

Primacin

Tablets 7.5 mg

Primaquine phosphate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Primacin.

This leaflet answers some common questions about Primacin. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.ebs.tga.gov.au.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Primacin against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Primacin is used for

Primacin contains primaquine phosphate. It works by killing the malarial parasite at different stages of its life cycle, both in the blood and in the liver.

Primacin is used to treat the vivax and ovale forms of malaria following an attack. It is also used to aid in the treatment of falciparum malaria.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

Primacin is only available with a doctor's prescription.

Primacin is not addictive.

Before you take Primacin

Primacin is not suitable for everyone.

When you must not take it

Do not take Primacin if you:

- have severe glucose-6-phosphate (G6PD) deficiency
- You may not know if you have this deficiency but your doctor can do a quick blood test to check.
- are pregnant
- have rheumatoid arthritis or lupus erythematosus
- are taking quinacrine hydrochloride to treat malaria
- are taking other medicines that affect your red blood cells or bone marrow.

Do not take Primacin if you are allergic to any medicine containing primaquine or other 8-aminoquinolines or any of the ingredients listed at the end of this leaflet.

Do not take it after the expiry date ('Expiry') printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Primacin, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Primacin tablets contain small amounts of lactose and wheat starch (gluten), which can cause an allergic reaction in some people.

Tell your doctor if you have or have had any medical conditions, especially the following:

- NADH methaemoglobin reductase deficiency
- heart disease
- irregular heartbeat
- slow heart rate
- low potassium or magnesium levels in the blood
- a recent attack of malaria that was treated with quinacrine hydrochloride.

Do not take this medicine if you are pregnant or intend to become pregnant.

The safety of the use of this medicine in women who are pregnant or may become pregnant has not been established.

Do not breastfeed if you are taking this medicine.

There is no information on the safe use of this medicine during breastfeeding.

Use with caution if you are over 65 years old.

Elderly persons are more sensitive to the effects of the medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Primacin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are taking Primacin.

Some medicines and Primacin may interfere with each other. These include:

- proguanil, which is used to treat malaria
- medicines that reduce the ability of your bone marrow to produce red blood cells and platelets, such as medicines used in chemotherapy
- some medicines used to treat irregular heartbeat
- ketoconazole, used to treat fungal infections.

The above medicines may be affected by Primacin, or may affect how well it works. You may need different amounts of Primacin, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Primacin.

How to take Primacin

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The treatment and dose will depend upon the area where you were infected with malaria. In South East Asia and the Pacific region close to Australia (Papua New Guinea, Vanuatu, Solomon Islands), there are malaria parasites that are more resistant to treatment. If your stay has been in one of these areas, the treatment may include an increased dose of Primacin, or the use of Primacin over a longer period of time.

The treatment is usually one of the following:

For adults

- 15 mg daily for 14 days
- up to 30 mg daily for 14 days in areas where resistant malaria strains occur or where treatment has failed with lower doses
- treatment may be extended to 21 days in most of South East Asia and the Pacific region, and other medicines to treat malaria may be given at the same time as Primacin
- if you have G6PD deficiency: up to 45 mg once weekly for 8 weeks
- if you have falciparum malaria: 45 mg as a single dose.

For children

- 0.3 mg/kg/day
- if your child has falciparum malaria: 0.7 - 1.0 mg/kg/day.

Your doctor will tell you how much Primacin you should take or give to your child.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your

condition and whether or not you are taking any other medicines.

If you take the wrong dose, Primacin may not work as well and your problem may not improve.

Swallow Primacin whole with a full glass of water.

When to take it

Take it at about the same time each day with a meal.

Primacin must be taken regularly. Taking it at the same time each day will have the best effect. It will also help you to remember when to take it. Make sure that you take Primacin with food, or an upset stomach may occur.

How long to take it

Continue taking the medicine for as long as your doctor tells you to.

Primacin helps to control your condition, but may not cure it.

If you feel chilly or have a fever following return from a malaria area, see your doctor even if you have taken a course of tablets.

Relapses may occur in some people.

Continue taking the tablets until you finish the pack or until your doctor tells you to stop.

If you are unsure whether you should stop taking Primacin, talk to your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you miss more than one dose, consult your doctor.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

While you are taking Primacin

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Primacin. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do tests to check the levels of cells in your blood or check how your heart is working.

See your doctor if you feel that your condition is not improving or is getting worse.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Do not take Primacin to treat any other complaints unless your doctor tells you to.

Do not stop taking Primacin or change the dosage without checking with your doctor.

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Primacin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- abdominal cramps, vomiting or burning pain in the upper abdomen
- irregular heartbeat, slow or increased heart rate
- dark-coloured urine
- feeling tired, weak, dizzy, confused or sick
- pale or bluish hue to your skin
- headache
- shortness of breath
- fever
- pain, tingling or weakness in your arms or legs
- sore mouth and gums, mouth ulcers or bleeding gums.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Primacin.

Like all medicines, Primacin may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- abdominal cramps and pains
- nausea
- vomiting
- dizziness
- headache
- rash
- itching of the skin.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- dark-coloured urine
- irregular heartbeat or slow heart rate
- feeling tired, weak, confused or sick
- pale or bluish hue to your skin
- shortness of breath
- fever
- pain, tingling or weakness in your arms or legs
- sore mouth and gums, mouth ulcers or bleeding gums.

These may be serious side effects. You may need urgent medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing).

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Primacin

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep Primacin in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Primacin past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Primacin is available in bottles with child-resistant closures of 28 or 56 tablets. The tablets are round, flat, orange uncoated tablets.

Ingredients

Active ingredient:

- 7.5 mg primaquine base as 13.2 mg primaquine phosphate

Inactive ingredients:

- lactose
- wheat starch
- purified talc
- gelatine
- povidone

- magnesium stearate
- glycerol.

Sponsor details

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