

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[MA202 trade name][†]
Primaquine (as phosphate)

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [MA202 trade name] is and what it is used for
2. What you need to know before you take [MA202 trade name]
3. How to take [MA202 trade name]
4. Possible side effects
5. How to store [MA202 trade name]
6. Contents of the pack and other information

1. What [MA202 trade name] is and what it is used for

[MA202 trade name] is a medicine used to treat malaria. It contains the active substance primaquine phosphate.

Malaria is caused by infection with a parasite called *Plasmodium*, spread by the bite of an infected mosquito. [MA202 trade name] is used for malaria caused by the types of malaria parasite called *Plasmodium vivax* and *Plasmodium ovale*. It is combined with treatment using another malaria medicine and helps to stop the infection from coming back again (relapsing).

Your health care provider will usually carry out a blood test to check for G6PD deficiency.

[MA202 trade name] can also be used in some areas, where the disease is not too common, to reduce the spread of another type of malaria caused by *Plasmodium falciparum*.

Your health care provider will follow the most recent official guidelines on the use of malaria medicines to select the right medicine for your malaria treatment.

2. What you need to know before you take [MA202 trade name]

Do not take [MA202 trade name] if:

- You are allergic to primaquine or any of the ingredients of this medicine (listed in Section 6).
- You have a disease where your white blood cell count is low. For example, systemic lupus erythematosus (SLE) or rheumatoid arthritis.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- You are taking a medicine called quinacrine [mepacrine] (has been used for treatment of certain parasite infections) or some other medicines that may increase the risk of side effects affecting your blood cells (see ‘Other medicines and [MA202 trade name]’, below)
- You are pregnant, could be pregnant, or are planning to become pregnant. You must **NOT** become pregnant while taking [MA202 trade name] or for **2 menstrual cycles** after stopping (see also ‘Contraception’, below)
- You are breastfeeding a baby younger than 1 month.

If you are breastfeeding, do **not** take this medicine unless your baby has been tested and shown not to have G6PD deficiency (a condition that affects red blood cells).

Your health care provider may advise you to:

- stop breastfeeding while taking this medicine, or
- delay treatment until you have finished breastfeeding.

[MA202 trade name] must also not be used in babies less than 1 month old.

Warnings and precautions

Talk to your health care provider before you take [MA202 trade name] if you:

- Have, or have a family history of, G6PD deficiency (also known as favism). Your health care provider will usually carry out a blood test to see if you have this condition, so they can select the right dose for you. If you have intermediate or severe G6PD deficiency, you may be able to use this medicine, but you will be given a lower dose. Your health care provider will advise you on this.
- Have a rare blood disease called nicotinamide adenine dinucleotide (NADH) methaemoglobin reductase deficiency.
- Have anaemia. This is a lower-than-normal level of red blood cells.
- Have haemolytic anaemia. This is a condition where your red blood cells are destroyed before their normal lifespan is over.
- Have a liver or kidney disease.
- Have or have had:
 - heart disease
 - an irregular heartbeat
 - low levels of magnesium or potassium in your blood
 - a resting heart rate below 50 beats per minute

Contraception

If you are a **woman** who can get pregnant you must use reliable birth control while you are taking [MA202 trade name], and for 2 menstrual cycles after stopping.

If you are a **man** taking this medicine and your partner can get pregnant, you must use reliable birth control while you are taking [MA202 trade name] and for 3 months after stopping.

Other medicines and [MA202 trade name]

Tell your health care provider if you are taking any other medicine or if you have recently taken other medicines. Talk to your health care provider before you take any other medicine during your treatment with [MA202 trade name].

[MA202 trade name] should not be used together with:

- Quinacrine (also called mepacrine, a medicine for certain parasite infections)
- Medicines that can destroy or damage red blood cells or reduce formation of red or white blood cells. Such medicines include
 - some medicines to treat infections (sulfonamides, dapsone, cotrimoxazole, quinolones)
 - medicines used to treat cancer
 - colchicine

- methylene blue
- penicillamine
- gold salts.

The following medicines may interact with [MA202 trade name]:

- Medicines that are known to affect the electrical activity of your heart, including:
 - anti-arrhythmics (medicines used for an abnormal heart rhythm) such as quinidine, disopyramide, sotalol, dofetilide, ibutilide and amiodarone
 - tricyclic antidepressants (medicines for depression) such as amitriptyline, imipramine
 - antipsychotics (medicines used to treat other mental health problems, such as haloperidol or thioridazine)
 - azithromycin, erythromycin (used to treat bacterial infections)
 - moxifloxacin (used to treat tuberculosis)
 - some medicines used to treat other infections, such as pentamidine
 - medicines used to treat malaria, particularly halofantrine
- digoxin (medicine for heart problems)
- dabigatran (medicine to control blood clots)
- fluoxetine, paroxetine (medicines for depression called SSRIs)

Other warnings you should know about

Before you start taking [MA202 trade name], your health care provider will normally do a blood test to see if you have G6PD deficiency. This is because [MA202 trade name] can cause the destruction of red blood cells (haemolysis) in people whose red blood cells have low activity of the enzyme G6PD. Based on the results of this test, your health care provider may need to change your treatment.

Some women may have G6PD deficiency even if a test looks normal. Because of this you may get a different dose

If G6PD testing is not available, your health care provider will decide whether or not to use [MA202 trade name] by weighing up the expected benefits of treatment against the risks of causing haemolysis.

[MA202 trade name] can also cause methaemoglobinaemia (a condition affecting how oxygen is carried in the blood) and abnormal heart rhythm.

Contact your health care provider right away if you have any of the conditions mentioned above and **see section 4 for signs and symptoms to look out for.**

Before and during your treatment, your health care provider may ask for blood tests to make sure there is no trouble with your red blood cells.

Driving and using machines

[MA202 trade name] may cause dizziness. Do not drive or operate machinery until you know how [MA202 trade name] affects you.

Other ingredients of [MA202 trade name]

This medicine contains glucose. If you have been told by your health care provider that you have an intolerance to some sugars, you must talk to your health care provider before taking this medicine.

3. How to take [MA202 trade name]

Always use [MA202 trade name] exactly as prescribed by your health care provider. You should check with your health care provider if you are not sure.

Malaria caused by Plasmodium vivax or Plasmodium ovale

The recommended dose of [MA202 trade name] is based on your weight and the activity of an enzyme called G6PD in your red blood cells, which can affect your risk of side effects.

Your health care provider will work out the right dose for your condition, and how often you should take it.

Your health care provider will usually give you a test for G6PD before starting treatment.

Patients who have normal G6PD activity

[MA202 trade name] is given **once a day for 7 days**. Usual doses are:

Patient weight	Dose
5 to less than 6 kg	1 tablet
6 to less than 12 kg	1.5 tablets
12 to less than 21 kg	3 tablets
21 to less than 26 kg	4 tablets

Patients who have reduced (intermediate) G6PD activity

[MA202 trade name] is given **once a day for 14 days**. Usual doses are:

Patient weight	Dose
12 to less than 21 kg	1.5 tablet
21 to less than 26 kg	2 tablets

Patients with very low G6PD activity (severe G6PD deficiency)

[MA202 trade name] is given **once a week for 8 weeks**. Usual doses are:

Patient weight	Dose
5 to less than 6 kg	1 tablet
6 to less than 12 kg	1.5 tablets
12 to less than 21 kg	3 tablets
21 to less than 26 kg	4 tablets

To reduce the spread of malaria caused by Plasmodium falciparum

To reduce the spread of malaria due to the *Plasmodium falciparum* parasite, you may be given a single dose of [MA202 trade name]. It is given at the same time as the first dose of other medicines to treat your malaria. G6PD testing is not needed because [MA202 trade name] is taken only once. The number of tablets to take depends on your weight as indicated below:

Patient weight	Single dose
10 to less than 20 kg	1 tablet
20 to less than 40 kg	2 tablets
40 to 60 kg	3 tablets

How to take [MA202 trade name]

Taking [MA202 trade name] with food may help to decrease stomach pain or cramps.

Instructions for use

1. Look up your weight in the table above.
2. Then look for the number of tablets that will be required.
3. If the dose is 1 to 2 tablets, then you will need 5 mL of water to make them into a mixture to take. If the dose needed is 3 to 4 tablets, then you will need 10 mL of water

4. Place the required volume of drinking in a small clean cup and add the required number of primaquine tablets.
5. Stir gently until the tablets break up completely to form a liquid mixture.
6. Drink the entire mixture straight away.
7. Rinse the cup with an additional 10 mL of water, which you should also drink.
8. The mixture must be drunk straight away after it is made up. If more than 30 minutes have gone by since the mixture was made up, do not take it. Instead, throw it away and make up a new mixture.

If you miss a dose of [MA202 trade name]:

If you miss a dose of [MA202 trade name], take it as soon as possible. However, if it is time for your next dose, do not take a double dose. Just carry on with your regular schedule, until you are finished taking all your pills.

If you take more [MA202 trade name] than you should:

If you think you have taken too much [MA202 trade name], contact your health care provider, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Symptoms that you have taken too much [MA202 trade name] include: stomach cramps, vomiting, yellowing of the skin and the whites of the eyes, heartburn, heart problems, including problems with your heartbeat rhythm, bluish skin discoloration, tiredness, difficulty breathing, shortness of breath, confusion, light-headedness, dizziness, difficulty sleeping, pale skin.

If you have any other questions about how to use this medication, ask your healthcare provider.

4. Possible side effects

Like all medicines, [MA202 trade name] can cause side effects, although not everybody gets them. If you get any side effects, particularly if severe and persistent, or have any change to your health that you think may be due to [MA202 trade name], you should speak to your health care provider.

Serious side effects and what to do about them:

Low red blood cells due to their destruction (Haemolytic anaemia)

This causes dark urine, back pain, and pale skin. It may also cause shortness of breath, dizziness, and tiredness. If you develop symptoms of haemolytic anaemia, you must stop taking [MA202 trade name] and get immediate medical help.

Methaemoglobinaemia

This is caused by a different type of damage to your red blood cells. It can make your lips and nails turn a bluish colour. If you develop these symptoms you should talk to your health care provider.

Abnormal heart rhythm

If you get an irregular heartbeat, you should talk to your health care provider.

Very common side effects (affects more than 1 in 10 users):

- pain in the belly (abdominal pain)
- destruction of red blood cells (haemolysis) in patients with G6PD deficiency

Common side effects (affect between 1 and 10 users in 100):

- feeling sick (nausea)
- being sick (vomiting)
- stomach pain (epigastric distress)

Uncommon side effects (affect 1 to 10 users in 1000):

- destruction of red blood cells (haemolysis) in patients without G6PD deficiency
- effect on red blood cells (methaemoglobinaemia) see also below
- effect on the electrical activity of the heart (QT-interval prolongation)

- itching (pruritis)
- dizziness
- headache

Rare side effects (affect less than 1 user in 1000):

- low levels of white blood cells (leucopenia)
- disturbances of heart rhythm (arrhythmias)
- rash

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [MA202 trade name]

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Store tablets in the blisters in the provided box or carton. Protect from light. Avoid excursions above 30°C.

Do not use this medicine after the expiry date stated on the label or carton after 'EXP'.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [MA202 trade name] contains

- The active ingredient is primaquine 5 mg.
- The other ingredients of [MA202 trade name] are pregelatinized starch, saccharin sodium, orange flavour (containing glucose), microcrystalline cellulose, magnesium stearate, polyvinyl alcohol-partially hydrolysed, talc, titanium dioxide, glyceryl monocaprylocaprate, sodium lauryl sulfate, iron oxide red, black iron oxide and iron oxide yellow.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [MA202 trade name] looks like and contents of the pack

Pink, oval, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have a break line on one side and are plain on the other side.

The break line can be used to divide [MA202 trade name] into equal doses.

[MA202 trade name] is packed in aluminium foil on aluminium foil blister cards, each containing 7 tablets. Available in cartons of 30 x 7 tablets

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in May 2026.

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>