

## Hydroxychloroquine Sulfate 200mg Film-coated Tablets

### Uses

Hydroxychloroquine Sulfate tablets contain an active substance called hydroxychloroquine sulfate.

Hydroxychloroquine Sulfate works by reducing inflammation in people with autoimmune diseases (this is where the body's immune system attacks itself by mistake).

It can be used for: Rheumatoid Arthritis (inflammation of the joints), Juvenile Idiopathic Arthritis (in children), Discoid and Systemic Lupus, Erythematosus (a disease of the skin or the internal organs), Skin problems which are sensitive to sunlight

**Do not take Hydroxychloroquine Sulfate and tell your doctor if:** You are allergic (hypersensitive) to Hydroxychloroquine, Other similar medicines such as Quinolones and Quinine, Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

You have an eye problem which affects the retina, the inside of the eye (maculopathy) or you get a change in eye colour or any other eye problem.

- You are pregnant, might become pregnant or think you may be pregnant (see 'Pregnancy and breast-feeding' below).
- Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Hydroxychloroquine Sulfate.

**Children and adolescents:** This medicine is not suitable for children and adolescents who weigh less than 31 Kg (around 5 stones).

### Other medicines and Hydroxychloroquine Sulfate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you can buy without a prescription, including herbal medicines. This is because Hydroxychloroquine Sulfate can affect the way some other medicines work. Also some medicines can affect the way Hydroxychloroquine Sulfate works.

**In particular, tell your doctor if you are taking any of the following:**

- The following medicines may increase the chance of you getting side effects when taken with Hydroxychloroquine Sulfate:
- Some antibiotics used for infections (such as Gentamicin, Neomycin or Tobramycin)
- Cimetidine — used for stomach ulcers
- Neostigmine and Pyridostigmine — used for muscle weakness (Myasthenia Gravis)
- Medicines that may affect the kidney or liver
- Medicines that affect the skin or the eyes
- Halofantrine, Mefloquine — used for Malaria
- Amiodarone — used for heart problems
- Moxifloxacin — used to treat infections
- Medicines used for epilepsy
  
- The following medicines can change the way Hydroxychloroquine Sulfate works or Hydroxychloroquine Sulfate may affect the way some of these medicines work:
- Digoxin — used for heart problems
- Medicines for diabetes (such as Insulin or Metformin)
- Antacids — used for heartburn or indigestion. You should leave a gap of at least 4 hours between taking these medicines and Hydroxychloroquine Sulfate
- Rabies vaccine
- Ciclosporin — used after an organ transplantation to help prevent rejection
- Praziquantel — used to treat worm infections
- Agalsidase — used to treat a rare condition called Fabry's disease

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Hydroxychloroquine Sulfate if:

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast-feed. This is because small amounts may pass into mothers' milk

### How to take Hydroxychloroquine Sulfate

Taking this medicine:

Take this medicine by mouth. Swallow the tablets whole with a meal or a glass of milk. Do not crush or chew your tablets.

If you are taking this medicine for skin problems that are sensitive to sunlight, only take Hydroxychloroquine Sulfate during periods of high exposure to light.

The doctor will work out the dose depending on your body weight. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

If you have been taking this medicine for rheumatoid arthritis for a long time (more than 6 months) and you do not feel that it is helping you, see your doctor. This is because the treatment may need to be stopped.

The recommended dose for adults, including the elderly, is:

- One or two tablets each day
- Use in children and adolescents
- One tablet each day
- This medicine is only suitable for children who weigh more than 31 kg (around 5 stones)
- It may take several weeks before you notice the benefit of taking hydroxychloroquine sulfate.

If you take more Hydroxychloroquine Sulfate than you should:

Tell your doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: headache, problems with your eyesight, fall in blood pressure, convulsions (fits), heart problems, followed by sudden severe breathing problems and possibly heart attack.

Young children and babies are particularly at risk if they accidentally take hydroxychloroquine sulfate. Take the child to hospital straight away.

If you forget to take Hydroxychloroquine Sulfate

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Hydroxychloroquine Sulfate

Keep taking hydroxychloroquine sulfate until your doctor tells you to stop. Do not stop taking hydroxychloroquine sulfate just because you feel better. If you stop, your illness may get worse again.

**Stop taking Hydroxychloroquine Sulfate and see a doctor or go to a hospital straight away if:**

You have an allergic reaction. The signs may include: a red or lumpy rash, swallowing or breathing problems, swelling of your eyelids, lips, face, throat or tongue. Severe skin reactions such as blistering, widespread scaly skin, pus-filled spots together with a high temperature, reddening and being more sensitive to the sun. Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson Syndrome.

Stop taking Hydroxychloroquine Sulfate and see a doctor straight away if you notice any of the following serious side effects - you may need urgent medical treatment:

**Common (may affect up to 1 in 10 people):** You have any eye problems. This includes changes in the colour of your eye and problems with your eyesight such as blurring, sensitivity to light or the way you see colour.

**Uncommon (may affect up to 1 in 100 people):** You have any muscle weakness, cramps, stiffness or spasms or changes in sensation such as tingling. If you take this medicine for a long time, your doctor will occasionally check your muscles and tendons to make sure they are working properly.

**Very common (may affect more than 1 in 10 people):** Stomach pain, Feeling sick

**Common (may affect up to 1 in 10 people):** Skin rashes, itching, Being sick, Diarrhoea, Loss of appetite (Anorexia), Headache  
Changes in mood with uncontrollable laughing or crying

**Uncommon (may affect up to 1 in 100 people):** Changes in the colour of your skin or the inside of your nose or mouth, Hair loss or loss of hair colour  
Feeling nervous, Ringing in the ear (Tinnitus), Balance problems (Vertigo) or feeling dizzy, Liver problems shown by blood tests.

**How to store**

Store in original package in order to protect from light.