WHO-PQ recommended clinical and preclinical information for the patient

This information reflects the recommendations of current WHO guidelines and the scope of WHO's prequalification programme.

Information for the patient

Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets*

Dihydroartemisinin/piperaquine phosphate

Carers or parents looking after the person who takes this medicine should use this information to give the medicine correctly and take note of the warnings and side effects

1. What Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet is and what it is used for

Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet 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. Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets

Do not take Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets if you:

- are allergic (hypersensitive) to the active substances, dihydroartemisinin or piperaquine phosphate, or to any of the other ingredients of Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets (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;
- 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 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 domperidone or droperidol;

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

  - 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets.

Take special care with Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets

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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets. 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet works or increase the risk of side effects if taken together, so your health care provider may decide that Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets**', above) other medicines that may interact with Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets without food and drink

You should take Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets. 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets 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.

Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets.

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

Driving and using machines

Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet does not affect your ability to drive or use machines.

Driving and using machines

Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablet is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

3. How to take Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets

Always take Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets exactly as your health care provider 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 film-coated tablets of Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets 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
5 kg to less than 8 kg	1 tablet per day for 3 days
8 kg to less than 11 kg	1½ tablets per day for 3 days
11 kg to less than 17 kg	2 tablets per day for 3 days
17 kg to less than 25 kg	3 tablets per day for 3 days

Patients weighing **25 kg or more** should be given a different tablet containing a more suitable 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets. 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. You should swallow all the mixture immediately.

Vomiting when taking this medicine:

If you vomit within 30 minutes after taking Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets, 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated 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 the heart (see also section 4).

If you forget a dose of Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets:

If you forget to take the second dose of Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets:

For the medicine to work effectively, you should take the film-coated tablets as instructed and should 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets, your health care provider may decide that a second course of the medicine can be taken. 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets, 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, Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets, 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets.

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.

Problems with red blood cells

Sometimes damage to your red blood cells, called haemolytic anaemia can occur after receiving malaria treatment, especially in young children and if you have previously received artesunate injections to treat malaria. This can happen up to one month following treatment with Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets. In most cases, the anaemia recovers without specific treatment, but if it is severe a blood transfusion may be required. If the breakdown of red blood cells is suspected to be caused by your immune system (autoimmune haemolytic anaemia) you may need further treatment. Your health care provider will carry out tests to check your blood.

If you get one or more of the following symptoms after treatment with Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets you should contact your health care provider immediately: pale skin, general weakness, headache, shortness of breath and rapid heartbeat; particularly with exercise, confusion, dizziness, or dark-coloured urine.

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, damage to liver cells, 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 Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets

Product specific information on the storage conditions is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.

6. Contents of the pack and other information

What Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets contains

What Dihydroartemisinin/piperaquine phosphate 20 mg/160 mg film-coated tablets looks like and contents of the pack

Supplier and Manufacturer

This leaflet was last revised in September 2025

Product specific information on the composition, visual appearance of the formulation, appearance and size of packs as well as on the supplier, is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.