

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

[MA177 trade name][†]
Dihydroartemisinin/piperaquine phosphate

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 [MA177 trade name] is and what it is used for
2. What you need to know before you take [MA177 trade name]
3. How to take [MA177 trade name]
4. Possible side effects
5. How to store [MA177 trade name]
6. Contents of the pack and other information

1. What [MA177 trade name] is and what it is used for

[MA177 trade name] is a medicine used to treat uncomplicated malaria (when the infection is not severe enough to affect the brain or other key organs). It contains the active substances dihydroartemisinin and piperaquine phosphate, which work together to kill the parasites that cause malaria.

Malaria is caused by infection with a parasite called *Plasmodium*, spread by the bite of an infected mosquito. There are different types of *Plasmodium* parasite. [MA177 trade name] kills all types of *Plasmodium* parasite.

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 [MA177 trade name]

Do not take [MA177 trade name] if you:

- are allergic (hypersensitive) to the active substances, dihydroartemisinin or piperaquine phosphate, or to any of the other ingredients of [MA177 trade name] (see section 6);
- have a severe type of malaria infection which has affected parts of the body such as the brain, lungs or kidneys (your health care provider will check this before giving the medicine);
- have a heart condition affecting the rhythm or electrical activity of the heart, or have an unusually slow heart rate;
- know that any member of your family (parents, grandparents, brothers or sisters) died suddenly due to a heart problem or was born with heart problems;

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

- suffer from changes to the levels of salts in the body (electrolyte imbalances);
- are taking other medicines that can have an effect on heart rhythm, such as:
 - the heart medicines quinidine, disopyramide, procainamide, amiodarone, dofetilide, ibutilide, hydroquinidine or sotalol;
 - medicines used to treat depression;
 - medicines used to treat mental health problems such as phenothiazines, sertindole, sultopride, chlorpromazine, haloperidol, mesoridazine, pimozide, or thioridazine;
 - medicines used to treat infections. These include some of the types of medicines used to treat bacterial infections (macrolides [such as erythromycin or clarithromycin] and fluoroquinolones [such as moxifloxacin and sparflaxacin]) or fungal infections (including fluconazole and imidazole) as well as pentamidine (used to treat a specific type of pneumonia) and saquinavir (for treatment of HIV);
 - antihistamines used to treat allergies or inflammation such as terfenadine, astemizole or mizolastine;
 - certain medicines used to treat stomach problems such as domperidone or droperidol;
 - other medicines such as vinca alkaloids and arsenic trioxide (used to treat certain cancers), bepridil (used to treat angina), diphemanil (used to treat stomach disturbances), levomethadyl and methadone (used to treat drug addiction), and probucol (used to treat high blood cholesterol levels).
- have recently (for example within about one month) been treated for malaria with certain medicines or taken certain medicines to prevent malaria. These medicines include: mefloquine, halofantrine, lumefantrine, chloroquine or quinine.

If any of the above applies or if you are unsure, tell your health care provider before taking [MA177 trade name].

Take special care with [MA177 trade name]

Check with your health care provider before taking this medicine if you (or a child taking the medicine):

- have liver or kidney problems;
- are taking or have taken any other medicines for the treatment of malaria (other than those mentioned above), especially if these were given by injection or drip;
- are pregnant or breastfeeding (see below);
- are elderly (over 65 years)
- are vomiting (especially in young children);
- are taking any other medicines which could interact with [MA177 trade name]. Examples are listed in the section “Taking other medicines”.

If you are not sure about any of the above, please ask your health care provider.

Taking other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Other medicines can affect the way [MA177 trade name] works or increase the risk of side effects if taken together, so your health care provider may decide that [MA177 trade name] is not suitable or that extra checks are needed.

As well as medicines that affect the heart rhythm and some malaria medicines (see ‘**Do not take [MA177 trade name]**’, above) other medicines that may interact with [MA177 trade name] include:

- some *medicines for HIV*
- medicines to treat *infections such as tuberculosis*
- medicines for *epilepsy*
- *hormonal contraceptives*
- some *medicines for heart problems, high blood pressure or high cholesterol*

- medicines such as *ciclosporin* (used after organ transplants or for autoimmune disease), *midazolam* (for anxiety or sleep problems), *nefazodone* (used to treat depression), *omeprazole* (for stomach acid), *paracetamol* (a painkiller), and *theophylline* (to help breathing)
- some herbal medicines such as *St John's wort* (for anxiety).

Make sure you tell your health care provider about any medicines you may take.

Taking [MA177 trade name] without food and drink

You should take [MA177 trade name] tablets with water only.

You should take this medicine on an empty stomach as food, especially fatty or oily food, can increase the risk of side effects. You should take each dose at least 3 hours after the last time you ate, and no food should be taken within 3 hours after each dose of [MA177 trade name]. For example, if you eat at midday, you can take your dose after 3 pm and then eat again after 6 pm, or if you eat at 6 pm, you can take your dose at 9 pm and then eat your breakfast at your normal time the next morning.

You can drink water at any time. You should not take [MA177 trade name] with grapefruit juice due to possible interactions.

Pregnancy and breast-feeding

Tell your health care provider if you are pregnant, think you may be pregnant or become pregnant, or if you are breast-feeding.

[MA177 trade name] is one of several malaria treatments that can be used in pregnancy – your health care provider will select the most appropriate malaria medicine for your situation. If you are given [MA177 trade name] while pregnant, your health care provider may carry out extra checks on how your pregnancy progresses.

You may breast-feed your baby while taking this medicine.

If you are taking folate supplements to reduce the risk of birth defects, you can continue taking them at the same time as [MA177 trade name].

Ask your health care provider for advice before taking any medicine during pregnancy or breast-feeding.

Driving and using machines

[MA177 trade name] does not affect your ability to drive or use machines.

Other ingredients of [MA177 trade name]

[MA177 trade name] contains FD&C yellow #6/sunset yellow FCF aluminium lake which may cause allergic reactions.

3. How to take [MA177 trade name]

Always take [MA177 trade name] exactly as your doctor has told you to. You should check with your health care provider if you are not sure.

Your health care provider will explain to you how many tablets of [MA177 trade name] to take. The dose depends on the patient's weight.

You should take the medicine for 3 days, with no breaks in between. You should try to take the dose at about the same time on each of the 3 days.

The usual doses of the medicine for patients of different weights are described below:

Body weight	Dose
11 kg to less than 17 kg	1 tablet per day for 3 days
17 kg to less than 25 kg	1½ tablets per day for 3 days
25 kg to less than 36 kg	2 tablets per day for 3 days
36 kg to less than 60 kg	3 tablets per day for 3 days

60 kg to less than 80 kg	4 tablets per day for 3 days
80 kg or more	5 tablets per day for 3 days

Children weighing **less than 11 kg** should be given a different tablet containing a lower dose. Tell your health care provider if this applies so that they can prescribe a suitable tablet.

Take this medicine with water. You should take each dose at least 3 hours after your last meal. You should also avoid eating until 3 hours after taking [MA177 trade name]. For example, if you eat at midday, you can take your dose at 3 pm and then eat again after 6 pm, or if you eat at 6 pm, you can take your dose at 9 pm and then eat your breakfast at your normal time the next morning. This is to ensure the stomach is empty when taking the medicine, as food in the stomach, especially fatty or oily food, can increase the risk of side effects. Drinking water is permitted at any time.

If you cannot swallow the tablet, break or crush the tablet (by using the tip of a spoon) and add it to a small amount of liquid or semi-solid food. Swallow all the mixture immediately.

Vomiting when taking this medicine:

If you vomit within 30 minutes after taking [MA177 trade name], the **whole dose** must be taken again.

If you vomit between half an hour and 1 hour after the dose, **half the dose** must be taken again. If you vomit after this time, you do not need to take another dose.

If you also vomit after the second dose, do not take another dose. Contact your health care provider urgently to obtain an alternative treatment for malaria.

If you take more [MA177 trade name] tablets than you should:

If you take more than the recommended dose, tell your health care provider. Your health care provider may suggest special monitoring for you because doses higher than those recommended may have an unwanted, severe effect on your heart (see also section 4).

If you forget to take [MA177 trade name]:

If you forget to take the second dose of [MA177 trade name] at the right time, take it as soon as you remember. Then take the third (last) dose approximately 24 hours after the second dose.

If you forget to take the third (last) dose at the right time, take it as soon as you remember.

Never take more than one dose on the same day to make up for a missed dose. Check with your health care provider if you are not sure.

If you stop taking [MA177 trade name]:

For the medicine to work effectively, you should take the tablets as instructed and complete the 3 days course of treatment. If you are not able to do this, talk to your health care provider.

Taking this medicine, if the malaria infection returns:

If you get another attack of malaria within a year of taking [MA177 trade name], your health care provider may decide that a second course of this medicine can be given. However, patients must not take more than two courses within one year.

If you get malaria more often than this, or get malaria again within a month or two after taking [MA177 trade name], talk to your health care provider. You will be prescribed another treatment.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, [MA177 trade name] can cause side effects, although not everybody gets them. Most of the side effects are not severe and normally disappear within a few days or weeks after treatment.

If you get a rash, swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, these may be signs of an allergic reaction. Tell your health care provider immediately or go immediately to the emergency department of your nearest hospital, taking this leaflet with you.

A heart problem called QT prolongation can occur in some people who take [MA177 trade name], particularly those who have a heart condition or are taking another medication that can cause the same problem. Tell your health care provider if you have a heart condition or are taking any medications. Your health care provider can advise you about using [MA177 trade name].

If you notice anything different about your heart rhythm or have symptoms (such as palpitations or irregular heart beat) you should contact your health care provider as soon as possible and before the next dose is due.

Side effects in adults:

Common (affecting less than 1 in 10 patients but more than 1 in 100):

Low red blood cell counts (anaemia), headache, heart rhythm disturbances (ECG changes or noticing unusually fast heart beats or palpitations), fever, general weakness.

Uncommon (affecting less than 1 in 100 patients but more than 1 in 1000):

Flu, respiratory infections, poor appetite or loss of appetite, dizziness, convulsions (fits), irregular or slow heart rate, cough, vomiting, abdominal pain, diarrhoea, nausea, inflammation or enlargement of the liver, abnormal liver function tests, itching, pain in the muscles or joints.

Side effects in children:

Very common (affecting more than 1 in 10 patients):

Flu, cough, fever.

Common (affecting less than 1 in 10 patients but more than 1 in 100):

Respiratory infections, ear infection, low red blood cell counts (anaemia), abnormalities in various types of blood cells (white blood cells and platelets), poor appetite or loss of appetite, eye infection, heart rhythm disturbances (changes as in adults, ECG changes), abdominal pain, vomiting, diarrhoea, skin inflammation, rash, general weakness.

Uncommon (affecting less than 1 in 100 patients but more than 1 in 1000):

Abnormalities in red blood cells, excessive numbers of platelets, enlargement of some organs (such as liver or spleen), swollen lymph glands, convulsions (fits), headache, abnormal heart sounds (heard by your doctor with a stethoscope), nose bleeds, runny nose, nausea, inflammation of the mouth, inflammation or enlargement of the liver, yellowing of the skin and eyes, abnormal liver function blood tests, skin itching and inflammation, pain in the joints.

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 [MA177 trade name]

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

Do not store above 25°C. Store in the original pack in a place protected from light and humidity.

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

Do not use this medicine if you notice visible signs of deterioration.

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 [MA177 trade name] contains

- The active ingredients are 40 mg dihydroartemisinin and 320 mg piperaquine (as phosphate).
- The other ingredients of [MA177 trade name] are maize starch, dextrin, hypromellose, sodium starch glycolate, magnesium stearate, polyvinyl ethanol, titanium dioxide, talc, macrogol/polyethylene glycol, FD&C Blue #2/indigo carmine aluminium lake, lecithin (soya), FD&C blue #1/brilliant blue FCF aluminium lake and FD&C yellow #6/sunset yellow FCF aluminium lake.

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

What [MA177 trade name] looks like and contents of the pack

Blue, round, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'D•C' debossed (stamped into) one side and a break line on the other side.

The break line can be used to divide [MA177 trade name] into equal doses.

Plastic (PVC) on aluminium foil blister cards. The blister cards are sealed in a plastic (PET/PE) and aluminium pouch inside the carton.

Aluminum-PVC blister of 6 tablets; 2 blisters / outer pouch bag; 1 pouch /carton.
Pack size: 2 x 6 x 1 tablets.

Aluminum-PVC blister of 6 tablets; 1 blisters / outer pouch bag; 1 pouch /carton.
Pack size: 1 x 6 x 1 tablets.

Aluminum-PVC blister of 6 tablets; 1 blisters / outer pouch bag; 25 pouch /carton.
Pack size: 1 x 6 x 25 tablets.

Aluminum-PVC blister of 9 tablets; 1 blisters / outer pouch bag; 1 pouch /carton.
Pack size: 1 x 9 x 1 tablets.

Aluminum-PVC blister of 9 tablets; 1 blisters / outer pouch bag; 25 pouch /carton.
Pack size: 1 x 9 x 25 tablets.

Supplier and Manufacturer

Supplier

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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>

Dihydroartemisinin/Piperaquine (as phosphate)
40 mg/320 mg tablets
(Beijing Holley-Cotec Pharm Co. Ltd.), MA177

WHOPAR Part 3

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