

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/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[MA157 trade name] †

Dihydroartemisinin /Piperaquine (as phosphate) 30mg/240mg dispersible tablets

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 has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness seem to be the same as your child's.
- 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 [MA157 trade name] is and what it is used for
2. What you need to know before you give [MA157 trade name] to your child
3. How to give [MA157 trade name]
4. Possible side effects
5. How to store [MA157 trade name]
6. Contents of the pack and other information

1. What [MA157 trade name] is and what it is used for

[MA157 trade name] contains the active substances piperaquine tetraphosphate and dihydroartemisinin. It is used to treat uncomplicated malaria in children when use of a medicine given by mouth is appropriate.

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. [MA157 trade name] kills all types of *Plasmodium* parasite.

The medicine can be taken by children and infants over 6 months old who weigh 5 kilograms or more.

2. What you need to know before you give [MA157 trade name] to your child

Do not give [MA157 trade name] if your child:

- is allergic (hypersensitive) to the active substances, piperaquine tetraphosphate or dihydroartemisinin, or to any of the other ingredients of [MA157 trade name] (see section 6 for a list of these);
- has a severe type of malaria infection which has affected parts of the body such as the brain, lungs or kidneys;
- has a heart condition, such as changes to the rhythm or rate of the heartbeat, or heart disease;
- knows that any member of your family (parents, grandparents, brothers or sisters) died suddenly due to a heart problem or was born with heart problems;
- suffers from changes to the levels of salts in the body (electrolyte imbalances);
- is taking other medicines that can have an effect on heart rhythm, such as:
 - 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;

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

- 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 sparfloxacin]) 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 cisapride, 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).
- has recently (for example within about one month) been treated for malaria with certain medicines or has taken certain medicines to prevent malaria. These medicines include: mefloquine, halofantrine, lumefantrine, chloroquine or quinine.

If any of the above applies to your child or if you are unsure, tell your health care provider before giving [MA157 trade name] to your child.

Take special care with [MA157 trade name]

Check with your health care provider before taking this medicine if your child:

- has liver or kidney problems
- is taking or has taken any other medicines for the treatment of malaria (other than those mentioned above)
- is female or vomiting
- is taking certain other medicines which could interact with [MA157 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.

Use in children

[MA157 trade name] can be used in infants and children. The dose depends on the weight of the child. Your health care provider will tell you how many tablets of [MA157 trade name] to give your child.

Taking other medicines

Please tell your health care provider if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription. Some medicines can affect the way [MA157 trade name] works and your health care provider may decide that [MA157 trade name] is not suitable or that extra checks are needed while your child is taking certain medicines which may interact with [MA157 trade name]. Examples are listed below (but there are several others):

- some medicines used to treat high cholesterol in the blood (such as atorvastatin, lovastatin, simvastatin)
- medicines used to treat high blood pressure and heart problems (such as diltiazem, nifedipine, nitrendipine, verapamil, felodipine, amlodipine);
- some medicines used to treat HIV (antiretroviral medicinal products): protease inhibitors (such as amprenavir, atazanavir, indinavir, nelfinavir, ritonavir), non-nucleoside reverse transcriptase inhibitors (such as efavirenz, nevirapine)
- some medicines used to treat microbial infections (such as telithromycin, rifampicin, dapsone)
- medicines used to help you fall asleep: benzodiazepines (such as midazolam, triazolam, diazepam, alprazolam), zaleplon, zolpidem
- medicines used to prevent/treat epileptic seizures (fits): barbiturates (such as phenobarbital), carbamazepine or phenytoin

- medicines used after organ transplantation and in autoimmune diseases (such as cyclosporin, tacrolimus)
- sex hormones, including those contained in hormonal contraceptives (such as gestodene, progesterone, estradiol), testosterone
- glucocorticoids (hydrocortisone, dexamethasone)
- omeprazole (used to treat diseases related to gastric acid production)
- paracetamol (used to treat pain and fever)
- theophylline (used to make breathing easier)
- nefazodone (used to treat depression)
- aprepitant (used to treat nausea); - some gases (such as enflurane, halothane and isoflurane) used to give a general anaesthetic

Giving [MA157 trade name] without food and drink

You should give your child [MA157 trade name] tablets with water only.

This medicine should be taken on an empty stomach. You should give your child each dose no less than 3 hours after the last food intake, and no food should be taken within 3 hours after each dose of [MA157 trade name]. Your child can drink water at any time. You should not give your child [MA157 trade name] with grapefruit juice due to possible interactions.

3. How to give [MA157 trade name]

Always give your child [MA157 trade name] exactly as your health care provider has told you to. You should check with your health care provider if you are not sure.

A course of [MA157 trade name] lasts 3 consecutive days with one dose on each day. The number of tablets for a full dose will depend on your child's body weight, but they should all be taken together. You should try to give the dose to your child at about the same time on each of the three days.

The daily dose depends on the patient's **body weight**. Your health care provider should have prescribed a dose that is appropriate for your child's weight as follows:

Dosing should be based on body weight as shown in the following table:

Body weight	Number of tablets	Daily dose	
		Dihydroartemisinin	Piperaquine
5 kg to less than 8 kg	--*	--	--
8 kg to less than 11 kg	1 tablet per day for 3 days	30 mg	240 mg
11 kg to less than 16 kg	--*	--	--
17 kg to less than 25 kg	2 tablets per day for 3 days	60 mg	480 mg

* For these patients, other suitable tablet strengths are available and should be used if required.

The safety and efficacy of Eurartesim in infants aged less than 6 months and in children weighing less than 5 kg has not been established.

Disperse the tablets in drinking water before taking the dose. Each tablet should be dispersed in a minimum of 10 mL water; the maximum volume of water recommended for dispersion of a dose is 50 mL.

Give this medicine with water. Your child should take each dose at least 3 hours after their last meal. You should also avoid feeding your child until 3 hours after taking [MA157 trade name]. This means the stomach should be empty when giving the medicine. Drinking water is permitted at any time.

Giving [MA157 trade name]

1. Look up the patient's weight in the table above.
2. Then look for the number of tablets that will be required.

3. Place the required volume of water in a small, clean cup or bowl and add the required number of tablets.
4. Stir gently until the tablets disperse.
5. Administer the entire medicine mixture immediately.
6. Rinse the cup with a little additional water and get the child drink this water.

Vomiting when taking this medicine:

If this happens within:

- 30 minutes of taking [MA157 trade name], the whole dose must be taken again.
- 31-60 minutes, half the dose must be given again.

If your child vomits the second dose as well, do not give your child another dose. Contact your health care provider urgently to obtain an alternative treatment for malaria.

If your child takes more [MA157 trade name] tablets than he/she should:

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

If you forget to give [MA157 trade name] to your child:

If you forget to give your child the second dose of [MA157 trade name] at the right time, give it as soon as you remember. Then give the third (last) dose approximately 24 hours after the second dose. If you forget to give your child the third (last) dose at the right time, give it as soon as you remember.

Never give 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 your child stops taking [MA157 trade name]:

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

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

If your child weighs

- less than 8kg or
- between 11 and less than 17 kg or
- more than 25 kg, tell your health care provider.

With this tablet strength, the recommended dose cannot be achieved. Your health care provider will give a different strength tablet for your child.

Taking this medicine if the malaria infection returns:

If you or your child gets another attack of malaria you may take a second course of [MA157 trade name] within one year if your health care provider thinks this is a suitable treatment. You or your child must not take more than two courses within one year. If you or your child get malaria more often, talk to your health care provider. You will be prescribed another treatment.

4. Possible side effects

Like all medicines, [MA157 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 your child gets 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 [MA157 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 your child has a heart condition or is taking any medications. Your health care provider can advise you about using [MA157 trade name].

If you notice anything different about your child's heart rhythm or if your child has 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 children:

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

Influenza, 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 (change 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 health care provider with a stethoscope), nose bleeds, runny nose, nausea, inflammation of the mouth, inflammation or enlargement of the liver, jaundice, abnormal liver function blood tests, skin itching and inflammation, pain in the joints.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Reporting of side effects

If your child gets any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [MA157 trade name]

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

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

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 [MA157 trade name] contains

- The active ingredients are Dihydroartemisinin and Piperaquine (as phosphate)
- The other ingredient(s) of [MA151 trade name] is are excipients:

Core tablet: Pregelatinized starch, Microcrystalline cellulose, Dextrin, Croscarmellose sodium, Magnesium stearate, Sweet flavour, Orange flavour, Sucralose

What [MA157 trade name] looks like and contents of the pack

[MA157 trade name] are white or pale-yellow, round, tablet debossed with "D" on one side and a score-line on the other side.

The score-line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses

Nature and contents of the pack

Dihydroartemisinin /Piperaquine (as phosphate) 30mg/240mg Dispersible Tablets
(Guilin Pharmaceuticals Co. Ltd), MA157

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PA/Alu/PVC-Alu blister. Each blister contains 3 tablets. 25 such blisters are packed in a carton or 2 blisters are packed in a carton.

Pack size: 25×3 Tablets or 2 ×3 Tablets

Supplier

Guilin Pharmaceutical Co., Ltd
No. 43, Qilidian Road, Guilin 541004
Guangxi, China

Manufacturer

Guilin Pharmaceutical Co., Ltd
Oral Solid Dosage Workshop 1
No. 43, Qilidian Road, Guilin 541004
Guangxi, China

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

This leaflet was last revised in March 2021

Detailed information on this medicine is available on the World Health Organization (WHO) website:
<https://extranet.who.int/pqweb/medicines>