

# Package leaflet: Information for the patient

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours. If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

## **MALCOVIR 200 mg film-coated tablets** *Hydroxychloroquine*

### **What is in this leaflet:**

1. What **Malcovir** is and what it is used for
2. What you need to know before you take **Malcovir**
3. How to take **Malcovir**
4. Possible side effects
5. How to store **Malcovir**
6. Contents of the pack and other information

### **1. What Malcovir is and what it is used for**

**Malcovir** contains hydroxychloroquine sulfate as an active substance. 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

### **2. What you need to know before you take Malcovir**

Do not take **Malcovir** if:

You are allergic (hypersensitive) to:

- Hydroxychloroquine, other similar medicines such as quinolones and quinine, any of the other ingredients of hydroxychloroquine sulfate (listed in section 6)

Signs of 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.

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 **Malcovir**.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking **Malcovir** if:

- You have liver or kidney problems.
- You have serious stomach or gut problems.
- You have heart problems.
- You have any problems with your blood. You may have blood tests 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.

### **Before treatment with Malcovir**

Before you take this medicine you should have your eyes examined. This testing should be repeated at least every 12 months whilst taking **Malcovir**.

If you are over 65, need to take a high dose (2 tablets a day) or have kidney problems then this examination should be performed more often. **Malcovir** can cause lowering of blood glucose level. Please ask your doctor to inform you of signs 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 **Malcovir**.

### **Other medicines and Malcovir**

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

- 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 kidneys 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 **Malcovir** works or **Malcovir** 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.
- Cyclosporin – 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**

Use of this medicine is not recommended during pregnancy. If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to re-assess the need or treatment.

Do not take **Malcovir** if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mother's milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

### **Driving and using machines**

You may get eye problems while taking this medicine. If this happens, do not drive or use any tools or machines, and tell your doctor straight away.

### **Malcovir contains lactose**

If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking **Malcovir**.

### **3. How to take Malcovir**

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

##### **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

31 kg (around 5 stones).

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

#### **If you take more Malcovir than you should**

If you take more **Malcovir** 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 **Malcovir**. Take the child to hospital straight away.

#### **If you forget to take Malcovir**

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 Malcovir**

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

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

#### **4. Possible side effects**

Like all medicines, **Malcovir** can cause side effects, although not everybody gets them. Stop taking **Malcovir** and see a doctor or go to a hospital straight away if:

##### **Not known (frequency cannot be estimated from available data)**

- You have an allergic reaction. The signs may include: a red or lumpy rash, swallowing or breathing problems, swelling of the 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 **Malcovir** and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:*

##### **Common side effects (may affect less than 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 side effects (may affect less than 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.

##### **Not known (frequency cannot be estimated from available data)**

- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leucopenia' or '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'.

- Weakening of the heart muscle (cardiomyopathy) resulting in difficulty breathing, coughing, high blood pressure, swelling, increased heart rate, low amount of urine.

- Low blood sugar levels (hypoglycaemia). You may feel a sense of nervousness, shaky or sweaty.

- You notice yellowing or your skin or your eyes or your urine becomes darker in colour. This could be a liver problem, such as jaundice or hepatitis.

- Fits.

- Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue.

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

##### **Very common side effects (may affect more than 1 in 10 people)**

- Stomach pain

- Feeling sick

##### **Common side effects (may affect less than 1 in 10 people)**

- Skin rashes, itching

- Being sick, diarrhoea

- Loss of appetite (anorexia)

- Headache

- Changes in mood with uncontrollable laughing or crying

##### **Uncommon side effects (may affect less than 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

##### **Not known (frequency cannot be estimated from available data)**

- Psoriasis (red scaly patches on the skin usually affecting the knees, elbows and scalp)

- Hearing loss

- Mental problems (such as delusions, hallucinations and changes in mood)

- Symptoms of a condition called 'porphyria' which may include stomach pain, being sick, fits, blisters, itching

##### **Tests**

Your doctor may monitor:

- Your heart's electrical activity using an ECG (electrocardiogram) machine.

- Your muscle function and tendon reflexes.

- The levels of specific cells in your blood using occasional blood tests. A blood test may also show changes in the way the liver is working and occasionally the liver may stop working.

##### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Malcovir**

Do not store above 30°C. Store in the original package. Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Contents of the pack and other information**

##### **What Malcovir contains**

Each film-coated tablet contains 200 mg of the active substance, hydroxychloroquine sulfate.

##### **The other ingredients:**

**Tablet core:** lactose monohydrate, pregelatinized starch, povidone, silica, colloidal anhydrous, magnesium stearate.

**Film:** Hypromellose, titanium dioxide, polydextrose, talc, maltodextrin, medium chain triglyceride.

##### **What Malcovir looks like and contents of the pack**

**Malcovir** 200 mg film-coated tablets are white, rounded film-coated tablets

Box containing 30 (3 x 10) film-coated tablets in blister pack.

##### **Marketing Authorisation Holder and Manufacturer**

ZADA Pharmaceuticals Ltd.

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