

Warnings and precautions

Talk to your doctor before taking PRILARIA 15 if you:

- Suffer from nicotinamide adenine dinucleotide (NADH) methaemoglobin reductase deficiency
- Suffer from haemolytic anaemia, a condition in which red blood cells are destroyed and removed from the bloodstream before their normal lifespan is over.
- Have or have had heart disease, an irregular heartbeat, low levels of magnesium or potassium in your blood, or a resting heart rate below 50 beats per minutes.

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Other medicines and PRILARIA 15

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:

PRILARIA 15 can interact with medications that have an effect on heart rhythm (prolong the QT interval).

PRILARIA 15 with food and drink:

Taking **PRILARIA 15 mg** after a meal may reduce abdominal pain or cramps associated with ingestion of the medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking medicine.

Do not take **PRILARIA 15** if you are pregnant or breastfeeding your baby.

Driving and using machines

PRILARIA 15 may affect your concentration, ability to react/respond, and may make you feel dizzy. Be especially careful while driving or operating machinery, if **PRILARIA 15** affects you in this way. It is not always possible to predict to what extent **PRILARIA 15** 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 **PRILARIA 15** affects them.

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3. How to take PRILARIA 15

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

Always take **PRILARIA 15** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Take **PRILARIA 15 mg** exactly as your doctor has told you.

Your doctor will decide how long you must continue treatment for.

If you have the impression that the effect of **PRILARIA 15** is too strong or too weak, talk to your doctor or pharmacist.

If you take more PRILARIA 15 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 PRILARIA 15

It is important to take your **PRILARIA 15** 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 PRILARIA 15

If **PRILARIA 15** mg is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take PRILARIA 15 for as long as your doctor has prescribed.

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4. Possible side effects

PRILARIA 15 can have side effects.

Not all side effects reported for **PRILARIA 15** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PRILARIA 15**, please consult your healthcare provider for advice.

If any of the following happens, stop taking **PRILARIA 15** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- if you develop signs of haemolytic anaemia which include darkening of the urine, dizziness, confusion, fatigue, light-headedness, or shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious reaction to **PRILARIA 15**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown side effects:

- Irregular heartbeat,
- Nausea, vomiting, heartburn, stomach pain,
- Darkening of the urine, Blood problems such as leukopenia (decrease in white blood cells) which could increase infections, or methaemoglobinaemia (reduced ability of the blood to deliver oxygen) with symptoms such as shortness of breath, confusion, light headedness, dizziness, fatigue
- dizziness
- Rash, itching

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

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Reporting of side effects

If you get side effects, talk to your doctor or 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 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 **PRILARIA 15**.

5. How to store PRILARIA 15

Store at or below 25 °C.

Keep the blisters in the carton until required for use.

Keep the HDPE container tightly closed

Keep in the original packaging until required for use.

KEEP OUT OF THE REACH OF CHILDREN.

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 PRILARIA 15 contains

The active ingredient is Primaquine Phosphate

Contains sugar – (60 mg lactose monohydrate)

The other ingredients are: Microcrystalline cellulose (Avicel PH 101), Lactose monohydrate (Pharmatose 200 M), Pregelatinized Starch (Starch 1500), Povidone (Kollidon 30), Isopropyl Alcohol, Magnesium Stearate (Ligamed MF-2-V), Opadry Pink 13B540033, Purified Water.

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What PRILARIA 15 looks like and contents of the pack

PRILARIA 15: Pink coloured, round shaped, biconvex, film coated tablets, break line on one side and plain on other side.

Contents of the pack:

1) Blister Pack:

Tablets are packed in cold form laminate 25 micron OPA/45 micron aluminum foil/60 micron PVC as the forming material and Plain 25 µ aluminium plain foil/ 6-8 gsm heat seal lacquer (HSL) as the lidding material, packed in a pre-printed carton.

Pack size include 10's, 14's, 28's and 30's Tablets.

2) HDPE Container Pack:

Tablets are packed in round white 60 cc HDPE container with 33 mm neck finish (barrier container) which are closed with 33 mm closure with pulp and white printed heat seal liner and packed in outer carton.

Pack size include 100's Tablets.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Ground Floor, Block 1,
Bassonia Estate Office park (east),
1 Cussonia Drive, Bassonia rock Ext12,
Alberton Gauteng

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PRILARIA 15 mg: 60/20.2.6/0332

Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://www.macleodspharma.com>

or email macleodsrsa@macleodspharma.com or contact 011 682 1169

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