

HYDROXYCHLOROQUINE SULFATE 100 mg Tablets

PATIENT INFORMATION LEAFLET

Keep this leaflet, as you may need to read it again

This medicine has been prescribed for you as an experimental therapy for the prevention or treatment of coronavirus (COVID-19)

Do not give it to anyone else

If you have any questions or potential side effects, talk to your doctor, pharmacist or clinical trial staff

Why am I taking Hydroxychloroquine Sulfate?

Hydroxychloroquine Sulfate has been prescribed for you as an experimental therapy for the prevention or treatment of coronavirus (COVID-19).

This medicine is approved for use in Australia for other conditions (including lupus, rheumatoid arthritis and malaria), but it is not currently known how, or if, it works for COVID-19.

You may be receiving Hydroxychloroquine tablets as part of a clinical trial. If so, the clinical trial staff will provide you with information about the clinical trial and what it means to take part.

What do I need to know before I take Hydroxychloroquine Sulfate?

Tell your doctor or clinical trial staff if:

- You have had a previous allergic reaction to Hydroxychloroquine, Chloroquine or Quinine. If you are uncertain, talk to your doctor, pharmacist or clinical trial staff. If you are allergic, you should not take this medicine.
- You have an eye disease that affects the retina, at the back of the eye. If you are uncertain, talk to your doctor, pharmacist or clinical trial staff. People with certain eye diseases should not take this medicine.
- You are pregnant or are breastfeeding. Ask your doctor or clinical trial staff about the risks and benefits of taking Hydroxychloroquine in these circumstances.

Tell your doctor or clinical trial staff if you have or have had any of these medical conditions:

- liver or kidney problems;
- diabetes or problems with low blood sugar levels (hypos) during diabetes treatment;
- disease of the heart muscle or problems with heart rhythm, including long QT syndrome;
- glucose-6-phosphate deficiency;
- skin diseases, such as psoriasis as this may increase your chance of skin reactions;
- porphyria – a rare disease of blood pigments;
- epilepsy.

Tell your doctor or clinical trial staff if you are taking any of these medicines:

- medicines to treat depression, anxiety, schizophrenia or other mood disorders;
- digoxin – a medicine for heart disease;
- medicines to treat diabetes;
- medicines to suppress the immune system, such as cyclosporine;
- medicines for heart rhythm problems, such as amiodarone;
- medicines for infections;
- antimalarial drugs;
- medicines to treat epilepsy;
- tamoxifen.

These medicines may affect the way Hydroxychloroquine works or be affected by it and increase your risk of side effects.

Potential side effects

You should seek medical attention if you think you are experiencing a side effect. In an emergency, call 000.

This safety information is based on what is known about some of the serious side effects of Hydroxychloroquine when it is used for approved conditions such as Lupus and rheumatoid arthritis. Other side effects may occur if Hydroxychloroquine is taken to prevent or treat COVID-19.

Hypoglycaemia (low blood sugar): Hydroxychloroquine is known to cause problems with low blood sugar. The following symptoms may indicate you have low blood sugar and that you need to seek medical attention urgently: weakness, trembling or shaking, sweating, light-headedness, headache, dizziness, lack of concentration, tearfulness or crying, irritability, hunger and numbness around the lips and fingers.

Visual problems: Hydroxychloroquine can cause problems with your eyesight. Your doctor may arrange tests of your eyesight, especially if you are taking this medicine to prevent COVID-19. **You need to wear sunglasses when outdoors to protect your eyes from the sun.** You should seek medical attention if you have problems with your eyesight while taking Hydroxychloroquine.

Blood reactions: Blood reactions have been reported with Hydroxychloroquine. Your doctor will need to perform blood tests while you are taking this medicine.

Heart rhythm problems: Hydroxychloroquine can cause serious abnormal heart rhythm problems, which can be fatal. Your doctor may need to check your ECG to look for any effect of Hydroxychloroquine on your heart rhythm.

Tell your doctor or seek medical attention if you experience any of these symptoms of serious side effects:

- visual disturbances, hearing loss, suicidal thoughts or behaviour, palpitations or other changes in your heart beat, symptoms of low blood sugar, faints, seizures or convulsions.

If you have any of these symptoms and they worry you talk to your doctor, pharmacist or clinical trial staff:

- nausea, vomiting, diarrhoea, abdominal cramps
- loss of appetite, muscle weakness, dizziness, ringing in the ears, headache, nervousness, skin rash and itching, hair loss.

Side effects should be reported to the Therapeutic Goods Administration at www.aems.tga.gov.au or (freecall) 1800 020 653.

If you are taking this medicine as part of a clinical trial, your doctor or the trial staff will tell you how to report any side effects you experience.

Dose

Your doctor or the clinical trial staff will provide you with information about your dose and how to take Hydroxychloroquine tablets. The dosing instructions relating to COVID-19 might be different from the doses for the treatment of other conditions.

You should ask your doctor or the clinical trial staff if you have any questions about how to take your medicine.

Storing your medicines

KEEP HYDROXYCHLOROQUINE TABLETS WHERE YOUNG CHILDREN CANNOT REACH THEM.

Keep your Hydroxychloroquine tablets in the packaging provided in a cool, dry place. They will not keep well out of that packaging.

Overdose

Hydroxychloroquine in overdose may cause serious harm and deaths have occurred.

If you take too many Hydroxychloroquine tablets call the Poisons Information Centre (13 11 26) for advice or go to the Emergency Department at your nearest hospital.

If someone else accidentally takes your tablets, immediately call the Poisons Information Centre (in Australia 13 11 26) for advice or go to the Emergency Department at your nearest hospital.

Product details

Packaged by **IDT Australia Limited**
45 Wadhurst Drive, Boronia VIC 3155
Australia
Phone + 61 3 9801 8888
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Product Presentation:

Boxes of three blister packs of 14 tablets each; or
Bottles of 100 tablets each

Manufactured by **SPH Zhongxi Pharmaceutical Co.**
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Batch details: