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

[MA208 trade name][†]
Primaquine (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 [MA208 trade name] is and what it is used for
2. What you need to know before you take [MA208 trade name]
3. How to take [MA208 trade name]
4. Possible side effects
5. How to store [MA208 trade name]
6. Contents of the pack and other information

1. What [MA208 trade name] is and what it is used for

[MA208 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. [MA208 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.

[MA208 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 [MA208 trade name]

Do not take [MA208 trade name] if:

- You are allergic to primaquine or any of the ingredients of this medicine (listed in Section 6).
- You are pregnant, could be pregnant, or are planning to become pregnant. You must NOT become pregnant while taking [MA208 trade name] or for **2 menstrual cycles** after stopping (see also 'Contraception', below).
- You are breastfeeding a baby younger than 1 month.

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

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.

[MA208 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 [MA208 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 a disease where your white blood cell count is low. For example, systemic lupus erythematosus (SLE) or rheumatoid arthritis.
- 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

If you are over 65 years old, your health care provider will monitor how well the medicine is working for you and any side effects you may have.

Contraception

If you are a **woman** who can get pregnant you must use reliable birth control while you are taking [MA208 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 [MA208 trade name] and for 3 months after stopping.

Other medicines and [MA208 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 [MA208 trade name].

[MA208 trade name] should not be used together with:

- Quinacrine (also called mepacrine, a medicine for certain parasite infections)
- Medicines that can cause the destruction of red blood cells (haemolysis) such as sulfonamides, methylene blue, dapsone, cotrimoxazole, quinolones.
- Medicines that may affect bone marrow or reduce the number of blood cells such as medicines to treat cancer, colchicine, penicillamine or gold salts.
- Medicines that may increase the amount of methaemoglobin in the blood, such as acetylsulfafurazol, benzocaine, dapsone, flutamide, metoclopramide, prilocaine, sodium nitroprusside, sulfadiazine, sulfadoxine, sulfafurazole, sulfaguanidine, sulfamethizole, sulfamethoxazole. If one of these combinations cannot be avoided, your health care provider may need to monitor your blood closely.

The following medicines may interact with [MA208 trade name]:

- Medicines that are known to affect the electrical activity of your heart, including:
    - antiarrhythmics (medicines used for an abnormal heart rhythm) such as quinidine
    - antipsychotics (medicines used to treat certain mental health problems)
    - antidepressants (medicines used to treat depression), such as citalopram, escitalopram
    - domperidone (a medicine used to treat nausea and vomiting)
    - methadone (a medicine used to treat opioid dependence and severe pain)
    - hydroxyzine (a medicine used to treat anxiety and allergic conditions)
    - azithromycin and moxifloxacin (medicines used to treat bacterial infection)
    - fluconazole (a medicine used to treat fungal infection)
    - pentamidine (a medicine used to treat certain infections)
    - medicines used to treat malaria, such as chloroquine, halofantrine, lumefantrine, hydroxychloroquine
    - medicines that may slow heart rate, such as beta-blockers, certain calcium-channel blockers, digoxin, pilocarpine, and anticholinesterases
    - certain diuretics (water tablets) that may lower potassium (medicines used to treat high blood pressure or excess fluid in the body)
    - stimulant laxatives (medicine used to treat constipation)
    - glucocorticoids and tetracosactide (medicines used to treat or assess certain hormonal or inflammatory conditions)
    - amphotericin B given into a vein (medicine used to treat serious fungal infections)

- paroxetine, fluoxetine and bupropion (medicines used to treat depression or certain other mental health conditions)
- duloxetine (medicine used to treat depression and certain types of pain)
- terbinafine (a medicine used to treat fungal infection)
- cinacalcet (a medicine used to treat a certain condition associated with abnormal calcium or parathyroid hormone levels)
- monoamine oxidase-A (MAO-A) inhibitors (medicine used to treat depression and certain other conditions)
- artemether, mefloquine, quinine, pyronaridine/artesunate, dihydroartemisinin/piperaquine and sulfadoxine/pyrimethamine (medicines used to treat malaria)
- alosetron (a medicine used to treat certain bowel diseases)
- theophylline (a medicine used to treat breathing problems)
- clozapine (a medicine used to treat certain mental health problems)
- levonorgestrel and ethinyl estradiol (hormonal medicine used for contraception and certain other conditions)
- rivaroxaban and dabigatran (medicines used to prevent or treat blood clots)
- ciclosporin (a medicine used to suppress the immune system)
- tyrosine kinase inhibitors (certain medicines used to treat cancer)
- tizanidine (a medicine used to relax muscles)
- ergot derivatives (medicines used to treat conditions such as migraine)

Other warnings you should know about

Before you start taking [MA208 trade name], your health care provider will normally do a blood test to see if you have G6PD deficiency. This is because [MA208 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 [MA208 trade name] by weighing up the expected benefits of treatment against the risks of causing haemolysis.

[MA208 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. 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

[MA208 trade name] may cause dizziness. Do not drive or operate machinery until you know how [MA208 trade name] affects you.

Excipients

Patients with congenital lactase deficiency, galactosaemia or glucose-galactose intolerance must not be given this medicine unless strictly necessary. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance 'in other patients'.

Patients who are allergic to cow's milk proteins must not be given this medicine unless strictly necessary.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

3. How to take [MA208 trade name]

Always use [MA208 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 [MA208 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.

Patients who have normal amounts of G6PD (normal G6PD activity)

[MA208 trade name] is given **once a day for 7 days**. Usual doses are:

Patient weight	Dose
6 to less than 12 kg	1 tablet
12 to less than 21 kg	2 tablets
21 to less than 26 kg	3 tablets
26 to less than 36 kg	4 tablets

Patients who have reduced (intermediate) G6PD activity

[MA208 trade name] is given **once a day for 14 days**. Usual doses are:

Patient weight	Dose
6 to less than 12 kg	0.5 tablet
12 to less than 21 kg	1 tablet
21 to less than 26 kg	1.5 tablets
26 to less than 36 kg	2 tablets
36 to less than 51 kg	3 tablets

Patients with very low G6PD activity (severe G6PD deficiency)

[MA208 trade name] is given **once a week for 8 weeks**. Usual doses are:

Patient weight	Dose
6 to less than 12 kg	1 tablet
12 to less than 21 kg	2 tablets
21 to less than 36 kg	3 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 [MA208 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 [MA208 trade name] is taken only once. The number of tablets to take depends on your weight as indicated below:

Patient weight	Single dose
25 to less than 50 kg	1 tablet
50 kg to 100 kg	2 tablets

How to take [MA208 trade name]

Taking [MA208 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. The mixture must be drunk straight away after it is made up.

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 [MA208 trade name]:

If you miss a dose of [MA208 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 [MA208 trade name] than you should:

If you think you have taken too much [MA208 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 [MA208 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 health care provider.

4. Possible side effects

Like all medicines, [MA208 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 [MA208 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 [MA208 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 (heamolysis) 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 [MA208 trade name]

Do not store above 30°C.

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 [MA208 trade name] contains

- The active ingredient is primaquine (phosphate).
- The other ingredients of [MA208 trade name] are lactose, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, purified talc, sucralose, trusil tonovin SPLand magnesium stearate.

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

What [MA208 trade name] looks like and contents of the pack

[MA208 trade name] is a mottled orange to light orange, round, dispersible tablets. They are biconvex (rounded on top and bottom) with bevelled 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 [MA208 trade name] into equal doses.

[MA207 trade name] is provided in aluminium foil on aluminium foil blister cards, each containing 7 tablets. Available in cartons of 2×7 or 24×7 tablets.

Supplier and Manufacturer

Supplier

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

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