Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Quinbisul.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Quinbisul against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What it is used for

Quinbisul is used to treat malaria, together with other medicines. It works by interfering with the growth of the parasite that causes

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

Your doctor, may have prescribed it for another purpose.

Quinbisul is only available with a doctor's prescription.

There is no evidence that it is addictive.

Before you take it

When you must not take it Do not take Quinbisul if you are allergic to:

- medicines containing quinine (e.g. Oninate)
- tonic water or bitter lemon drinks which contain quinine
- any of the ingredients at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, flushing of the skin, swelling of the face, fever, shortness of breath, ringing in the ears and changes in vision.

Do not take Quinbisul if you have or have ever had:

- a severe side effect caused by quinine (such as unusual bruising or bleeding or kidney problems)
- myasthenia gravis a condition causing muscle weakness
- tinnitus ringing in the ears
- optic neuritis a disease of the nerves of the eye, causing blindness
- glucose-6-phosphate dehydrogenase (G-6-PD) deficiency an inherited condition
- blackwater fever.
- haemoglobinuria presence of excess haemoglobin in the urine.

Do not take Quinbisul if the expiry date (Exp.) printed on the pack has passed. If you take this medicine after the expiry date, it may not work as well.

Do not take Quinbisul if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking Quinbisul during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Small amounts of Quinbisul passes into breast milk. Your doctor will discuss the risks and benefits of taking Quinbisul when breastfeeding.

Tell your doctor if you have any medical conditions, including an irregular heart beat.

Your doctor may want to take special care.

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

You should not take more than the prescribed dose as a condition called 'cinchonism' may occur, even with normal doses. Symptoms of cinchonism include abdominal pain, diarrhoea, disturbed vision (blurred vision, changes in colour perception or field of vision, total blindness), headache, feeling or being sick, ringing in the ears or impaired hearing, rashes, loss of consciousness, fits, shock due to heart problems, irregular heartbeats, death. Tell your doctor if you experience any of them.

Taking other medicines

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

Some medicines may be affected by Quinbisul or may affect how well it works. These medicines include:

- warfarin; used to prevent blood clots (e.g. Coumadin, Marevan)
- digoxin; used for heart conditions (e.g. Lanoxin)
- flecainide; used to treat irregular heartbeats
- other medicines for malaria, such as mefloquine (e.g. Lariam) and pyrimethamine (e.g. Daraprim)
- medicines used to relieve the symptoms of urinary tract disorders and infections (e.g. Ural, Citralite)
- cimetidine; commonly used to treat reflux and ulcers (e.g. Tagamet, Magicul)
- antacids containing aluminium, which may reduce the absorption of Quinbisul (e.g. Mylanta, Gaviscon).
- pimozide or thioridazine (to treat some mental disorders)
- moxifloxacin, rifampicin or antifungals (to treat infections)
- barbiturates, carbamazepine or phenytoin (medicines to treat epilepsy)
- · HIV medicines
- suxamethonium (muscle relaxant)
- · terfenadine; used for allergic reactions

· medicines to treat diabetes

To make sure there is no problem with absorption, Quinbisul is best taken at least one hour before or one hour after taking antacids.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

How much to take

Quinbisul is taken together with other antimalarial medicines.

The dose varies from person to person.

The usual dose of Quinbisul for adults is 2 tablets three times a day after meals, for 7 to 14 days.

Elderly people and children may need smaller doses.

How to take Quinbisul

Swallow the tablets whole with a glass of water.

When to take Quinbisul

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Quinbisul. Do this even if there are no signs of discomfort or poisoning.

If you take too much Quinbisul, you may experience dizziness, ringing in the ears, stomach cramps, skin rash and impaired vision. You may also vomit, have a headache or fever, feel nervous or confused, or have fits

While you are taking it

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Quinbisul.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Quinbisul.

Keep taking Quinbisul for as long as your doctor recommends.

If you become pregnant while taking Quinbisul, tell your doctor.

If you need to have any tests on your urine, tell your doctor you are taking Quinbisul.

It may affect the results of some tests.

If you plan to have surgery that requires the use of muscle relaxants (e.g. suxamethonium, pancuronium) tell your doctor, anaesthetist or dentist that you are taking Quinbisul.

Things you must not do

Do not use Quinbisul to treat any other conditions unless your doctor tells you to. Do not give this medicine to anyone else, even if they have the same condition as

Things to be careful of

you.

Avoid drinking large amounts of tonic water and bitter lemon drinks while you are taking Quinbisul.

Tonic water and bitter lemon drinks contain quinine and may increase the risk of side effects of Quinbisul.

Be careful driving or operating machinery until you know how Quinbisul affects you.

Quinbisul may cause dizziness and affect vision in some people. If this occurs, do not drive or operate machinery or do anything else which could be dangerous.

Treatment for night cramps should be stopped if symptoms of cinchonism emerge. Serious hypersensitivity reactions including Stevens Johnson syndrome have been reported with quinine.

Quinine should be used with caution in patients with atrial fibrillation, conduction defects and heart blocks, or other serious heart disease. It may cause hypoprothrombinaemia.

Quinine has dose dependant QT-prolonging effects. Caution is recommended in patients with conditions which predispose to QT-prolongation and in patients with atrioventricular block.

Side effects

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

Like all medicines, Quinbisul may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

You may not experience any of them.

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

ringing in the ears, loss of hearing

- dizziness, fainting
- · headache
- · confusion, nervousness
- nausea, vomiting, stomach cramps
- · disturbed vision.
- diarrhoea

The above list includes the milder side effects of Quinbisul.

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

- · skin rash or redness, itching
- wheezing or difficulty breathing, swelling of the face
- · sweating
- bruising or bleeding more easily than normal
- decreased or no urine production
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- · chest pain, irregular heart beats
- symptoms of liver disease with yellowing of the eyes or skin (jaundice) and dark urine.
- · loss of consciousness, coma, death.

The side effects listed above are very serious. You may need urgent medical attention or hospitalisation.

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

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep it 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.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store Quinbisul or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Quinbisul, or your tablets has passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Quinbisul is a round, plain, white film coated, unscored, convex tablet. Each bottle contains 50 tablets.

Ingredients

Each Quinbisul tablet contains 300 mg of quinine bisulfate heptahydrate as the active ingredient.

It also contains the following inactive ingredients:

- · lactose monohydrate
- microcrystalline cellulose
- · povidone
- purified talc

- sodium starch glycollate
- pregelatinised maize starch
- · colloidal anhydrous silica
- · magnesium stearate
- carnauba wax
- · opadry white OY-LS-28908.

Quinbisul does not contain sucrose, gluten, tartrazine or any other azo dyes.

Contains sugars as lactose.

Sponsor

Arrow Pharma Pty Ltd 15 – 17 Chapel Street Cremorne VIC 3121

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