Prostaphlin advertisement.

[s.l.]: [s.n.], 1971

Every day, healthy people leave the hospital—

carrying resistant staph.

Penicillin G-resistant staph remains a major problem in hospitals. Not only because of serious infection, but because its very presence makes carriers out of patients, neonates and hospital personnel alike.

Every day, these virulent strains leave the hospital, and are introduced into the community.

Today, an estimated 50% of community staph are resistant to penicillin G.

TREAT RESISTANT STAPH INFECTIONS AS EFFECTIVELY IN THE OFFICE AS YOU DO IN THE HOSPITAL

Prostaphlin® (sodium oxacillin)

CAPSULES
I.M./I.V.
FOR ORAL SOLUTION

Prostaphlin controls the staph penicillin G can't touch. In pneumonia and postsurgical infections in the hospital, in skin and soft-tissue infections in the office...when bacteriologic tests show staph to be resistant to penicillin G and susceptible to Prostaphlin.

As with all penicillins, severe allergic reactions including anaphylaxis may occur.

BRIEF SUMMARY OF PRESCRIBING INFORMATION. (9) 7/29/71. For complete information, consult Official Package Circular.

Indications: The principal indication for sodium oxacillin is in the treatment of infections known to be due to penicillinase-producing staphylococci which have been shown to be sensitive to it.

Bacteriologic studies to determine the causative organisms and their sensitivity to sodium oxacillin should be performed.

If antibiotic therapy is considered necessary in potentially serious infections while awaiting reports of cultures and sensitivity studies, sodium oxacillin may be used to initiate therapy in such patients in whom a penicillinase-producing staphylococcus is suspected (see Important Note below).

In serious, life-threatening infections, oral preparations of the penicillinase-resistant penicillins should not be relied on for initial therapy.

Important Note: When it is judged necessary that treatment be initiated before definitive culture and sensitivity results are known, the choice of sodium oxacillin should take into consideration the fact that it has been shown to be effective only in the treatment of infections caused by pneumococci, Group A beta-hemolytic streptococci and penicillin G-resistant and penicillin G-sensitive staphylococci. If the bacteriology report later indicates the infection is due to an organism other than a penicillin G-resistant staphylococcus sensitive to sodium oxacillin, the physician is advised to continue therapy with a drug other than sodium oxacillin or any other penicillinase-resistant semi-synthetic penicillin.

Methicillin is a compound that acts through a mechanism similar to that of sodium oxacillin against penicillin G-resistant staphylococci. Strains of staphylococci resistant to methicillin have existed in nature and it is known that the number of these strains reported has been increasing. Such strains of staphylococci have been capable of producing serious disease, in some instances resulting in fatality. Because of this, there is concern that widespread use of the penicillinase-resistant penicillins may result in the appearance of an increasing number of staphylococcal strains which are resistant to these penicillins.

Methicillin-resistant strains are almost always resistant to all other penicillinase-resistant penicillins (cross resistance with cephalosporin derivatives also occurs frequently). Resistance to any penicillinase-resistant penicillin should be interpreted as evidence of clinical resistance to all, in spite of the fact that minor variations in *in vitro* sensitivity may be encountered when more than one penicillinase-resistant penicillin is tested against the same strain of staphylococcus.

Routine methods of antibiotic sensitivity testing may fail to detect strains of organisms resistant to the penicillinase-resistant penicillins. For this reason, the use of large inocula and 48-hour incubation periods may be needed to obtain accurate sensitivity studies with these antibiotics.

Contraindications: A history of allergic reactions to penicillins.

Warning: Serious and occasionally fatal anaphylaxis have been reported in patients on either oral or parenteral penicillin therapy. Check for a history of allergy to penicillins, cephalosporins or other allergens. If an allergic or anaphylactic reaction occurs, discontinue the drug and institute appropriate treatment.

Usage in Pregnancy: Safety for use in pregnancy is not established.

Precautions: Because of limited experience, use cautiously and evaluate organ system function frequently in prematures and neonates. Mycotic or bacterial superinfections may occur. As with any potent drug, periodic assessment of organ system function, including renal, hematopoietic and hepatic, should be made during long-term therapy.

Adverse Reactions: Skin rashes, pruritus, urticaria, eosinophilia, nausea, vomiting, diarrhea, fever and anaphylaxis. Rare cases of reversible hepatocellular dysfunction have occurred.

One patient developed granulocytopenia while receiving intravenous sodium oxacillin and vancomycin. The blood count returned to normal after both drugs were discontinued.

Moderate SGOT elevations have been noted. Thombophlebitis has occurred occasionally during intravenous therapy and leukopenia was noted in two cases. Transient renal dysfunction (hematuria, albuminuria and azotemia) has occurred in some neonates and infants on high doses. Observe this class of patients carefully for such signs during therapy.

Usual Oral Dosage: Adults: 500 mg. q. 4 or q. 6 h. Children: 12.5 mg./Kg. q. 6 h. Administer on empty stomach for maximum absorption.

Treat Group A beta-hemolytic streptococcal infections for at least 10 days. Give oral drug 1 to 2 hours before meals.

Usual Parenteral Dosage: Adults: 250 to 500 mg. q. 4 or q. 6 h. Children: 12.5 mg./Kg. q. 6 h.

Group A beta-hemolytic streptococcal infections should be treated for 10 days. Children weighing 40 Kg. or more should receive the adult dose.

Supplied: Capsules—250 and 500 mg. in bottles of 48. Injectable—250 mg., 500 mg. and 1 Gm. dry filled vials for I.M./I.V. use. For Oral Solution—100 ml. bottle, 250 mg./5 ml. when reconstituted.

A.H.F.S. Category 8:12.16

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