

UNIQUIN (Hydroxychloroquine Sulphate 200mg Film Coated Tablet)

(Hydroxychloroquine Sulphate 200mg)

What is in this leaflet

1. What UNIQUIN is used for
2. How UNIQUIN works
3. Before you UNIQUIN
4. How to use UNIQUIN
5. While you are using it
6. Side effects
7. Storage and Disposal of UNIQUIN
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What UNIQUIN is used for

UNIQUIN contains a medicine called hydroxychloroquine sulphate. And is used for Treatment of rheumatoid arthritis (inflammation of the joint), juvenile chronic arthritis (in children), discoid and systemic lupus erythematosus (a disease of the skin or the internal organs), and dermatological conditions caused or aggravated by sunlight (skin problem which are worsen by sunlight).

How UNIQUIN works

works by reducing inflammation in people with autoimmune disease (this is where the body immune system attacks itself by mistake).

Before you use UNIQUIN

- When you must not use it

- UNIQUIN may be associated with a small increased risk of malformations and should not be used during pregnancy unless your doctor considers the benefits outweigh the risks

Do not take UNIQUIN if you:

- Think you may be allergic (hypersensitive) to:
 - Hydrochloroquine,
 - Other similar medicine such as quinolones and quinine,
 - any other ingredients of UNIQUIN
 - 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.

Signs of an allergic reaction including: a rash, swallowing or breathing problems, swellings of your lips, face, throat or tongue.

- You are pregnant, might become pregnant or think you may be pregnant

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 UNIQUIN.

Pregnancy and lactation

Do not take UNIQUIN 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 amount may pass into mothers' milk

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Take special care with UNIQUIN and check with your doctor or pharmacist before using this medicine if you are suffering or have ever suffered from any of the following conditions or illnesses:

- You have liver or kidney problems
- You have serious stomach or gut problem
- You have any problems with your blood. You may have blood test to check this.
- You have any problems with your nervous system or brain
- You have psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)
- You have had a bad reaction to quinine in the past.
- You have a genetic condition known as 'glucose-6-dehydrogenase deficiency'
- You have a rare illness called 'porphyria' which affects your metabolism

If the answer to any of these questions is YES, tell your doctor or pharmacist because UNIQUIN might not be the right medicine for you.

- Before you start use it

Take special care and check with your doctor if:

- You have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used for breathing). You may notice aggravation of symptoms such as muscle weakness, difficulty in swallowing, double vision, drooping of the upper eyelid etc.
- Hydroxychloroquine may cause heart, kidney or muscle disorders. Please ask your doctor to inform you of signs and symptoms of drug induced phospholipidosis. Hydroxychloroquine may need to be stopped.
- Before you take this medicine, you should have your eyes examined.
- This testing should be repeated at least every 12 months while taking Uniquin.

- If you are above 65, need to take a high dose (2 tablets a day) or have kidney problems then this examination should be performed more often
- Hydroxychloroquine can cause lowering of the blood glucose level. Please ask your doctor to inform you the sign and symptoms of low blood glucose levels. A check of the blood glucose level may be necessary.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking UNIQUIN

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription, including herbal medicines. This is because UNIQUIN can affect the way some other medicines work. Also some medicines can affect the way UNIQUIN works.

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

The following medicines may increase the chances of getting side effects when taken with UNIQUIN:

- Digoxin (used to treat heart failure)
- Anti-diabetic drugs
- Drugs known to prolong the QT interval/with potential to induce cardiac arrhythmia (heart rhythm problems)
- Ciclosporin (a immunosuppressant. It is used to reduce rejection following organ and bone marrow transplantation, and to treat a variety of long-term (chronic) inflammatory and autoimmune diseases.)
- Tamoxifen (used to treat breast cancer)
- Agalsidase (use in the treatment of Fabry disease. It is a serious genetic disorder that can lead to life-threatening heart and kidney problems)
- Drugs affecting the convulsive threshold (convulsive threshold is a person's likelihood to have a seizure)

How to use UNIQUIN

Always take UNIQUIN exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

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- If you are taking this medicine for skin problems that are sensitive to sunlight, only take UNIQUIN 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.

- How much to use

Adults, including the elderly:

One or two tablets each day

Children and Adolescents:

- One tablet each day.
- This medicine is only suitable for children who weigh more than 31kg (around 5 stones).

It may take several weeks before you notice the benefit of taking UNIQUIN.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Uniquin for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there is no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdosage include 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 UNIQUIN. Take the child to a hospital straight away

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors and pharmacists treating you that you are taking UNIQUIN.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Uniquin to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

This medicine contains lactose. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking UNIQUIN.

Driving and using machines

You may get vision problems soon after taking this medicine. If this happens, do not drive or use any tools or machines, and tell your doctor straight away. If the condition is not self-limiting, it will resolve on reducing the dose or stopping treatment.

Some people being treated with UNIQUIN can experience mental health problems such as irrational thoughts, anxiety, hallucinations, feeling confused or feeling depressed, including thoughts of self-harm or suicide, even those who have never had similar problems before. If you or others around you notice any of these side effects seek medical advice straight away.

Side effect

Like all medicines, Uniquin can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Accumulation of a type of fat in tissues causing harm. The doctor may decide to stop the treatment with UNIQUIN
- 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
- Skin reaction including plum-colored, raised, painful sores, particularly on

your arms, hands, fingers, face and neck, which may also be accompanied by fever. This could be a condition called Sweet's syndrome

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

- 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
- 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
- Severe skin reactions such as blistering, widespread scaly skin, pus-filled spots together with a high temperature
- 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
- You may get infections more easily than usual. This could be due to bone marrow depression or a blood disorder called 'agranulocytosis'
- You may bruise more easily than usual. This could be due to a blood problem called 'thrombocytopenia'
- You feel tired, faint or dizzy and have pale skin. These could be symptoms of something called 'anaemia'
- You feel weak, short of breath, bruise more easily than usual and get infections more easily than usual. These could be symptoms of something called 'aplastic anaemia'
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Lowering of the blood glucose level (hypoglycaemia), frequency unknown. You may feel a sense of nervousness, shaky or sweaty

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Skin rashes, itching, changes in the colour of your skin or the inside of your nose or mouth
Psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)
- Hair loss or loss of hair colour

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- Feeling or being sick, diarrhoea, loss of appetite (anorexia) or stomach pain
- Feeling nervous, ringing in the ear (tinnitus), hearing loss, headache, fits, balance problems (vertigo) or feeling dizzy, mental problems (such as delusions, hallucinations or changes in mood)
- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty in breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine
- You may get infections more easily than usual. This could be due to bone marrow depression
- Symptoms of a condition called 'porphyria' which may include stomach pain, being sick, fits, blisters, itching
- Common: mood swings
- Uncommon: nervousness
- Not known: Feeling depressed or having thoughts of self-harm or suicide, feeling nervous or anxious, feeling confused, hallucinations, agitated, feeling elated or overexcited, difficulty sleeping.

Blood Tests

- A blood test may show changes in the way the liver is working and rarely the liver may stop working

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF)]

Storage and Disposal of Uniquin

- Storage

Store at dry place, below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Hydroxychloroquine Sulfate 200mg Film coated tablet, is Round shaped, light yellow colored film coated tablet

having score line on one side and 'INCEPTA' debossed on other.

- Ingredients

- Active ingredient(s)

Hydroxychloroquine Sulphate 200mg

- Inactive ingredient(s)

Lactose Monohydrate, maize starch, hypromellose, croscarmellose sodium, magnesium stearate, talc, macrogol 6000, titanium dioxide, iron oxide yellow, polysorbate 80, (methanol and methylene chloride are used as solvent and does not exist in finished product).

MAL number(s):

MAL17065020AZ

Manufacturer

INCEPTA PHARMACEUTICALS LTD
Dewan Idris Road, Bara Rangamatia,
Zirabo, Dhaka, Bangladesh

Product Registration Holder

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