包材名称	交沙霉素片说明书
包材代码	112008868
尺寸	130*190mm
材质	70g书写纸
备注	通用
修改内容	1.根据中国药典2020版修改执行标准；2.增加药品上市许可持有人信息；3.更新包装材质描述；4.更新联系电话。

包装设计稿 生效日期：2020年11月04日	分发部门	彩色稿： QA、QC 复印稿： OSD、PD、LD
设计：李艳秀 复核： 审核： 批准：		

色标

CMYK:0/0/0/100

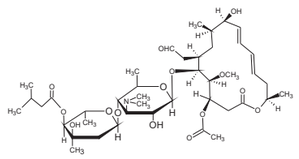
CMYK:0/0/0/40

Date of approval:2007.06.04
Date of modification: 2009.06.08
2010.08.23
2012.08.14
2015.05.05
2015.11.11
2020.10.26

LEAFLET FOR JOSAMYCIN TABLETS

Please read the leaflet carefully and use under the guidance of a physician

[DRUG NAME]
Common name: Josamycin Tablets
English name: Josamycin Tablets
Chinese Pinyin: Jiaoshameisu Pian
[INGREDIENTS] The active pharmaceutical ingredient of this product is Josamycin.
Chemical structure:



Molecular formula: $C_{42}H_{69}O_{15}$
Molecular weight: 827.99
[DESCRIPTION] The product is sugar-coated tablet, the color is white or almost white after removing the coating.
[INDICATION] The product is suitable for pharyngitis and tonsillitis caused by Streptococcus pyogenes, nasosinusitis caused by sensitive bacteria, otitis media, acute bronchitis and oral abscess, pneumonia caused by mycoplasma pneumoniae, skin and soft tissue infection caused by sensitive bacteria, and can also be used for penicillin, erythromycin resistant staphylococcus infection.
[STRENGTH] 0.2g (200,000 units)
[USAGE AND DOSAGE]
For adults, 0.8~1.2g (4~6 tablets) per day, more severe infection can increase to 1.6g (8 tablets) per day;
For child, 30mg/kg per day according to body weight.
Take it evenly 3 to 4 times (1 hour before meals or 3 to 4 hours after meals).
[ADVERSE REACTION]
1. Gastrointestinal adverse reactions occasionally included diarrhea, nausea, vomiting, middle and upper abdominal pain, mouth and tongue pain, loss of appetite, abdominal discomfort, stomatitis, etc. The incidence is related to the dosage size.
2. Occasional liver dysfunction and jaundice, usually presents with, but is not limited to cholestasis reaction associated with moderate hepatic impairment.
3. Large doses of this product, especially in patients with liver and kidney diseases or elderly patients, may cause hearing loss, most of which can be recovered after withdrawal.
4. Occasionally allergic reactions, manifested as drug fever, rash, eosinophilia, etc.
5. Others: Occasionally arrhythmia, oral candida infection, vaginal candida infection, pseudomembranous colitis, facial edema, angioedema, bullous dermatitis, erythema multiforme, purpura, Stevens-Johnson syndrome, toxic epidermal necrolysis, or urticaria occur.
[CONTRAINDICATION]
1. People who are allergic to this product, erythromycin or other macrolide antibiotics should not be allowed to use.
2. Patients with hepatosis.
[CAUTIONS]
1. Patients who are allergic or intolerant to one of the macrolides (such as erythromycin) may also be allergic or intolerant to other macrolides (such as this product).
2. Patients with hemolytic streptococcus infection should be treated with this product for at least 10 days to prevent occurrence of acute rheumatic fever.
3. Patients with renal dysfunction generally do not need to reduce the dosage.
4. It is advisable to follow up liver function regularly during the administration of this product.
5. Interference to laboratory test indicators: This product can interfere with the Higerty method fluorescence determination, so that the urinary catecholamine determination value appears false increase. Serum alkaline phosphatase, bilirubin, alanine aminotransferase and aspartate aminotransferase may be increased.
6. Because the sensitivity of different bacteria to this product has certain differences, it is appropriate to test drug sensitivity.
7. Some patients treated with Josamycin have reported severe skin adverse reactions, such as toxic epidermal necrolysis and Stevens-Johnson syndrome. When severe skin adverse reactions occur, Josamycin should be discontinued and appropriate treatment and/or measures taken.
8. Concomitant administration of Josamycin with antihistamines containing terfenadine or astemizole must be taken with caution, as this may cause delayed excretion of these drugs, which may lead to severe arrhythmias.
9. Cross-resistance may occur with other macrolide antibiotics.
[MEDICATION FOR PREGNANT AND LACTATING WOMEN]
1. Because this product can pass the blood-placental barrier, although it is not detected in newborn and fetal blood, pregnant women should weigh the advantages and disadvantages when taking this product.
2. Because this product can enter breast milk, lactating women should stop breastfeeding when taking it during lactation.
[Drug use in children] Not clear.
[Drug use in the elderly] Large doses of this product may cause hearing loss in elderly patients, but most of them can recover after withdrawal.
[DRUG INTERACTION]
1. The combination of this product with penicillins may interfere with the latter's bactericidal activity.
2. Josamycin may interact with antihistamines containing terfenadine or astemizole (see [Cautions]).
3. There have been reports that Josamycin can increase serum theophylline levels in children. Theophylline levels may increase due to prolonged half-life. If theophylline toxicity occurs, the dosage of theophylline should be adjusted appropriately according to the serum concentration of theophylline.
4. Simultaneous use of ergot alkaloids may result in increased vasoconstriction. Concurrent use of ergot alkaloids should be avoided, and if peripheral signs and symptoms of ergotism are present, the drug should be discontinued and appropriate treatment provided, such as local heating and the use of vasodilators.
5. Simultaneous administration of Josamycin and cyclosporin/tacrolimus may cause blood concentrations of cyclosporin/tacrolimus to rise to levels that can cause renal injury. Plasma concentrations of cyclosporin/tacrolimus should be monitored regularly.
6. Josamycin may enhance the effect of triazolam and cause drowsiness. If triazolam overdose occurs, temporary discontinuation is recommended.
7. Josamycin can enhance the effect of bromocriptine mesylate and cause drowsiness, dizziness, ataxia, etc. If bromocriptine mesylate poisoning occurs, temporary discontinuation is recommended.
8. Josamycin can increase the effect of oral anticoagulants, such as warfarin and its derivative vitamin K antagonists. Josamycin reduces the production of vitamin K by gut bacteria. If bleeding occurs, it is recommended to discontinue Josamycin and/or oral anticoagulants and to give vitamin K depending on the severity of the bleeding or the degree of coagulation based on prothrombin time or international normalized ratios.
[OVERDOSE]
Excessive Josamycin can cause gastrointestinal disorders, such as nausea and diarrhea, and should be treated appropriately.
[PHARMACOLOGY AND TOXICOLOGY]
This product is a macrolide antibiotic produced by Streptomyces narbonensis var. Josamyceticus. Its antibacterial spectrum is similar to erythromycin, but it still has antibacterial activity against induced drug-resistant strains. Neisseria meningitidis and Pertussis bacillus are sensitive to this product. It has good antibacterial effect on Peptococcus, Peptostreptococcus, Propionibacterium, Eubacterium and other anaerobic bacteria. Intracellular pathogens such as Mycoplasma, Chlamydia, Legionella are also sensitive to this product. This product does not induce resistance of Staphylococcus to macrolides, and is a non-inductive antibiotic.
[PHARMACOKINETICS]
The product is quickly absorbed by mouth, fast and wide distribution in the body, and high concentration in organs and tissues. 0.75~1 hour after taking this medicine 1g orally, the peak plasma concentration (Cmax) will reach to 2.7-3.2mg /L, and concentrations in aqueous humor and prostate were 0.4mg/L and 4.3mg/kg respectively. After taking 500mg, the concentration in urine, bone, gum, tonsil, etc., can reach 0.43~13.7mg/L(kg); High concentration in bile and lung; The concentration in phagocytic cells is 20 times than that of serum.
After taking this product, the drug concentration in sputum for 2 to 6 hours was 8 to 9 times than the blood concentration, the drug concentration in breast milk was 1/3 to 1/4 of the blood concentration, and the drug concentration in cord blood and amniotic fluid was 1/2 of the blood concentration, but it could not be detected in newborn and fetal blood. It can't pass through the blood-cerebrospinal fluid barrier. It is mainly excreted by metabolites from bile, urine excretion is less than 20%, and blood elimination half-life (t1/2) is 1.5~1.7 hours.
[STORAGE] Stored in tightly closed containers, place in a dry place.
[PACKAGING] Pharmaceutical aluminum foil + polyvinyl chloride solid pharmaceutical hard sheet packaging, 12 tablets/blister/box, 12 tablets/blister ×2 blisters/box.
[VALIDITY PERIOD] 36 months
[MANUFACTURER]
Company Name: Guilin Pharmaceutical Co., Ltd.
Address: No.43 Qilidian Road, Guilin, Guangxi, China
Tel：0773-3675101、0773-3675535

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