Front Side

300 mm

PRILARIA 15

PATIENT INFORMATION LEAFLET

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) 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.

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.

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.

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.

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.

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

This leaflet was last revised in 07/07/2026

Registration numbers
PRILARIA 15 mg: 60/20.2.6/0332

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

235 mm

Back Side

300 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

PRILARIA 15 (filmbedekte tablette)
Primaquinefosfaat
Bevat suiker – laktosemonohidraat.
PRILARIA 15 mg: bevat 60 mg laktosemonohidraat.

Lees hierdie hele inligtingsblad noukeurig deur voordat u PRILARIA 15 begin gebruik.
- Bewaar hierdie inligtingsblad. U mag dit weer moet lees.
- Indien u verdere vrae het, raadpleeg u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **PRILARIA 15** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al het hulle dieselfde simptome as u.

Wat is in hierdie inligtingsblad

1. Wat **PRILARIA 15** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **PRILARIA 15** gebruik
3. Hoe om **PRILARIA 15** te gebruik
4. Moontlike newe-effekte
5. Hoe om **PRILARIA 15** te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat PRILARIA 15 is en waarvoor dit gebruik word

PRILARIA 15 bevat primaquinefosfaat.

PRILARIA 15 word gebruik om sekere vorme van malaria (spesifiek *Plasmodium vivax*-malaria) uit te skakel en om te help voorkom dat dit terugkeer.
PRILARIA 15 mg behoort aan 'n groep medisyne wat antimalariamiddels genoem word. Dit word gebruik om malaria by geïnfekteerde persone te behandel. **PRILARIA 15 mg** het 'n invloed op die parasiet wat malaria veroorsaak en maak die parasiet dood. Dit verhoed dat die infeksie voortduur.

2. Wat u moet weet voordat u PRILARIA 15 mg gebruik

Moet nie PRILARIA 15 gebruik nie
- Indien u allergies is vir primaquine of enige van die ander bestanddele van hierdie medisyne wat in afdeling 6 gelys is.
- Indien u aan 'n mediese toestand soos rumatoïede artritis of lupus eritematose ly en indien u akuut siek is met 'n sistemiese siekte.
- Indien u quinakrien gebruik of onlangs gebruik het (nog 'n antimalariamiddel).
- Indien u medisyne gebruik wat bloedselle of hul vorming kan beskadig (soos kefalosporiene, levodopa, metieldopa of nitrofurantoïen).
- Indien u aan ernstige G6PD-tekort ly (ook bekend as favisme).
- Indien u swanger is.

Waarskuwings en voorsorgmaatreëls
Gesels met u dokter voordat u **PRILARIA 15** gebruik indien u:
- Aan nikotinamied-adenien-dinukleotied (NADH)-methemoglobienreduktase-tekort ly.
- Aan hemolitiese anemie ly, 'n toestand waarin rooibloedselle vernietig en uit die bloedstroom verwyder word voordat hul normale lewensduur verstryk het.
- Hartsiekte het of gehad het, 'n onreëlmatige hartklop het, lae vlakke van magnesium of kalium in u bloed het, of 'n rustende harttempo van minder as 50 slae per minuut het.

Ander medisyne en PRILARIA 15
Vertel altyd u gesondheidsorgpraktisyn indien u enige ander medisyne gebruik. (Dit sluit komplementêre en tradisionele medisyne in.)
Vertel u dokter of apteker indien u enige van die volgende medisyne gebruik:
PRILARIA 15 kan interaksie hê met medisyne wat die hartritme beïnvloed (die QT-interval verleng).

PRILARIA 15 saam met kos en drank
Die gebruik van **PRILARIA 15 mg** ná 'n maaltyd kan buikpyn of buikkrampe wat met die gebruik van die medisyne geassosieer word, verminder.

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of borsvoed, dink dat u swanger mag wees, of beplan om swanger te raak, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u hierdie medisyne gebruik.

Moet nie **PRILARIA 15** gebruik indien u swanger is of u baba borsvoed nie.

Bestuur van voertuie en gebruik van masjiene
PRILARIA 15 kan u konsentrasie en reaksievermoë beïnvloed en kan duiseligheid veroorsaak. Wees veral versigtig wanneer u bestuur of masjiene gebruik indien **PRILARIA 15** u op hierdie manier beïnvloed.
Dit is nie altyd moontlik om te voorspel in watter mate **PRILARIA 15** 'n pasiënt se daaglikse aktiwiteite kan beïnvloed nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is tot watter mate **PRILARIA 15** hulle beïnvloed nie.

3. Hoe om PRILARIA 15 te gebruik

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Gebruik **PRILARIA 15** altyd presies soos deur u dokter voorgeskryf. Raadpleeg u dokter of apteker indien u onseker is.

Gebruik **PRILARIA 15 mg** presies soos u dokter u ingelig het.
U dokter sal besluit hoe lank u behandeling moet wees.

Indien u voel dat die werking van **PRILARIA 15** te sterk of te swak is, raadpleeg u dokter of apteker.
Indien u meer PRILARIA 15 gebruik as wat u moet
In geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifinligtingsentrum.

Indien u vergeet om PRILARIA 15 te gebruik
Dit is belangrik om **PRILARIA 15** gereeld elke dag op dieselfde tyd te gebruik. Indien u 'n dosis vergeet het, neem dit sodra u daaraan dink, tensy dit amper tyd is vir u volgende dosis. Moenie twee dosisse gelyktydig neem om vir 'n gemiste dosis op te maak nie.

Indien u ophou om PRILARIA 15 te gebruik
Indien **PRILARIA 15 mg** vroeër gestaak word as wat u dokter voorgeskryf het, kan u simptome terugkeer of vererger. Gebruik altyd **PRILARIA 15** vir so lank as wat u dokter voorgeskryf het.

4. Moontlike newe-effekte

PRILARIA 15 kan newe-effekte veroorsaak.
Nie alle newe-effekte wat vir **PRILARIA 15** aangemeld is, word in hierdie inligtingsblad genoem nie. Indien u algemene gesondheid versleg of u enige ongewenste effekte ervaar terwyl u **PRILARIA 15** gebruik, raadpleeg u gesondheidsorgverskaffer.

Indien enige van die volgende voorkom, staak die gebruik van **PRILARIA 15** en kontak u dokter onmiddellik of gaan na die ongevalle-afdeling van u naaste hospitaal:
- indien u tekens van hemolitiese anemie ontwikkel, insluitend donker verkleuring van die uriene, duiseligheid, verwarring, moegheid, lighoofdigheid of kortasem.

Dit is almal baie ernstige newe-effekte. U mag 'n ernstige reaksie op **PRILARIA 15** gehad het en dringende mediese behandeling of hospitalisasie mag nodig wees.

Kontak u dokter indien u enige van die volgende waarneem:
Newe-effekte met onbekende frekwensie
- Onreëlmatige hartklop,
- Naarheid, braking, sooibrand, maagpyn,
- Donker verkleuring van die uriene, bloedafwykings soos leukopenie (vermindering van witbloedselle wat infeksies kan verhoog) of methemoglobinemie (verminderde vermoë van die bloed om suurstof te vervoer) met simptome soos kortasem, verwarring, lighoofdigheid, duiseligheid en moegheid.
- Duiseligheid.
- Uitslag en jeuk.

Indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) wat op die SAHPRA-webwerf beskikbaar is, of aan Macleods Pharmaceuticals SA (Pty) Ltd by safety@macleodspharma.com. Deur newe-effekte aan te meld, help u om meer inligting oor die veiligheid van **PRILARIA 15** te verskaf.

5. Hoe om PRILARIA 15 te bêre

Berg by of onder 25 °C.
Hou die stolpverpakking in die karton totdat dit benodig word.
Hou die HDPE-houer dig toe.
Hou in die oorspronklike verpakking totdat dit benodig word.
HOU BUITE BEREIK VAN KINDERS.
Moenie in 'n badkamer bêre nie.
Moenie gebruik ná die vervaldatum wat op die stolpverpakking, etiket of karton aangedui word nie.
Gee alle ongebruikte medisyne terug aan u apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels weggooi nie (bv. toilette).

6. Inhoud van die verpakking en ander inligting

Wat PRILARIA 15 bevat
Die aktiewe bestanddeel is primaquinefosfaat.
Bevat suiker - 60 mg laktosemonohidraat.
Die ander bestanddele is: Mikrokristallyne sellulose (Avicel PH 101), laktosemonohidraat (Pharmatose 200 M), voorafvergelatiniseerde stysel (Starch 1500), povidoon (Kollidon 30), isopropielalkohol, magnesiumstearaat (Ligamed MF-2-V), Opadry Pink 13B540033 en gesuiwerde water.

Hoe PRILARIA 15 lyk en inhoud van die verpakking
PRILARIA 15: Pienk, ronde, bikonvekse, filmbedekte tablette met 'n breeklyn aan die een kant en glad aan die ander kant.

Inhoud van die verpakking
1) Stolpverpakking
Tablette word verpak in koudgevormde gelamineerde OPA/45 mikron aluminiumfoelie/60 mikron PVC-materiaal as vormingsmateriaal met 25 mikron aluminiumfoelie/6-8 g hitteverseëllak as bedekkingmateriaal. Stolpverpakkings word in 'n voorafgedrukte karton verpak.
Verpakkingsgroottes sluit 10, 14, 28 en 30 tablette in.
2) HDPE-houerverpakking
Tablette word verpak in 'n ronde wit 60 cc HDPE-houer met 33 mm nekafwerking en toepaslike skroefprop met hitteverseëlde voering. Die verseelde houer word verpak in 'n kartonhouer.
Verpakkingsgroottes sluit 100 tablette in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. HOUER VAN DIE REGISTRASIESERTIFIKAAT

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1 Bassonia Estate Office Park (Oos) Cussoniaweg 1,
Bassonia Rock Uitbreiding 12 Alberton, Gauteng

Hierdie inligtingsblad is laas hersien op 07/07/2026.

Registrasienommer
PRILARIA 15 mg: 60/20.2.6/0332

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

235 mm

22/09/2026

PM0304-01