

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Macladin<sup>®</sup>**  
500mg film-coated tablets  
Clarithromycin

**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 further questions, ask your doctor or your 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 you get any side effects, please talk to your doctor, or pharmacist or other healthcare professional or directly to the National Medicines Agency (Mesogion 284, 15562, Chologos, [www.eof.gr](http://www.eof.gr)).

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**1. WHAT MACLADIN<sup>®</sup> IS AND WHAT IS USED FOR**

Antibiotic: Clarithromycin belongs to a group of antibiotics called macrolides.

**Macladin<sup>®</sup>** is used for the treatment of infections due to susceptible to clarithromycin microorganisms. Such infections include:

- Lower respiratory tract infections (e.g. bronchitis and pneumonia).
- Upper respiratory tract infections (e.g. pharyngitis, sinusitis).
- Skin and soft tissue infections (e.g. folliculitis, cellulitis, erysipelas).
- Complementary therapy (in combination with other anti-tuberculosis medicines) for the treatment of generalized or localized infections due to atypical mycobacteria (e.g. *Mycobacterium avium* or *Mycobacterium intracellulare*, *Mycobacterium chelonae*, *Mycobacterium fortuitum* and *Mycobacterium kansasii*).
- Eradication of *Helicobacter pylori* to treat duodenal ulcers and prevent relapses when combined with inhibitors of gastric secretion.
- Treatment of dental infections as a second line therapy.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MACLADIN<sup>®</sup>****Do not take Macladin<sup>®</sup> if**

- You are allergic (hypersensitive) to clarithromycin or other macrolide antibiotics or any of the other ingredients of **Macladin<sup>®</sup>**.
- You are taking medicines that contain astemizole, cisapride, pimozone, terfenadine and ergotamine or dihydroergotamine.

**Take special care with Macladin<sup>®</sup>**

- If you have renal failure
- If you are pregnant or breast-feeding
- If you have liver disease

- If you feel dizzy during treatment with **Macladin**<sup>®</sup>, caution is needed as this dizziness may affect your ability to drive or operate machines.
- If you have hypokalemia
- In case of persistent diarrhea
- In case of co-administration of colchicine
- In case of a severe and persistent infection
- In case the symptoms of severe myasthenia worsens

### **Taking other medicines**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those that you purchase without medicinal prescription.

Below are mentioned interactions related to CYP3A isoenzyme, which have been reported with erythromycin and/or clarithromycin post-marketing.

Inform your doctor if you are taking medicines that contain theophylline, valproic acid, carbamazepine, cilostazol, cisapride, digoxin, colchicine, oral anticoagulants (e.g. warfarin), ergotamine or dihydroergotamine derivatives, triazolam, midazolam, alprazolam, methylprednisolone, disopyramide, phenytoin, astemizole, terfenadine, tacrolimus, cyclosporine, pimozone, quinidine, rifabutin, sildenafil, tadalafil, vardenafil, tolterodine, lovastatin, simvastatin, omeprazole, vinblastine, efavirenz, nevirapine, rifampicin, rifabutin, rifapentin, fluconazole, atazanavir, itraconazole & saquinavir. It is possible that adjustments to the dosages of the mentioned medicines might be required during treatment with clarithromycin (see section take special care with **Macladin**<sup>®</sup>).

If you have kidney failure and you take as treatment ritonavir, you should inform your doctor as it might be needed to receive a reduced dosage of clarithromycin.

In adult patients that receive treatment with zidovudine in co-administration with **Macladin**<sup>®</sup>, these two medicines should be taken at different times.

### **Taking Macladin<sup>®</sup> with food and drink**

**Macladin**<sup>®</sup> may be taken with or without food.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before you take any medicine.

### **Driving and using machines**

If you feel dizzy during treatment with **Macladin**<sup>®</sup>, caution is needed as this dizziness may affect your ability to drive or operate machines.

## **3. HOW TO TAKE MACLADIN<sup>®</sup>**

Always take **Macladin**<sup>®</sup> exactly as your doctor has prescribed. If you have doubts you should ask your doctor or pharmacist.

### ***For all infections that clarithromycin is indicated for and are not listed below:***

Usual recommended dose is 250 mg twice a day. For more severe infections the dosage may be increased to 500 mg twice a day. Duration of the treatment is for 6 to 14 days. Doses should be taken in the morning and in the evening.

If you have renal impairment, **Macladin**<sup>®</sup> dose should be reduced to half, i.e. 250 mg once daily or 250mg twice daily for severe infections. Duration of the treatment should not exceed 14 days.

Film-coated tablets of 500 mg should not be administered to children younger than 12 years.

### ***Infections caused by mycobacteria***

Clarithromycin can be used in combination with other anti-mycobacterial medicines.

For generalized or localized infection caused by mycobacteria (*M. avium*, *M. intracellulare*, *M. chelonae*, *M. fortuitum*) the recommended dose is 500 mg twice a day. Treatment continues as long as clinical improvement is maintained. Doses should be taken in the morning and in the evening

### ***Eradication of Helicobacter pylori***

#### **Triple treatment regiment**

**Macladin**<sup>®</sup> 500 mg twice a day, in combination with amoxicillin 1000 mg twice a day and omeprazole 20 mg twice a day for 7 days.

**Macladin**<sup>®</sup> 500 mg twice a day, in combination with amoxicillin 1000 mg twice a day and omeprazole 40 mg twice a day for 7 days.

#### **Double treatment regiment**

Recommended dose is 500 mg three times a day for 14 days, in combination with gastric secretion inhibitors.

#### **Dental infections**

250 mg twice a day for 5 days.

Your doctor will decide which treatment combination is suitable for you.

Even if your health condition has improved before the end of the recommended treatment, do not stop the administration of the medicine. Continue the treatment for all the days that your doctor has recommended.

#### **If you take more Macladin<sup>®</sup> than you should**

Reports indicate that following excess ingestion of clarithromycin may lead to gastrointestinal symptoms. Adverse events that are related to overdose should be managed via gastric lavage and supportive measures.

In such cases, inform your doctor or the Poison Center of Athens Tel.:+30 210 7793 777.

#### **If you forget to take Macladin<sup>®</sup>**

If you forget to take a dose, take it as soon as you remember and continue with your next dose as instructed by your doctor. Do not take a double dose to make up for a forgotten dose.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, **Macladin**<sup>®</sup> may cause side effects, although not everybody gets them.

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

Common side effects of this medicine are: diarrhea, vomiting, abdominal pain, nausea, indigestion, skin rashes, headache or taste alterations.

Post marketing experience report the below listed side effects:

- mouth candidiasis
- Leucopenia, thrombocytopenia
- anaphylactic reaction, hypersensitivity
- hypoglycemia
- psychotic disorder, hallucinations, disorientation, confusional state, depersonalization, depression, anxiety, insomnia, abnormal dreams
- convulsions, dizziness, lack of taste, anosmia, dysgeusia, parosmia
- deafness, vertigo, tinnitus
- Torsades de pointes, QT prolongation, ventricular tachycardia
- acute pancreatitis, glossitis, stomatitis, discoloration of the tongue, dental discoloration
- Liver failure, hepatitis, liver cholestasis, cholestatic jaundice, hepatocellular jaundice, abnormal liver function
- Stevens-Johnson syndrome, toxic epidermal necrosis, urticaria , rash

- interstitial nephritis
- increased plasma levels of creatinine, increased levels of liver enzymes

When clarithromycin is co-administered with omeprazole, sometimes reversible discoloration of the tongue and taste alterations may be observed.

**There are post-marketing reports on colchicine toxicity, when co-administered with clarithromycin, especially in elderly, some of which occurred in patients with renal insufficiency. Some patients were reported dead.**

#### **Side effects to immunosuppressed patients**

Patients with mycobacterial infections receiving **Macladin**<sup>®</sup>, for long intervals should be closely monitored on their clinical condition as well as their lab exam results.

If any reaction occurs during treatment, you should inform your doctor.

If you get any side effect, talk to your doctor or pharmacist or any other health care professional or directly to the National Drug Organization (284 Mesogeion Av., 15562, Cholargos, Greece [www.eof.gr](http://www.eof.gr)).

### **5. HOW TO STORE MACLADIN<sup>®</sup>**

Keep out of reach and sight of children.

Store at room temperature.

Do not use **Macladin**<sup>®</sup> after the expiry date that is mentioned on the container.

Expiry date refers to the last day of the month mentioned.

Do not throw away any medicine via wastewater 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 Macladin<sup>®</sup> contains**

- Active ingredient is: Clarithromycin.
- Other ingredients are: Crosscarmellose sodium, Cellulose microcrystalline (Avicel PH 102), Silicon dioxide, Povidone (K value 29-32), Stearic acid, Magnesium stearate, Talc. Film-coating: Hydroxypropylmethylcellulose 2910, Titanium dioxide E 171, CI 77891, Hydroxypropylcellulose, Propylene glycol, Sorbitan monooleate, Sorbic acid, Vanillin, Quinoline yellow aluminium lake E 104, CI 47005.

#### **Nature and content of the container of Macladin<sup>®</sup>**

Carton containing 14 or 21 film-coated tablets and a leaflet.

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**Manufacturer:** Pharmaceutical industry PROEL EPAM. G. KORONIS S.A, 9 Dilou st. 12134, Athens, Greece

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