OXACILLIN

FOR INJECTION USP 1 gm

For IM / IV use

10 Vials

Prescription only medicine

OXACILLIN

FOR INJECTION USP 1 gm

For IM / IV use

SWISS™

Composition :
Each vial contains :
Oxacillin Sodium USP
Equivalent to Oxacillin 1 gm
(As Sterile Oxacillin Sodium Buffered)

Dosage : AS DIRECTED BY THE PHYSICIAN.

Storage :
Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Please refer pack insert for complete information on dosage and administration.

10 Vials

Prescription only medicine

OXACILLIN

FOR INJECTION USP 1 gm

For IM / IV use

SWISS™

Use the reconstituted solution immediately after use.

Discard any unused portion immediately after use.

Batch No. :
Mfg. Date :
Exp. Date :

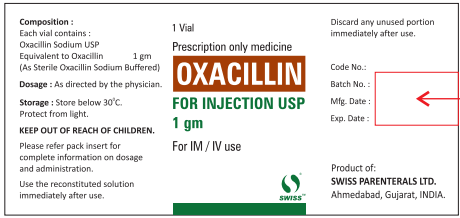
Space for Batch Details
Size : 29 x 14 mm

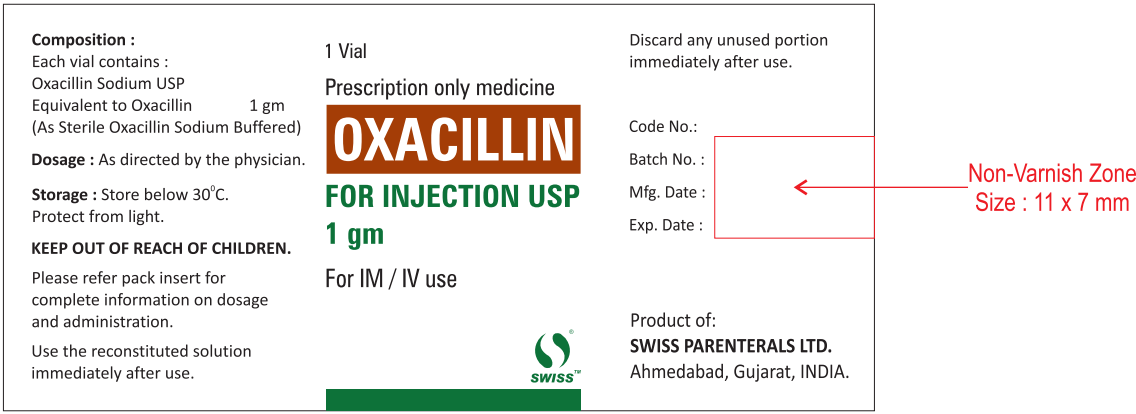
Product of:
SWISS PARENTERALS LTD.
Ahmedabad, Gujarat, INDIA.

Code No.:

Non Varnish Zone
For
2D Barcode
(Global Trade Item Number)
(Compulsory)

128 53 60





Enlarge Size

Prescription only medicine

OXACILLIN For Injection USP 1gm

(For IM / IV use)

Composition :
Each Vial contains:
Oxacillin Sodium USP
Equivalent to Oxacillin 1 gm
(As Sterile Oxacillin Sodium Buffered)

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

Oxacillin is indicated in the treatment of infections caused by penicillinase producing staphylococci which have demonstrated susceptibility to the drug. Cultures and susceptibility tests should be performed initially to determine the causative organism and its susceptibility to the drug.
Oxacillin may be used to initiate therapy in suspected cases of resistant staphylococcal infections prior to the availability of susceptibility test results. Oxacillin should not be used in infections caused by organisms susceptible to penicillin G. If the susceptibility tests indicate that the infection is due to an organism other than a resistant Staphylococcus, therapy should not be continued with Oxacillin.
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Oxacillin for Injection USP and other antibacterial drugs, Oxacillin for Injection USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

POSOLOGY AND METHOD OF ADMINISTRATION

The penicillinase-resistant penicillins are available for oral administration and for intramuscular and intravenous injection. The sodium salts of methicillin, Oxacillin, and nafcillin may be administered parenterally.
Bacteriologic studies to determine the causative organisms and their susceptibility to Oxacillin should always be performed. Duration of therapy varies with the type and severity of infection as well as the overall condition of the patient, therefore it should be determined by the clinical and bacteriological response of the patient. In severe staphylococcal infections, therapy with Oxacillin should be continued for at least 14 days. Therapy should be continued for at least 48 hours after the patient has become a febrile, asymptomatic, and cultures are negative. The treatment of endocarditis and osteomyelitis may require a longer term of therapy. Concurrent administration of Oxacillin and Probenecid increases and prolongs serum penicillin levels. Probenecid decreases the apparent volume of distribution and slows the rate of excretion by competitively inhibiting renal tubular secretion of penicillin. Penicillin-Probenecid therapy is generally limited to those infections where very high serum levels of penicillin are necessary.
For intramuscular gluteal injections, care should be taken to avoid sciatic nerve injury. With intravenous administration, particularly in elderly patients, care should be taken because of the possibility of thrombophlebitis.

RECOMMENDED DOSAGES FOR OXACILLIN FOR INJECTION, USP

Drug	Adults	Infants and Children	Other
Oxacillin	250 to 1 g IM or IV every 4 to 6 hours (mild to moderate infections)	**<40 kg (88 lbs)** 50 mg/kg/day IM or IV in equally divided doses every 6 hours (mild to moderate infections)	**Recommendations**
	1 g IM or IV every 4 to 6 hours (severe infections)	100 mg/kg/day IM or IV in equally divided doses every 4 to 6 hours (severe infections)	Premature and Neonates 25 mg/kg/day IM or IV

CONTRAINDICATIONS

A history of a hypersensitivity (anaphylactic) reaction to any penicillin is a contraindication.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Serious and occasionally fatal hypersensitivity (anaphylactic shock with collapse) reactions have occurred in patients receiving penicillin. The incidence of anaphylactic shock in all penicillin-treated patients is between 0.015 and 0.04 percent. Anaphylactic shock resulting in death has occurred in approximately 0.002 percent of the patients treated. Although anaphylaxis is more frequent following a parenteral administration, it has occurred in patients receiving oral penicillins.
When penicillin therapy is indicated, it should be initiated only after a comprehensive patient drug and allergy history has been obtained. If an allergic reaction occurs, the drug should be discontinued and the patient should receive supportive treatment, eg, artificial maintenance of ventilation, pressor amines, antihistamines, and corticosteroids. Individuals with a history of penicillin hypersensitivity may also experience allergic reactions when treated with a cephalosporin.

PRECAUTIONS

General
Penicillinase-resistant penicillins should generally not be administered to patients with a history of sensitivity to any penicillin.
Penicillin should be used with caution in individuals with histories of significant allergies and/or asthma. Whenever allergic reactions occur, penicillin should be withdrawn unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to penicillin therapy.
Prescribing Oxacillin for Injection in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Information for Patients
Patients should be counseled that antibacterial drugs including Oxacillin for Injection should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When Oxacillin for Injection is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Oxacillin for Injection or other antibacterial drugs in the future.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Tetracycline, a bacteriostatic antibiotic, may antagonize the bactericidal effect of penicillin and concurrent use of these drugs should be avoided.
Oxacillin blood levels may be prolonged by concurrent administration of probenecid which blocks the renal tubular secretion of penicillins.

PREGNANCY AND LACTATION

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been conducted with these drugs.
Studies on reproduction (nafcillin) in rats and rabbits reveal no fetal or maternal abnormalities before conception and continuously through weaning (one generation).

Pregnancy Category B
Reproduction studies performed in the mouse, rat, and rabbit have revealed no evidence of impaired fertility or harm to the fetus due to the penicillinase-resistant penicillins. Human experience with the penicillins during pregnancy has not shown any positive evidence of adverse effects on the fetus. There are, however, no adequate or well controlled studies in pregnant women showing conclusively that harmful effects of these drugs on the fetus can be excluded. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers
Penicillins are excreted in breast milk. Caution should be exercised when penicillins are administered to a nursing woman.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None

UNDESIRABLE EFFECTS

Body as a Whole
The reported incidence of allergic reactions to penicillin ranges from 0.7 to 10 percent Sensitization is usually the result of treatment but some individuals have had immediate reactions to penicillin when first treated. In such cases, it is thought that the patients may have had prior exposure to the drug via trace amounts present in milk and vaccines.
Two types of allergic reactions to penicillin are noted clinically, immediate and delayed.
Immediate reactions usually occur within 20 minutes of administration and range in severity from urticaria and pruritus to angioneurotic edema, laryngospasm, bronchospasm, hypotension, vascular collapse, and death. Such immediate anaphylactic reactions are very rare and usually occur after parenteral therapy but have occurred in patients receiving oral therapy. Another type of immediate reaction, an accelerated reaction, may occur between 20 minutes and 48 hours after administration and may include urticaria, pruritus, and fever. Although laryngeal edema, laryngospasm, and hypotension occasionally occur, fatality is uncommon.
Delayed allergic reactions to penicillin therapy usually occur after 48 hours and sometimes as late as 2 to 4 weeks after initiation of therapy. Manifestations of this type of reaction include serum sickness-like symptoms (ie, fever, malaise, urticaria, myalgia, arthralgia, abdominal pain) and various skin rashes. Nausea, vomiting, diarrhea, stomatitis, black or hairy tongue, and other symptoms of gastrointestinal irritation may occur, especially during oral penicillin therapy.

Nervous System Reactions
Neurotoxic reactions similar to those observed with penicillin G may occur with large intravenous doses of the penicillinase-resistant penicillins especially in patients with renal insufficiency.
Urogenital Reactions
Renal tubular damage and interstitial nephritis have been associated with the administration of methicillin sodium and infrequently with the administration of nafcillin and oxacillin. Manifestations of this reaction may include rash, fever, eosinophilia, hematuria, proteinuria, and renal insufficiency. Methicillin-induced nephropathy does not appear to be dose-related and is generally reversible upon prompt discontinuation of therapy.
Gastrointestinal Reactions
Pseudomembranous colitis has been reported with the use of Oxacillin Sodium. The onset of Pseudomembranous colitis symptoms may occur during or after antibiotic treatment
Metabolic Reactions
Agranulocytosis, neutropenia, and bone marrow depression have been associated with the use of methicillin sodium, nafcillin, Oxacillin, and cloxacillin. Hepatotoxicity, characterized by fever, nausea, and vomiting associated with abnormal liver function tests, mainly elevated SGOT levels, has been associated with the use of Oxacillin and cloxacillin.

OVERDOSE

If signs or symptoms occur, discontinue use of the medication, treat symptomatically, and institute appropriate supportive measures.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMICS PROPERTIES

Microbiology
Penicillinase-resistant penicillins exert a bactericidal action against penicillin-susceptible microorganisms during the state of active multiplication. All penicillins inhibit the biosynthesis of the bacterial cell wall.
The drugs in this class are highly resistant to inactivation by staphylococcal penicillinase and are active against penicillinase-producing and nonpenicillinase-producing strains of Staphylococcus aureus.
The penicillinase-resistant penicillins are active in vitro against a variety of other bacteria.

PHARMACOKINETIC PROPERTIES

Oxacillin Sodium, with normal doses, has insignificant concentrations in the cerebrospinal and ascetic fluids. It is found in therapeutic concentrations in the pleural, bile, and amniotic fluids. Oxacillin Sodium is rapidly excreted as unchanged drug in the urine by glomerular filtration and active tubular secretion.
Oxacillin Sodium binds to serum protein, mainly albumin. The degree of protein binding reported varies with the method of study and the investigator, but generally has been found to be 94.2 ± 2.1%.
Intramuscular injections give peak serum levels 30 minutes after injection. A 250 mg dose gives a level of 5.3 µg/mL while a 1 g dose peaks at 10.9 µg/mL. Intravenous injection gives a peak about 5 minutes after the injection is completed. Slow IV dosing with 1 g gives a 5 minute peak of 43 µg/mL with a half-life of 20 to 30 minutes.

PRECLINICAL SAFETY DATA

None

Mode of reconstitution:
IM use: Add 5.7 ml of sterile water for injection and mixed. Shake well.
IV/ INTRAVENOUS INFUSION Use: Add 10 ml of sterile water for injection or 10 ml of NS and mixed. Shake well.

SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN

NATURE AND CONTENTS OF CONTAINER

Available in glass vial.

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