**Patient Information Leaflet**

MACROLYN**®**

Azithromycin 500 mg Film-Coated Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you notice side effects not mentioned in this leaflet, it is advised to notify the doctor or healthcare professional. Do not pass this medicine on to others.

1. **What is Macrolyn® and what it is used for**

Macrolyn® contains the active substance azithromycin, which is a macrolide antibiotic (ATC code: J01FA10).

Macrolyn® is used in the treatment of certain infections caused by bacteria and other micro-organisms that are sensitive to it, such as:

* chest infections (such as bronchitis, pneumonia),
* throat or nasal infections (such as tonsillitis, sore throat and sinusitis),
* ear infections,
* skin and soft tissue infections,
* sexually transmitted, uncomplicated genital infections in males and females due to Chlamydia trachomatis or to Neisseria gonorrhoeae (however concurrent infection with Treponema pallidum should be excluded).

1. **What you need to know before you take Macrolyn®**

***Do not take Macrolyn® if you are***

* allergic to azithromycin or to any other macrolide antibiotic such erythromycin or clarithromycin,
* allergic to any of the other ingredients of this medicine (listed in section 6).

***Warnings and precautions***

***Talk to your doctor before taking Macrolyn®***

* if you have severe liver or kidney problems,
* if you develop signs of another infection,
* If you develop diarrhoea or loose stools during or after treatment, tell your doctor at once; do not take any medicine to treat your diarrhoea without first checking with your doctor; if your diarrhoea continues, please inform your doctor,
* If you have severe heart problems or problems with your heart beat such as long QT syndrome (shown on an electro-cardiogram or ECG machine),
* immediately if you feel your heart beating in your chest or have an abnormal heartbeat, or get dizzy or faint or suffer from any muscle weakness when taking Macrolyn®,
* if you are taking any ergot derivatives such as ergotamine (to treat migraine) as these medicines should not be taken together with Macrolyn®,
* if you have a certain type of muscle weakness called myasthenia gravis.

***Other medicines and Macrolyn®***

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, Macrolyn® may interact with the medicines listed below:

* antacids (for heartburn and indigestion): Macrolyn® should be taken at least 1 hour before or 2 hours after the antacid,
* digoxin (to treat heart failure),
* terfenadine (for hay fever or a skin allergy),
* zidovudine or nelfinavir (to treat HIV infections),
* ergotamine (for migraine) should not be taken at the same time as serious side effects may develop (with numbness or tingling sensations in the limbs, muscle cramps, headaches, convulsions, abdominal or chest pain),
* cholesterol lowering medicines (statins),
* warfarin or any similar medicine to prevent blood clots,
* nelfinavir,
* cyclosporine (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow): if co-administration is necessary, your doctor will regularly check your blood levels of cyclosporine,
* theophylline (for breathing problems such as asthma and chronic obstructive pulmonary disease (COPD),
* rifabutin (to treat tuberculosis),
* quinidine (to treat heart rhythm problems).

***Pregnancy, breast-feeding and fertility***

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

***Driving and using machines***

Macrolyn® is not expected to affect your ability to drive or use machines.

1. **How to take Macrolyn®**

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

The dosage for treatment of sexually transmitted diseases due to Chlamydia trachomatis, Haemophilus ducreyi or susceptible Neisseria gonorrhoeae is 1000 mg as a single oral dose.

The dosage for treatment of tonsillitis/pharyngitis due to S.pyogenes, is 500 mg on day 1 and 250 mg daily on days 2 through 5, the duration of therapy is 5 days.

For all other indications, total dosage is 1500 mg, taken as 500 mg daily for 3 days.

Children and adolescents under 45 kg should use other forms of this medicine.

Macrolyn® should be given as a single daily dose. The tablets should be taken with ½ glass of water. Macrolyn® can be taken 1 hour before or 2 hours after meals.

Always continue with the course even if you feel better. If your infection gets worse or you do not start to feel better within a few days or a new infection develops, go back and see your doctor.

***If you take more Macrolyn® than the prescribed dose***, get medical help immediately. If possible, take your tablets or the box with you to show the doctor.

***If you forget to take Macrolyn®****,* take the normal dose as soon as possible and then continue as prescribed. However, if it is almost time for your next dose, do not take a double dose to make up for a forgotten dose. If you forget a dose, still take all of your tablets. This means that you will finish your course a day later.

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

1. **Possible side effects**

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

**Tell your doctor immediately if you experience any of the following symptoms after taking Macrolyn® as the symptoms can be severe:**

* sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body),
* severe or prolonged diarrhoea, which may have blood or mucus in it, during or after treatment with Macrolyn® as this may be a sign of serious bowel inflammation,
* severe skin rash causing redness and flaking,
* rapid or irregular heartbeat,
* low blood pressure.

The most common side effects that occur when taking Macrolyn® are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

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

* stomach cramps, feeling sick, diarrhoea, wind.

**Common side effects** (may affect up to 1 in 10 people):

* loss of appetite, taste disturbance,
* dizziness, headache,
* numbness or pins and needles,
* visual disturbances, deafness,
* being sick, indigestion,
* skin rash and /or itching,
* joint pain,
* tiredness or weakness,
* low numbers of lymphocytes (type of white blood cells), higher number of eosinophils (type of white blood cells),
* low blood bicarbonate.

**Uncommon side effects** (may affect up **to** 1 in 100 people):

* yeast infections of the mouth and vagina (thrush),
* low numbers of leukocytes (type of white blood cells), low number of neutrophils (type of white blood cells),
* sleepiness or sleeplessness,
* allergic reactions of various severity,
* blistering of the skin, mouth, eyes and genitals,
* skin more sensitive to sunlight than normal,
* heart palpitations, chest pain,
* constipation, stomach pain associated with diarrhoea and fever,
* feeling nervous,
* reduced sense of touch or sensation,
* poor hearing or ringing in the ears,
* inflammation of the liver (hepatitis), changes in liver enzymes,
* swelling of the hands, feet, lips, genitals or throat,
* general discomfort,
* general loss of strength,
* abnormal laboratory test values (e.g. blood or liver tests).

**Rare side effects** (may affect up to 1 in 1,000 people):

* agitation,
* dizziness,
* abnormal in liver function.

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

* fits or fainting,
* aggression or anxiety,
* feeling hyperactive,
* localized muscle weakness,
* loss of smell or altered sense of smell, loss of taste,
* tongue discoloration,<
* inflammation of the pancreas (pancreatitis),
* inflammation of the kidney or kidney failure,
* yellowing of the skin or eyes (jaundice) or liver failure (rarely life-threatening),
* bruising or prolonged bleeding after injury,
* blistering of the skin, severe skin reaction,
* abnormal electrocardiogram (ECG),
* low blood pressure.

1. **How to store Macrolyn®:** Store below 30°C, in the original package. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.
2. **Other information**

***What Macrolyn® contains:***Active Substance: each tablet containsazithromycin dihydrate equivalent to 500 mg azithromycin. Other ingredients: Sodium laurilsulfate, Magnesium stearate, Microcrystalline cellulose, Carmellose sodium, Anhydrous calcium hydrogen phosphate. The coating contains titanium dioxide (E171).

**Macrolyn®** is presented as a white, film-coated, oblong tablet with “AZITRO” engraved on one side.

**Macrolyn®** is a prescription only medicine.

Name of Manufacturer: DEVA HOLDING A.Ş. Çerkezköy Organize Sanayi Bölgesi, Karaağaç Mah, Atatürk Cad., No: 32 Kapakli-Tekirdağ, Turkey.

Registration/Licence Holder: Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

**Date of Revision of This Text:** April 2019.