Macrolyn®

azithromycin

Upper & lower respiratory tract infections - Acute otitis media -
Skin and soft tissue Infections - Soft tissue ulcers -
Sexually transmitted, uncomplicated genital infections
in males and females

ADULTS	
Treatment of sexually transmitted diseases	1000 mg as a single oral dose
Treatment of tonsillitis/pharyngitis due to S.pyogenes	500 mg on day 1 250 mg 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 (> 45 kg)	
Adult doses are administered. Recommended total dosage is 1500 mg which is spread over 3 days (500 mg once daily).	
MACROLYN® should be given as a single daily dose. **MACROLYN®** tablets can be taken 1 hour before or 2 hours after meals.	

DAFRA PHARMA INTERNATIONAL

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3FIMACE 2021

Dafra PHARMA

Setting the Standard

www.dafrapharma.com

Macrolyn®

azithromycin

EUROPEAN GMP

Upper & lower respiratory tract infections
Acute otitis media
Skin and soft tissue infections
Soft tissue ulcers
Sexually transmitted, uncomplicated genital infections

EFFICACY IN ONLY 3 DAYS OF TREATMENT

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azithromycin

PRESENTATION

3 film-coated tablets. Each tablet contains azithromycin dihydrate equivalent to 500 mg azithromycin. Excipients: Sodium laurilsulfate, Magnesium stearate, Microcrystalline cellulose, Carmellose sodium, Anhydrous calcium hydrogen phosphate. The coating contains titanium dioxide (E171).

INDICATIONS

MACROLYN® is suitable for the treatment of:

- ✓ Upper & lower respiratory tract infections
- ✓ Skin and soft tissue infections
- ✓ Acute otitis media
- ✓ Soft tissue ulcers
- ✓ Sexually transmitted, uncomplicated genital infections in males and females

DOSAGE

MACROLYN® should be given as a single daily dose. Method of administration: For oral use. **MACROLYN®** tablets can be taken 1 hour before or 2 hours after meals.

Adults:

Treatment of sexually transmitted diseases: 1000 mg as a single oral dose.

Treatment of tonsillitis/pharyngitis due to S.pyogenes: 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.

Renal impairment: No dosage adjustment is recommended for subjects with mild to moderate renal impairment. Caution is needed with severe renal impairment.

Hepatic impairment: Same doses may be administered to patients with mild to moderate hepatic impairment, it should not be used in patients with severe hepatic impairment.

Pediatric population: For pediatric patients weighing over 45 kg, adult doses are administered. For indications except tonsillitis/pharyngitis, the recommended total dosage is 1500 mg which is spread over 3 days (500 mg once daily).

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.

Efficacy and safety of azithromycin have not been established for infants younger than 6 months of age, therefore its use is not recommended for infants younger than 6 months of age.

Geriatric population: Adult doses are administered in the elderly patients.

CONTRAINDICATIONS

Known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic or any of the excipients.

WARNINGS AND PRECAUTIONS

- ✓ Rare serious allergic reactions: angioneurotic oedema, anaphylaxis, Stevens Johnson Syndrome and toxic epidermal necrolysis.

- ✓ Despite initially successful symptomatic treatment of the allergic symptoms, when symptomatic therapy was discontinued, the allergic symptoms recurred soon thereafter in some patients without further azithromycin exposure.
- ✓ Diarrhoea has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. It has been reported to occur over two months after the administration of antibacterial agents.
- ✓ Exacerbations of symptoms and new onset of myasthenic syndrome are possible.
- ✓ QT interval prolongation has been seen in treatment with macrolides, including azithromycin.
- ✓ Gastrointestinal disturbances: In subjects with a GFR < 10 ml/min, a higher incidence of gastrointestinal adverse events was observed.
- ✓ Development of drug resistant bacteria: Prescribing **MACROLYN®** in the absence of a proven or strongly suspected bacterial infection increases the risk of the development of drug-resistant bacteria.
- ✓ Sodium content: Each **MACROLYN®** tablet contains sodium less than 1 mmol (23 mg); sodium-related side effect is not expected at this dose.

PREGNANCY AND LACTATION

Pregnancy category: B.

Women with child-bearing potential: appropriate contraceptive methods should be used in women planning to get pregnant or being uncertain about pregnancy while using this drug.

Pregnancy: azithromycin should be used during pregnancy only if clearly needed.

Lactation: a decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with **MACROLYN®** should be made taking into account the benefit of breast-feeding to the child and the benefit of **MACROLYN®** therapy to the woman.

COMMON SIDE EFFECTS

MACROLYN® is well tolerated with a low incidence of side effects. Very common: diarrhea, abdominal pain, nausea, flatulence. Common: anorexia, drowsiness, headache, paresthesia, dysgeusia, visual impairment, deafness, vomiting, dyspepsia, pruritus, rash, arthralgia, fatigue, decreased lymphocyte count, increased eosinophil count, decreased blood bicarbonate. Uncommon: candidiasis, oral candidiasis, vaginal infection, leukopenia, neutropenia, angioedema, hypersensitivity, nervousness, hypo-esthesia, somnolence, insomnia, hearing impaired, tinnitus; palpitation, gastritis, constipation, hepatitis, Stevens Johnson Syndrome, photosensitivity reactions, urticarial edema, chest pain, malaise, asthenia; increased aspartate aminotransferase, increased alanine aminotransferase, increased blood bilirubin, increased blood urea, increased blood creatinine, abnormal blood potassium. IN CASE OF AN UNEXPECTED SIDE EFFECT, CONSULT YOUR PHYSICIAN.

OVERDOSE

Adverse events experienced in higher doses than recommended doses were similar to those seen at normal doses. The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhea. In the event of overdose, the administration of medical charcoal and general symptomatic and supportive treatment is indicated as required.

PHARMACOLOGICAL PROPERTIES:

Pharmacotherapeutic group: Antibacterials for systemic use (ATC code: J01FA10). Azithromycin is a macrolide antibiotic belonging to the azalide group.

PHARMACEUTICAL PARTICULARS

Special precautions for storage: Store below 30°C in the original package. Keep out of reach and sight of children.

Shelf life: 3 years.

Legal categories: by prescription only.

For the complete SMPC, please visit www.dafrapharma.com