

DESCRIPTION

Albamycin (novobiocin), in the crystalline state, has a light yellow to white color depending upon the state of subdivision. It is odorless or practically odorless. The sodium salt is freely soluble in water, alcohol, glycerine and propylene glycol. One grain of the calcium salt dissolves in about 250 cc. of water, in about 30 ml. of alcohol, in about 450 ml. of ether and in about 1100 ml. of chloroform. In contrast to most antibiotics produced by actinomycetes, novobiocin, like penicillin, is acidic in nature and is stable to the degree of acidity or alkalinity present in the gastrointestinal tract.

ACTIONS

In vitro novobiocin shows activity against *Staphylococcus aureus* and against some strains of *Proteus vulgaris*. It shows no cross-resistance with penicillin against resistant strains of *M. pyogenes* var. *aureus* (*Staphylococcus aureus*); however, in vitro studies indicate that *M. pyogenes* var. *aureus* rapidly develops resistance to novobiocin.

INDICATIONS

Novobiocin is indicated in the treatment of serious infections due to susceptible strains of *Staphylococcus aureus* when the patient is sensitive to other effective antibiotics, such as the penicillins, cephalosporins, vancomycin, lincomycin, erythromycin, and tetracyclines, or when there are other contraindications to these antibiotics.

Add for the oral forms: Novobiocin may be useful in the few urinary tract infections caused by *Proteus* species sensitive to novobiocin but resistant to other therapy.

CONTRAINDICATIONS

This drug should not be administered to persons with known sensitivity to novobiocin.

WARNING (SEE "BOX WARNING")

Because novobiocin has been shown to affect bilirubin metabolism adversely, its use should be avoided in newborn and premature infants.

PRECAUTIONS

Novobiocin possesses a high index of sensitization and appropriate precautions should be taken. If allergic reactions develop during treatment and are not readily controlled by the usual measures, the product should be discontinued.

Hepatic and hematologic studies should be made routinely during treatment. In the case of development of liver dysfunction, the drug should be stopped. If hematologic studies show evidence of the development of leukopenia or other blood dyscrasias, the drug should be stopped.

If new infections appear during therapy, appropriate measures should be taken and consideration given to discontinuance of novobiocin.

ADVERSE REACTIONS

A relatively high incidence of hypersensitivity reactions, consisting most commonly of skin eruptions, has occurred. Skin eruptions may take the form of urticarial, erythematous, maculopapular or scarlatiniform rash. Erythema multiforme (Stevens-Johnson Syndrome) has occurred but is rare.

Leukopenia, eosinophilia and/or fever have occurred occasionally in patients receiving Albamycin (novobiocin). Rarely, other blood dyscrasias, including anemia, pancytopenia, agranulocytosis and thrombocytopenia have occurred.

Liver dysfunction including jaundice, elevation of serum bilirubin concentration, and impaired bromsulphalein excretion, have occurred.

Other adverse reactions include nausea and vomiting, loose stools and diarrhea and intestinal hemorrhage. Alopecia has been reported, but relationship to novobiocin has not been established.

DOSAGE AND ADMINISTRATION

Parenteral

This method of administration should be used only as a temporary measure in severe infections for those unable to take the preparation orally.