

HYDROXYCHLOROQUINE RBX

hydroxychloroquine sulfate 200 mg tablets

Consumer Medicine Information

What Is In This Leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about HYDROXYCHLOROQUINE RBX. It does not contain all the available Information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you. Keep this leaflet with your medicine.

You may want to read it again.

What HYDROXYCHLOROQUINE RBX Is Used For

The name of your medicine is HYDROXYCHLOROQUINE RBX. It contains the active ingredient hydroxychloroquine sulfate.

It may be used for any of the following conditions:

Rheumatoid Arthritis

Rheumatoid arthritis is a form of arthritis with inflammation of the joints, characterized by stiffness, swelling and pain.

HYDROXYCHLOROQUINE RBX may be used for short or long-term rheumatoid arthritis treatment.

In treating rheumatoid arthritis, HYDROXYCHLOROQUINE RBX may slow down the substances which harm the joints.

Systemic Lupus Erythematosus (SLE)

SLE is a disease in which a person's normal immunity is upset. The body produces an excess of blood proteins called antibodies and these antibodies may cause problems in any organ of the body.

These antibodies may end up, for example, in the skin causing a variety of skin rashes or deposit in the kidney, brain, lung and joints causing injury.

Discoid Lupus Erythematosus (DLE)

DLE is similar to SLE except it only affects the skin and is characterized by a scaling, red rash.

Malaria (treatment and control of symptoms)

Malaria is an infectious disease caused by the presence of parasites in red blood cells.

The disease is characterized by chills, fever and sweats. In malaria, HYDROXYCHLOROQUINE RBX destroys the harmful parasite which causes the illness.

Your doctor may have prescribed HYDROXYCHLOROQUINE RBX for another reason.

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

HYDROXYCHLOROQUINE RBX is not addictive. This medicine is available only with a doctor's prescription.

Before You Take HYDROXYCHLOROQUINE RBX

When you must not take it

Do not take this medicine if you have had an allergic reaction to hydroxychloroquine, chloroquine or related products or any of the ingredients listed at the end of this leaflet.

If you are uncertain whether you have had an allergic reaction to a related product ask your doctor or pharmacist.

Symptoms of an allergic reaction may include an asthma attack, facial swelling, skin rash or hay fever.

Ask your doctor about the risks and benefits of taking this medicine while you are pregnant.
When HYDROXYCHLOROQUINE RBX is taken for long periods of time, there is an increased risk to the unborn child. It may cause problems with brain function, hearing, balance and vision.

Ask your doctor about the risks and benefits of taking this medicine while you are breastfeeding.

Do not take this medicine if you have previously experienced changes in your eyesight when taking medicines for rheumatoid arthritis or malaria.

HYDROXYCHLOROQUINE RBX should not be used in children under 6 years.

HYDROXYCHLOROQUINE RBX should not be used in children over 6 years for long periods.

Do not take this medicine after the expiry date (EXP) printed on the pack.

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

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Do not take this medicine to treat any other complaint unless your doctor says it is safe.

Do not give this medicine to anyone else.

Before you start to take it

You must tell your doctor if:

1. You are allergic to quinine.
2. You have allergies to any ingredients listed under "Product Description" at the end of this leaflet.

3. You have any pre-existing eye disorders.
4. You have experienced low blood sugar levels (Hypoglycaemia or hypo). Hydroxychloroquine RBX may increase the risk of you having a hypo.
5. You have any of these medical conditions:
 - Chloroquine-resistant malaria
 - Liver or kidney problems
 - Diabetes
 - Stomach, brain or blood disorders
 - Skin diseases, in particular psoriasis which is a kind of itchy rash.
 - Glucose-6-phosphate dehydrogenase (G-6-PD) deficiency which is a lack of a chemical substance which causes the breakdown of sugar in the body.
 - Porphyria, which is a rare disease of blood pigments.
5. You plan to become pregnant or breast-feed.

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

Taking other medicines

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

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

- Any medicine to treat depression
- Digoxin - a medicine used to treat heart disease
- Medicines to treat diabetes
- Medicines used to suppress the immune system such as cyclosporine
- Antiarrhythmic drugs such as amiodarone
- Other antimalarial drugs
- Medicines to treat epilepsy

These medicines may be affected by HYDROXYCHLOROQUINE RBX or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking HYDROXYCHLOROQUINE RBX.

Other interactions not listed above may also occur.

How to take HYDROXYCHLOROQUINE RBX

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

The dosage will depend on why you are being treated with HYDROXYCHLOROQUINE RBX.

The usual doses are:

Rheumatoid arthritis

Adults

2-3 tablets daily. Your doctor may later reduce this to 1-2 tablets daily.

SLE and DLE

Adults

2-4 tablets daily. Your doctor may later reduce this to 1-2 tablets daily.

Control of Malaria Symptoms

Adults

2 tablets once a week. The tablets should be taken on exactly the same day of each week.

For example, if your first dose is taken on a Monday, then each weekly dose should be taken on a Monday.

Treatment of Malaria

Adults

The starting dose is 4 tablets. Take another 2 tablets six to eight hours later and two further tablets on each of the next 2 days.

Always follow the instructions given to you by your doctor.

Dosages for children are calculated according to the child's body weight.

Your doctor will work out the correct dose for you.

HYDROXYCHLOROQUINE RBX should not be used in children for long periods.

Your doctor may ask you to take a different dose. You should follow the instructions on the label.

If you are unsure what dose to take ask your pharmacist or doctor.

How to take it

Swallow tablets whole with a little water or other liquid.

When to take it

It is best to take HYDROXYCHLOROQUINE RBX at meal times.

How long to take it for

Continue taking your medicine for as long as your doctor tells you. Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you are being given HYDROXYCHLOROQUINE RBX for rheumatoid arthritis or SLE or DLE, do not take a double dose to make up for the dose missed. Just continue with the appropriate dose on the next day.

If you are being given HYDROXYCHLOROQUINE RBX for suppression or treatment of malaria, you should take your tablets as soon as you remember, and go back to taking it as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much HYDROXYCHLOROQUINE RBX.

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

You may need urgent medical attention.

If you take too much HYDROXYCHLOROQUINE RBX, you may experience headaches, drowsiness, visual disturbances or fits.

These symptoms may occur within 30 minutes of overdose.

While You Are Taking HYDROXYCHLOROQUINE RBX

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking HYDROXYCHLOROQUINE RBX.

Tell all doctors, dentists and pharmacists who are treating you that you are taking HYDROXYCHLOROQUINE RBX.

Tell your doctor if you experience any of the following symptoms including; weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers.

These symptoms may be associated with hypoglycaemia.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose urgently.

You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- 1/2 can of ordinary (non-diet) soft drink
- 2-3 concentrated glucose tablets
- unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates e.g. plain biscuits, fruit or milk - when over the initial symptoms. Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Make sure you, your friends, family and work colleagues can recognize the symptoms of hypoglycaemia and know how to treat them.

Your doctor will need to perform the following tests during treatment with HYDROXYCHLOROQUINE RBX.

Your doctor may monitor your blood sugar levels if you have experienced hypoglycaemia while taking hydroxychloroquine

Eye Tests

Your doctor will need to perform some eye tests every few months to check that your eyesight is not changing.

In extremely rare cases, HYDROXYCHLOROQUINE RBX has been associated with blindness. This can be avoided by having regular eye tests.

It is recommended you wear sunglasses when out in the sun.

Blood Reactions

Your doctor will need to perform occasional blood tests to check for any blood reactions.

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking HYDROXYCHLOROQUINE RBX.

Tell your doctor immediately if you become pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

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

Things to be careful of

Be careful while driving or operating machinery until you know how HYDROXYCHLOROQUINE RBX affects you.

HYDROXYCHLOROQUINE RBX may cause problems with the eyesight of some people. Make sure you know how you react to HYDROXYCHLOROQUINE RBX before you drive a car, operate machinery, or do anything else that could be dangerous with blurred vision.

Side Effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

HYDROXYCHLOROQUINE RBX helps most people with rheumatoid arthritis, SLE, DLE, treatment of malaria and the control of malaria symptoms, but it may have unwanted side effects in a few people.

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.

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

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

Less serious side effects

Stomach problems such as:

- Nausea
- Vomiting
- Diarrhoea
- Abdominal cramps

Other problems such as:

- Muscle weakness
- Loss of appetite

- Dizziness
- Ringing in the ears
- Headache
- Nervousness
- Skin rash and itching
- Hair loss

If you already have psoriasis, you are more likely to experience skin reactions than other people when taking HYDROXYCHLOROQUINE RBX.

More serious side effects

Tell your doctor if you notice any of the following:

- Visual disturbances
- Any hearing loss
- Suicidal behaviour
- Frequent fevers, severe chills, bruising, sore throat or mouth ulcers (these may be signs of blood reactions)
- More severe symptoms of hypoglycaemia including:
 - Disorientation
 - Seizures, fits or convulsions
 - Loss of consciousness

These are serious side effects. You may need medical attention.

Serious side effects are rare. Other side effects not listed above may occur in some patients.

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

After Using HYDROXYCHLOROQUINE RBX

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

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

Do not leave it on a window sill or in the car.

Heat, sunlight and dampness can destroy some medicines.

Keep it where children cannot reach it.

Children are particularly sensitive to the unwanted effects of HYDROXYCHLOROQUINE RBX.

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

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product Description

What

HYDROXYCHLOROQUINE RBX looks like

White to off-white, capsule-shaped tablets, embossed "HCQS" on one side, plain on the other side.

Packaged in bottles of 100 tablets.

Ingredients

Active ingredient:

Each tablet contains 200 mg of hydroxychloroquine sulfate as the active ingredient.

Inactive ingredients:

- anhydrous calcium hydrogen phosphate
- pregelatinised maize starch
- hypromellose
- magnesium stearate
- polysorbate 80
- colloidal anhydrous silica
- OPADRY II complete film coating system 85F18422 White.

This medicine does not contain gluten or lactose.

Sponsor

Ranbaxy Australia Pty Ltd.

9-13 Waterloo Road

Macquarie Park NSW 2113

Australian Registration Numbers

HYDROXYCHLOROQUINE RBX

200 mg tablets: AUST R 186392.

This leaflet was prepared in April 2015.