

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Dolquine 200 mg coated tablets

### Hydroxychloroquine sulphate

**Read all of this the 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 symptoms 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.

#### In this leaflet:

1. What Dolquine is and what it is used for
2. Before you take Dolquine
3. How to take Dolquine
4. Possible side effects
5. How to store Dolquine
6. Further information

## 1. WHAT DOLQUINE IS AND WHAT IT IS USED FOR

Dolquine belongs to the group of medicines called anti-malarial

Dolquine is indicated for:

#### Adults

- Treatment of acute or chronic rheumatoid arthritis.
- Treatment of chronic discoid and systemic lupus erythematosus.
- Prevention and treatment of malaria (paludism) uncomplicated caused by sensitive species of plasmodium (the parasite that causes malaria), when first-choice treatments are not adequate or not available.

Children (aged 9 to 11 years and with a body weight of over 31 kg and adolescents)  
Prevention and treatment of malaria (paludism) uncomplicated caused by sensitive species of plasmodium (the parasite that causes malaria), when first-choice treatments are not adequate or not available.

## 2. BEFORE YOU TAKE DOLQUINE

#### Do not take Dolquine

- If you are allergic (hypersensitive) to hydroxychloroquine or any of the other ingredients of Dolquine.
- If you suffer from disorders of the retina.
- Over long periods in children.
- Dolquine should not be used for the prevention or treatment of malaria caused by chloroquine-resistant parasites.
- If you are taking any of the following medicines:
  - Artemether/lumefantrine and mefloquine (used to treat malaria).
  - Natalizumab (used to treat multiple sclerosis).
  - Attenuated live virus vaccines
  - Pimecrolimus and Tacrolimus (used to treat skin inflammation (eczema)).
  - Moxifloxacin (antibiotic).
  - Agalsidase alpha and beta (used to treat Fabry disease, a hereditary disorder).

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

#### Take special care with Dolquine

- if you suffer from:
  - skin disorders, such as psoriasis,
  - severe kidney disease,
  - glucose-6-phosphate dehydrogenase deficiency (hemolytic anaemia),
  - liver disease,
  - myasthenia gravis (an auto-immune disease leading to muscle weakness and fatigue),
  - alcoholism.
- if malaria is caused by Plasmodium vivax or Plasmodium ovale, Dolquine should be taken in association with primaquin, to prevent relapses,
- if you suffer from porphyria (a hereditary metabolic disease), Dolquine may aggravate your symptoms,
- if you suffer from neurological disorders (epilepsy),
- elderly patients should take special precaution to distinguish vision disorders typical of the disease or of their age from those caused by the medicine,
- if you suffer from vision disorders. Before starting a prolonged treatment with Dolquine, your doctor will examine your eyes; regular checkups will also be scheduled. Consult your doctor if you notice any visula.

Avoid exposure to the sun (even on cloudy days) and ultraviolet rays (UVA) when using this medicine.



If you are taking Dolquine over long periods of time, your doctor will probably want to perform regular checkups. Use these occasions to notify your doctor of any new or unusual symptoms or circumstances.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Bear in mind that these instructions may also apply to medicines used previously or which may be used afterwards.

Dolquine may affect the action of certain medicines, and its own action may be affected by the use of other medicines.

Inform your doctor or pharmacist if you are taking any of the following medicines, as it may be necessary to adjust their doses:

- Kaolin or antacids.
- Insulin and other medicines used to treat diabetes.
- Anthelmintics (used to expel intestinal worms).
- Antipsychotics: phenothiazines (used to treat mental disorders).
- Medicines used to treat heart problems (digoxin and certain beta blockers).

Some medicines may increase the number of side effects caused by Dolquine or reduce its effects. These include:

- Dapsone (used to treat leprosy and certain skin diseases).
- Vaccines (inactivated).
- Echinacea (traditional plant-based medicine used to treat common colds).
- Trastuzumab (used to treat certain cancers).

Inform your doctor or pharmacist if you are taking any of the following medicines:

- Aminoglycoside antibiotics.
- Cimetidine (reduces acid production in the stomach).
- Neostigmine and pyridostigmine (for serious muscular weakness).
- Tacrolimus (in the case of organ transplants).
- Phenylbutazone (non-steroid anti-inflammatory).
- Hepatotoxic drugs.
- Drugs that may cause skin irritation or that may damage the liver or eyes.
- Bupropion (used to treat depression).
- Leflunomide (antirheumatic).

Taking Dolquine with food and drink

Dolquine is best taken with food or milk.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

Ask your doctor if you are pregnant or planning to have a baby. Your doctor will decide whether you can take Dolquine during that period.

Breast-feeding

Dolquine passes into mother's milk. Your doctor will decide whether you may take Dolquine during that period.

Driving and using machines

Do not drive or use any tools or machines until you know how this medicine affects you. Side effects such as dizziness and vision alterations have been known to occur.

3. HOW TO TAKE DOLQUINE

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dolquine is administered orally. Swallow the tablets without chewing, with meals or with a glass of milk (Dolquine tablets may be broken into smaller pieces in order to make swallowing easier, but not to divide a dose into two smaller doses).

The following are the normal doses:

Adults

Treatment of rheumatoid arthritis

- Starting dose: 2 - 3 tablets (400 - 600 mg) daily, depending on the patient's response to the medicine. If any adverse effects appear, the starting dose should be reduced, and then (5-10 days) increased gradually.
- Maintenance dose: once the desired response has been obtained (generally within 4-12 weeks), the patient will continue with a maintenance dose of 1-2 tablets (200-400 mg) daily.

The maximum daily dose for long-term treatment is 6.5 mg per kg of ideal body weight.

Treatment of lupus erythematosus

- Starting dose: 2 tablets (400 mg) daily or 1 tablet (200 mg) every 12 hours, depending on the patient's response.
  - Maintenance dose: 1-2 tablets (200-400 mg) daily.
- The maximum daily dose for long-term treatment is 6.5 mg per kg of ideal body weight.



## Prevention and treatment of uncomplicated malaria

Expert advice should be sought. Before commencing treatment, the species of plasmodium should be identified and its sensitivity determined by means of reliable tests.

**Prevention of uncomplicated malaria:** 2 tablets (400 mg) to be taken once weekly, always on the same day.

Prevention should commence 2 weeks before the first exposure and continue 4 weeks after leaving the endemic area. If prevention does not commence before exposure, a double initial dose may be taken (4 tablets), taking the tablets 2 by 2, 6 hours apart, and continuing as indicated above until 8 weeks after leaving the endemic area.

### Treatment of acute attacks of uncomplicated malaria:

First dose: 4 tablets (800 mg)

Second dose: 2 tablets (400 mg) 6 hours after the first dose.

Third dose: 2 tablets (400 mg) 24 hours after the first dose.

Fourth dose: 2 tablets (400 mg) 48 hours after the first dose.

The maximum total dose is 10 tablets (2000 mg).

**Children** (aged 9 to 11 years and with a body weight of over 31 kg and adolescents)

## Prevention and treatment of uncomplicated malaria

**Prevention of uncomplicated malaria:** 6.5 mg/kg ideal body weight once weekly, not exceeding the recommended adult dose.

Prevention should commence 2 weeks before first exposure and continue 4 weeks after leaving the endemic area. If prevention does not commence before exposure, a double initial dose may be taken, taking the tablets in two sessions, 6 hours apart, and continuing as indicated above until 8 weeks after leaving the endemic area.

### Treatment of acute attacks of uncomplicated malaria:

First dose: 13 mg/kg, not exceeding 4 tablets (800 g).

Second dose: 6.5 mg/kg, not exceeding 2 tablets (400 mg), 6 hours after the first dose.

Third dose: 6.5 mg/kg, not exceeding 2 tablets (400mg), 24 hours after the first dose.

Fourth dose: 6.5 mg/kg, not exceeding 2 tablets (400 mg), 48 hours after the first dose.

The maximum total dose for the complete treatment should not exceed 30 mg/kg ideal body weight not exceeding the recommended adult dose.

### Use in patients with liver or kidney problems:

If you have liver or kidney problems, your doctor will decide whether your dose should be adjusted.

### If you take more Dolquine than you should

If you take more than your recommended dose of Dolquine you may suffer from headache, sleepiness, vision disorders, circulatory collapse, convulsions and/or cardiac arrest.

Notify your doctor or pharmacist immediately or call the Toxicology Information Service (91 562 04 20), stating the medicine and quantity taken.

### If you forget to take Dolquine

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 Dolquine

Ask your doctor before suspending treatment.

If you forget to take several doses, consult your doctor, who will indicate a dose regime to be followed until the maintenance dose is reached.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

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

Side effects can occur at certain frequencies, as defined below:

**Common** (possibly affecting 1-10 per 100 patients)

- Headache.
- Problems in the cornea (a part of the eye), possibly causing blurred vision, halos, a reaction to bright lights and/or loss of visual acuity.
- Nausea, diarrhea, stomach pain, loss of appetite, vomiting.
- Weight-loss.

**Uncommon** (possibly affecting 1-10 per 1,000 patients)

- Mood changes; nervousness; seeing, feeling or hearing things that are not there (symptoms of psychosis).
- Convulsions, uncontrollable eye movements.
- Deafness, buzzing in the ears, dizziness (vertigo).
- Skin rashes.
- Changes in the colour of the skin and mucous membranes.
- Itchiness.



- Changes in hair colour (greying).
- Hairloss (alopecia).
- Skin rashes when exposed to sunlight.
- Muscular disease.

**Rare** (possibly affecting 1-10 per 10,000 patients)

- Insufficiency of the bone marrow (the tissue inside the bones that generates blood cells).
- Diseases of the retina (part of the eye), possibly leading to loss of vision.
- Disease of the heart muscle.
- Muscular weakness.

**Very rare** (possibly affecting fewer than 1 per 10,000 patients)

- Abnormal liver function, liver failure
- Psoriasis (a skin condition).

**Not known** (cannot be estimated from the available data)

- Low blood cell count (anaemia, leukopenia, thrombocytopenia), dissolution of red blood cells (in patients with glucose-6-phosphate dehydrogenase deficiency) and agranulocytosis (low white blood cell count).
- Nightmares.
- Difficulty in movement coordination.
- Paralysis of the extraocular muscles.
- Sudden difficulty breathing (bronchospasm) and respiratory insufficiency.
- Hives.
- Appearance or exacerbation of porphyria (genetic metabolic disorder).
- Irritability, fatigue.
- Loss of foveal reflex (a disorder of the retina (a part of the eye)).

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

## 5. HOW TO STORE DOLQUINE

Keep out of the reach and sight of children.

Do not use Dolquine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store below 30°C, in a dry place and with a body weight of over 35 kg and stable weight.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unwanted medicines and packaging. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Dolquine contains

- The active substance is hydroxychloroquine sulphate. Each coated tablet contains 200 mg hydroxychloroquine sulphate (equivalent to 155 mg hydroxychloroquine base).
- The other ingredients are:
  - microcrystalline cellulose (E400i),
  - calcium hydrogen phosphate,
  - crospovidone,
  - magnesium stearate (E470b).
- Coating: Opadry Y-1- 7000 White, which contains are: hypromellose (E464), macrogol and titanium dioxide (E171).

### What Dolquine looks like and contents of the pack

White, grooved, oval coated tablets.

Presented in packages of 30 and 60 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer:

LABORATORIOS RUBIÓ, S.A.

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**This leaflet was approved in October 2011**