



Resochin® Tablets

Active ingredient: chloroquine phosphate

Package leaflet: Information for the user

Resochin® Tablets 250 mg

For use in children and adults

Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their complaints are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- What Resochin Tablets are and what they are used for
- Before you take Resochin Tablets
- How to take Resochin Tablets
- Possible side effects
- Storing Resochin Tablets
- Further information

1. WHAT RESOCHIN TABLETS ARE AND WHAT THEY ARE USED FOR

Indications

Resochin Tablets are used for:

- Treating and preventing malaria.
- Resochin Tablets are effective against all four malaria parasites that infect humans, except for chloroquine-resistant species. Attention has been paid to geographically varying incidence of resistance.
- Chronic polyarthritis (rheumatoid arthritis) including juvenile chronic arthritis.
- Systemic Lupus erythematosus.

Explanations

Malaria (swamp fever, tertian fever) is a serious febrile disease, the causative agents of which are transmitted by mosquitoes. Chronic polyarthritis and juvenile chronic polyarthritis are diseases of the connective tissue, which generally affect the joints for the most part; they can, however, also affect internal organs. Systemic Lupus erythematosus (butterfly rash), is a disease of the connective tissue, which affects the skin, as well as internal organs.

2. BEFORE YOU TAKE RESOCHIN TABLETS

Do not take Resochin Tablets.

If you are hypersensitive (allergic) to chloroquine phosphate or to one of the other constituents of Resochin Tablets or to other 4-aminocoumarins (to which chloroquine phosphate, the active ingredient of Resochin Tablets, also belongs),
- if, in your case, there have been diseases of the retina and/or limitations to the field of vision diagnosed,
- if you have disorders relating to the formation of blood cells,
- if you have a deficiency of glucose-6-phosphate-dehydrogenase (a rare illness with possible destruction of red blood corpuscles),
- if you have contracted Myasthenia gravis (serious muscle weakness) or
- if you are pregnant or breast-feeding (with the exception of treating malaria) (see below, section entitled, **Pregnancy and breast-feeding**).

Take special care with Resochin Tablets:

- Retinopathy (retina damage)

An eye examination will be conducted before beginning long-term treatment, which will be repeated in intervals of three months. Treatment has to be discontinued at the first signs of retina damage (inability to see the colour red). Permanent damage to vision resulting from a retinopathy caused by Resochin is possible in the event of long-term therapy with high dosages. Examinations of the retina are recommended for patients, who are receiving long term treatment with Resochin. Cumulative total doses of 1 g per kg bodyweight chloroquine or total doses of 50 to 100 g can cause retina damage. Doses, which were recommended for malaria prophylaxis, seldom caused retinopathy. When using Resochin for prophylactic treatment, the occurrence of retinopathy is, therefore, only relevant in long-term use (> 5 years).
Impaired hepatic function
Since it is known that Resochin accumulates in the liver, patients with impaired hepatic function may need to take fewer Resochin Tablets.
- Impaired renal function
Resochin is primarily eliminated via the kidneys. Therefore, in patients with impaired renal function, it may be necessary to take a reduced amount of Resochin Tablets.
- Kidney failure
Due to the lack of sufficient experience, it is not advisable to administer Resochin to patients with kidney failure (with a certain laboratory value (creatinine clearance) falling below 10 mL/min).
- Nervous system
A regular medical examination is required in patients suffering from epilepsy (seizure, muscle cramps with unconsciousness).
- Haemogram
The haemogram also has to be checked prior to the start of long-term treatment, which is then repeated in intervals of every two months.
- Metabolic disturbances
Resochin should not be used in patients with psoriasis (dry, scaling patches) or porphyria (disturbance in the formation of the red blood pigment).
- QT-interval prolongation
Resochin can cause certain changes in the electrocardiogram (ECG, electrical recording of cardiac activity). A so-called prolongation of the QT-interval, i.e. retarded conveyance of electrical signals, can occur. This results in irregular heart rhythm.
- Continuous treatment in woman of childbearing age
Patients, who take Resochin Tablets in long-term treatment, should use reliable contraceptive protection during treatment and for three months thereafter (see section entitled **Pregnancy and breast-feeding**).
Continuous treatment for malaria prophylaxis in children
There should be no long-term use for malaria prophylaxis in children.

Taking Resochin Tablets with other medicines:

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, even those not prescribed.
Taking Resochin Tablets at the same time with the following medicines can influence the effect of Resochin:
- antacids (agent used to counteract excessive stomach acid) and kaolin (agent used to counteract diarrhoea) can reduce the absorption of Resochin; therefore, there should be at least four hours between taking antacids or kaolin and the administration of Resochin,
- phenylbutazone (active substance used to counteract gout and rheumatism) increase the possibility of exfoliative dermatitis (skin inflammation with scaling of the skin),
- probenecid (active substance used to counteract gout) increases the probability of sensitisation,
- corticosteroid derivatives (active substances, that have an anti-inflammatory effect) can enhance myopathies (muscle diseases) and cardiomyopathies (heart muscle diseases).
- Do not use Resochin Tablets with other hepatotoxic drugs (which have toxic effects on the liver, such as isoniazid, amiodarone, carbamazepine, phenytoin, phenothiazines and ketoconazole) and MAO inhibitors (medicinal products, such as tranylcypromine and selegiline, used for inhibiting a certain body substance),
- cimetidine (active substance used to counteract gastritis and stomach ulcers) can decrease the elimination of chloroquine,
- mellequine (active substance used in the treatment of malaria) and bupropion (active substance used to stop smoking) can increase the risk of convulsions,
- an acute dystonic reaction (change in the tension of muscle tone expressed by slow movements) has been observed following the administration of metronidazole (active substance used to treat protozoan infection (trichomonas)),
- penicillamine (an active substance used against bacteria) can increase the risk of severe side effects related to blood and / or the kidneys, as well as skin reactions,
- pyrimethamine and sulfadoxine (active substances used in the treatment of malaria) clearly increase the risk of skin diseases. Taking Resochin Tablets at the same time as the following medicines can influence the effect of the other medicinal product:
- by decreasing the formation of antibodies when vaccinating for rabies using HDC vaccine. If a simultaneous vaccination for rabies cannot be avoided, the vaccine should be intramuscular. A negative effect on routine vaccination (tetanus, diphtheria, measles, poliomyelitis, typhoid fever and tuberculosis) has not been observed,
- by increasing the digoxin plasma concentration with glycoside intoxication in the case of long-term concomitant use (danger of poisoning by the cardiac drug, digoxin, if concomitant administration has been sustained for a long period of time),
- by enhancing the effect of folic acid antagonists (methotrexate, an active substance used in the treatment of cancer),
- by decreasing the effect of neostigmine and pyridostigmine bromide (active substances used for muscle stimulation),
- by increasing the plasma concentration of cyclosporine (active substance used for autoimmune suppression),
- by reducing the absorption of an active substance used to counteract bacteria; ampicillin should be administered, at least, two hours following the administration of Resochin),
- by reducing the blood concentration of praziquantel (each accused to counteract infestation with trematoda or tapeworms or lung flukes or liver flukes, respectively).

Using Resochin with food and drink

You should try not to drink alcohol while taking Resochin Tablets.

Pregnancy and breast-feeding:

Use with Chronic Polyarthritis and systemic Lupus erythematosus :

Do not use Resochin Tablets during pregnancy, because they could cause organ damage in your foetus. Pregnancy has to be ruled out before starting treatment. Use effective contraceptive protection during treatment and for three months thereafter.
Do not use Resochin Tablets while you are breast-feeding, since there are only insufficient data available and chloroquine phosphate, the active substance of Resochin Tablets, does pass into the mother's milk.
Use in treating and in the prophylactic treatment of malaria:
Only use Resochin tablets during pregnancy after your doctor has conducted a careful risk/benefit assessment. This will generally be decided in favour of using Resochin Tablets, since the malaria infection itself damages the unborn child.
Pregnancy has to be ruled out before you start the treatment and the prophylactic treatment of malaria. When it has been ruled out, use effective contraceptive protection during treatment and for three months thereafter.
Do not breast feed (see above).
Ask your doctor or pharmacist for advice before taking/using any medicine.

The ability to drive and use machines:

Do not drive or use machines, if you experience side effects from Resochin Tablets, such as headaches, dizziness, drowsiness, disorientation, impairment of focused vision and hazy field of vision. These can also occur when used as instructed. This applies even more at the start of treatment, as well as in conjunction with alcohol.

3. HOW TO TAKE RESOCHIN TABLETS

Always take Resochin Tablets exactly according to your doctor's instructions. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

- for malaria prophylaxis:

two tablets once a week

You should start taking the tablets one to two weeks prior to travelling to malaria-infested areas. You should take the tablets on the same day of each week during your stay in malaria-infested areas and for a further four weeks after leaving the areas.
Pursuant to guidelines of the World Health Organization (WHO), taking a total amount of 1g chloroquine per kilogram bodyweight (or a total of approximately 50 to 100 g) over time can damage your retina. Therefore, the total dose should not exceed 50 g chloroquine. When considering the total dose, the overall length of use can vary according to the patient's bodyweight and specific prescription requirements. It is recommended for the first prescription to calculate the entire length of use individually for you and to assure that the length of use will be recalculated every time there is a change in the prescription parameters. You should be informed about individually calculated entire length of use. Take particular care as not to exceed the entire length of use.
Afterwards, continue use with a medicine, which does not contain chloroquine.
In certain malaria-infested areas, it is recommended to use double the total weekly dose for short stays. When doing this, distribute the pills evenly throughout the week. Please follow your doctor's recommendations.
Do not use in children for a period of several months.

- Treating malaria:

Start with a high initial dose in the event of a malaria infection; follow with three to four further single doses, which are half that amount, pursuant to the following table.
The single doses are calculated according to the patient's bodyweight. This is 8 mg chloroquine phosphate (active substance of

Resochin Tablets) per kilogram bodyweight. Thus, the following overview results:

Body weight (kg)	Day 1 1st Dose (number of film-coated tablets)	Day 1 2nd Dose [6 hours later] (number of film-coated tablets)	Daily dose for a further 2 to 3 days (number of film-coated tablets)
16	1	½	½
31	2	1	1
47	3	1½	1½
63	4	2	2
78	5	2½	2½
94	6	3	3

- Treating chronic polyarthritis (rheumatoid arthritis) and systemic Lupus erythematosus :

Your attending doctor will establish the Resochin dose you need for you individually. Due to the risk of contracting a disease of the retina, the dose during continuous treatment in adults and children should not amount to a daily dose of more than 4 mg chloroquine phosphate (active substance of Resochin Tablets) per kilogram bodyweight.
The success of therapy can, at the earliest, be assessed only after 4 to 12 weeks. Your doctor will discontinue treatment, if there has been no improvement after six months.
Pursuant to guidelines of the World Health Organization (WHO), taking a total amount of 1 g chloroquine per kilogram bodyweight (or a total of approximately 50 to 100 g) over time can damage your retina. Therefore, the total dose should not exceed 50 g chloroquine. Guidance note:
Patients with impaired kidney or liver function will require a lower dose of Resochin Tablets.

Route of administration

You should take the tablets whole (do not chew) with sufficient liquid (preferably with a glass of drinking water [200 mL]).

Length of administration

Your attending physician will determine the length of treatment. There should be no long-term use for malaria prophylaxis in children.
If you have the impression that the effect of Resochin Tablets is too strong or too weak, talk to your doctor or pharmacist.
If you take more Resochin Tablets than you should
Inadvertently taking one single dose of Resochin Tablets twice does not influence how you take further doses, i.e. you will continue to take Resochin Tablets as before.
If you have taken substantially excessive amounts of Resochin Tablets, this can cause paralyzing effects on your cardiovascular and respiratory systems. Early signs of poisoning are headaches, visual disturbances and irregular heart beat; cramps occur later. If these signs of affliction occur, you have to get immediate medical attention and go to hospital. Inform the nearest doctor, as soon as possible!
In an unsupervised moment, a child swallows Resochin Tablets, then make the child vomit immediately and notify the nearest doctor!

The following measures are recommended until the doctor arrives:

- Give the infant as much water as possible to drink or better fruit juice diluted with water. Then lay it over the knee of an adult, so that the head and face are pointing downward, compressing the abdomen slightly. Now, force the child to vomit by stimulating the back of its throat with your finger.
- Have an older child quickly drink warm salt water (1 to 2 spoonful of table salt in 1 glass of water). Again, induce vomiting by stimulating the back of the throat with your finger.
- Alternate drinking and vomiting until a clear liquid is being vomited.

If you forget to take Resochin Tablets:

During the prophylaxis and treatment of malaria, you should always take the tablets you missed, if you notice that you forgot them shortly after your usual time to take them. In the event that your next time to take the tablets is closer than the last time you should have taken them, please take the ones you missed, but take the next tablets a bit later, so that there is more of an equal interval between the times you take them.
If, during your treatment for chronic polyarthritis (rheumatoid arthritis) and for systemic Lupus erythematosus, you notice that you forgot to take your tablets on the previous day, do not catch up with taking them, rather continue taking the Resochin Tablets at your usual time.

If you stop taking Resochin Tablets:

In the event of unpleasant side effects, please discuss the matter immediately with your doctor with respect to which countermeasures there are and whether other medicinal products can be used for the treatment. Never discontinue taking the medicinal product without consulting your doctor!
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Resochin Tablets can cause side effects, although not everybody gets them.

The following incidence rating is used to evaluate the frequency of side effects:

- Common: 1 to 10 patients treated from among 100
- Uncommon: 1 to 10 patients treated from among 1,000
- Rare: 1 to 10 patients treated from among 10,000
- Very rare: less than 1 patient treated from among 10,000

The majority of the side effects observed, are dependent upon the amount taken. Therefore, please follow the advice of your doctor exactly.

Possible side effects:

Blood and lymphatic system disorders

Rare: agranulocytosis (severe reduction of certain white blood corpuscles), pancytopenia (severe reduction of all blood cells), thrombocytopenia (severe blood-platelet reduction)

Very rare: eosinophilia (augmentation of the number of certain white blood corpuscles), acquired methaemoglobinemia (change in the red blood pigment)

Immune system disorders

Very rare: drug-induced hypersensitivity syndrome (reported with symptoms, such as fever, rash with blisters, abdominal pain, diarrhoea, coughing and eosinophilia (augmentation of the number of certain white blood corpuscles), also with emphysema of these cells in tissue, mainly in the lung)

Metabolism and nutrition disorders

Common: lack of appetite

Rare: aggravation of porphyria (disrupted formation of red blood pigment), elimination of porphyrin (natural pigment) in urine
Very rare: acquired lipodosis (phospholipidosis) (increased accumulation of intracellular phospholipids), including renal phospholipidosis

Psychiatric disorders

Uncommon: anxiety reactions

Rare: psychoses (mental disorders)

Nervous system disorders

Uncommon: confusion, dizziness, headaches, reduced muscle tone, sleep disorders, paraesthesia (such as tingling or numbness), vertigo, drowsiness

Rare: seizure, nerve-related muscle disorders

Eye disorders

Common: corneal turbidity, visual disturbances, impairment of colour vision (reversible)

Uncommon: temporary impairment of focused vision

Rare: damage to the retina (irreversible), field of view loss, hazy vision

Ear and labyrinth disorders

Rare: hearing loss, tinnitus (perception of sound within the ear)

Cardiac disorders

Uncommon: drop in blood pressure, a change in measurement of heart function (depression of the T-wave in the electrocardiogram)

Very rare: cardiomyopathies (disorders of the cardiac muscle), electrocardiographic changes (changes in measurement of heart function)

Gastrointestinal disorders

Common: Gastrointestinal and abdominal pain (pain in the gastrointestinal and abdominal regions), diarrhoea, nausea, vomiting

Hepatobiliary disorders

Rare: impairment of the liver function, rise of certain liver values in blood

Skin and subcutaneous tissue disorders

Rare: hair loss, aggravation of psoriasis (scaly patches of skin), pigment disorders in the hair (disappearance of colour or greying of the hair), light sensitivity of the skin, itching, pigment disorders of the skin (dark discolouration of skin exposed to light) discolouration of the mucous membrane in the mouth, skin rash

Very rare: Stevens-Johnson syndrome (severe skin rash, causing fever during its course with mucous-membrane involvement), toxic epidermal necrolysis (epidermal scaling over large areas and mucosal damage)

Musculoskeletal, connective tissue and bone disorders

Rare: rapid muscle fatigue under stress, reduced muscle stamina, muscular disorders

General disorders and administration site conditions

Common: weight loss

Investigations

Rare: changed laboratory values

Please, tell your doctor or pharmacist if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet.

5. STORING RESOCHIN TABLETS

Not to be stored above 30° C.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the outer carton and the blister strip. The expiry date refers to the last day of the month indicated.

Storage conditions:

This medicinal product does not require special storage conditions.

6. FURTHER INFORMATION

What Resochin Tablets contain:

The active substance is chloroquine phosphate.

1 film-coated tablet of the Resochin Tablets contains 250 mg chloroquine phosphate (equivalent to 155 mg chloroquine). The other constituents are:
tablet core: maize starch, talc, magnesium stearate (Ph.Eur.)
tablet coating: hypromellose, macrogol 4000, titanium dioxide (E 171).

What Resochin Tablets look like and contents of the pack:

Resochin Tablets are round, white and convex.

Resochin Tablets are available in original packs of 30 film-coated tablets

Manufacturer

Bayer Schering Pharma AG

D-51368 Leverkusen

This leaflet was last approved in January 2009

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Bayer Schering Pharma AG, Germany
Bayer