

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

[MA196 trade name][†]
Primaquine

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 [MA196 trade name] is and what it is used for
2. What you need to know before you take [MA196 trade name]
3. How to take [MA196 trade name]
4. Possible side effects
5. How to store [MA196 trade name]
6. Contents of the pack and other information

1. What [MA196 trade name] is and what it is used for

[MA196 trade name] is a medicine used to treat malaria in adults and children from 6 months of age. 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. [MA196 trade name] is used when the malaria is 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).

[MA196 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 [MA196 trade name]

Do not take [MA196 trade name] if:

- You are allergic to primaquine or any of the ingredients of this medicine (listed in Section 6).
- You have been told that your red blood cells have a severe lack of an enzyme called G6PD (glucose-6-phosphate dehydrogenase). This is an inherited condition, also known as favism.
- You have a disease where your white blood cell count is low. For example, systemic lupus erythematosus (SLE) or rheumatoid arthritis.
- You are taking or have recently taken quinacrine. Quinacrine is another medicine used to treat malaria.

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

- You are taking a medication that can damage your blood cells or reduce the formation of new blood cells (see ‘Other medicines and [MA196 trade name]’, below)
- You are pregnant, could be pregnant, or are planning to become pregnant. You must NOT become pregnant while taking [MA196 trade name] or for **2 menstrual cycles** after stopping.

[MA196 trade name] must also not be used in babies less than 6 months old.

Warnings and precautions

Talk to your health care provider before you take [MA196 trade name] if you:

- Have, or have a family history of, G6PD deficiency (also known as favism). This medicine must not be used if you have severe G6PD deficiency. If you have mild or moderate G6PD deficiency, you may be able to use this medicine, but you will be given a different 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.
- Are breastfeeding or planning to breastfeed. Breastfeeding should be stopped while you are taking [MA196 trade name], or treatment with [MA196 trade name] should be delayed until the end of breastfeeding. You should NOT breastfeed while taking [MA196 trade name] unless your child has been tested and does not have G6PD deficiency.
- 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 [MA196 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 [MA196 trade name] and for 3 months after stopping.

Other medicines and [MA196 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 [MA196 trade name].

[MA196 trade name] should not be used together with:

- Quinacrine (a medicine for malaria)
- 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 [MA196 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)
 - 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 [MA196 trade name], your health care provider will normally do a blood test to see if you have G6PD deficiency. This is because [MA196 trade name] can cause the destruction of red blood cells (haemolysis) in people whose red blood cells have low levels of G6PD. Based on the results of this test, your health care provider may need to change your treatment.

If G6PD testing is not available, your health care provider will decide whether or not to use [MA196 trade name] by weighing up the expected benefits of treatment against the risks of causing haemolysis.

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.

Stop taking [MA196 trade name] right away and contact your health care provider if you get symptoms like: darkening of the urine, back pain, pale skin, dizziness, tiredness, or shortness of breath. These may be signs of haemolytic anaemia (low levels of red blood cells due to their destruction).

Contact your health care provider right away if you have bluish lips or nails. These may be signs of damage to your red blood cells (methaemoglobinemia).

Driving and using machines

[MA196 trade name] may cause dizziness. Do not drive or operate machinery until you know how [MA196 trade name] affects you.

[MA196 trade name] contains lactose

Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

This medicine may contain traces of cow's milk proteins. If you are allergic to cow's milk, talk to your health care provider before taking this medicine.

3. How to take [MA196 trade name]

Always use [MA196 trade name] exactly as prescribed by your health care provider. You should check with your health care provider if you are not sure.

Taking [MA196 trade name] with food may help to decrease stomach pain or cramps.

It is best to swallow the tablets whole. For people who cannot swallow tablets, they may be crushed and mixed with a sweet food such as apple sauce or chocolate pudding.

Malaria caused by Plasmodium vivax or Plasmodium ovale

The recommended dose of [MA196 trade name] is based on your weight and the amount of an enzyme called G6PD in your red blood cells, which can affect your risk of side effects. The dose may also need to take into account the strain of the parasite, which depends on what region you were in when you were infected.

Your health care provider will work out the right dose for your condition, and may give you a test for G6PD before starting treatment.

If your red blood cells have normal amounts of G6PD, then you will usually be given [MA196 trade name] **once a day for 14 days**. Usual doses of [MA196 trade name] are:

Patient weight	Dose
30 to less than 60 kg	1 tablet daily for 14 days
60 to less than 100 kg	2 tablets daily for 14 days
100 kg or over	3 tablets daily for 14 days

Alternatively, your health care provider may recommend a different dose, taken **once a day for 7 days**. Always take the medicine as your health care provider has recommended.

If testing shows that your red blood cells have reduced amounts of G6PD (mild to moderate G6PD deficiency) then you will usually be given [MA196 trade name] just **once a week**. Typical doses, depending on weight, are:

Patient weight	Dose
20 to less than 30 kg	1 tablet once a week for 8 weeks
30 to less than 60 kg	2 tablets once a week for 8 weeks
60 kg or over	3 tablets once a week for 8 weeks

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 (1 tablet) of [MA196 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 [MA196 trade name] is taken only once.

If you take more [MA196 trade name] than you should:

If you think you have taken too much [MA196 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 [MA196 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 miss a dose of [MA196 trade name]:

If you miss a dose of [MA196 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 have any other questions about how to use this medication, ask your health care provider.

4. Possible side effects

Like all medicines, [MA196 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 [MA196 trade name], you should speak 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

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 [MA196 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.

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 [MA196 trade name]

Do not store above 30°C. Protect from light.

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

Do not use this medicine after the expiry date stated on the label and carton after {EXP}. The expiry date refers to the last day of that month.

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 [MA196 trade name] contains

- The active ingredient is primaquine
- The other ingredients of [MA196 trade name] are:

Core tablet: lactose, microcrystalline cellulose, pregelatinised starch, purified Talc and magnesium stearate

Film coat : hypromellose, ethyl cellulose, triacetin, titanium dioxide and iron oxide red

What [MA196 trade name] looks like and contents of the pack

[MA196 trade name] are brown to light brown, round, 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.

[MA196 trade name] is packed in aluminium foil blister packs, each containing 7 or 10 tablets. Available in cartons of 1 x 7, 10 x 7 and 10 x 10 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 September 2025

Section 6 was updated in April 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>