

METHOTREXATE: ITS USE IN PSORIASIS

Psoriasis has for ages challenged the physician's therapeutic resources. A recurrent disease, it is characterized by exacerbations and remissions which sometimes are difficult to control with conventional therapies.

Some cases of psoriasis which are severe, disabling and resistant to conventional therapy have been effectively treated with the anti-metabolite drug, Methotrexate.

The Food and Drug Administration and the FDA's Advisory Committee on Dermatology have reviewed a series of clinical investigations and based on the recommendations of the Advisory Committee, the FDA has concluded that Methotrexate is safe and effective for the treatment of certain cases of psoriasis.

The FDA-approved directions for use in these cases will soon be available from the manufacturer, Lederle Labs., and should be reviewed carefully before the drug is used in the treatment of psoriasis.

The labeling of Methotrexate restricts its use in psoriasis to severe, disabling, proven cases recalcitrant to more conservative treatment and makes the following recommendations:

- screening of patients by all appropriate parameters to exclude administration of Methotrexate to pregnant women and to patients with preexisting renal, hepatic, or hematopoietic disease;
- screening of patients to disclose any preexisting infections that might be activated by use of an immunosuppressive agent; and
- ensuring the availability of facilities for close medical and laboratory supervision of patients receiving the drug for psoriasis. Supervision should include CBC, urinalysis, serum creatinine, liver function studies, and liver biopsy, if indicated.

Methotrexate should be used only by physicians who are thoroughly familiar with the severe adverse effects, including deaths, associated with the use of anti-metabolite drugs. Deaths that have occurred during Methotrexate treatment for psoriasis usually have been preceded by signs and symptoms of bone marrow aplasia (e.g.,

hemorrhagic enteritis). Patients should be fully informed of the risks involved and closely monitored. The drug should be discontinued promptly in the event of developing renal or hepatic toxicity.

Methotrexate has been marketed for 18 years as an important representative of anti-neoplastic chemotherapy. Use of an anti-neoplastic drug for treatment of an incurable dermatologic condition must be carefully weighed by the physician after consideration of the risks and benefit to his patient.

Methotrexate should be used only when other, less toxic drugs have failed to bring improvement to patients disabled with severe psoriasis. Please note that the drug is to be dispensed to patients *by physicians only*.

SPECTINOMYCIN FOR ACUTE GONORRHEA

FDA recently approved spectinomycin* for marketing. The drug is indicated only in the treatment of acute gonorrheal urethritis, proctitis, and cervicitis, when due to susceptible strains of *Neisseria gonorrhoeae*. This antibiotic, a product of *Streptomyces spectabilis*, is active against most strains of *N. gonorrhoeae* in a minimum inhibitory concentration varying between 7.5 and 20 mcg./ml. Cross resistance of *N. gonorrhoeae* between spectinomycin and penicillin has not been demonstrated.

Because of its high degree of efficacy and the long-term experience with penicillin, it is still considered the drug of choice for gonorrhea unless the organism is not sensitive to penicillin or the patient is allergic to penicillin. In addition, penicillin should be used when syphilis, suspected or confirmed, is concurrent with gonorrhea. Spectinomycin has no activity against syphilis. It should not be administered to children or during pregnancy.

Spectinomycin is administered only by intramuscular injection. It is rapidly absorbed. The antibiotic is not significantly bound to plasma protein. Spectinomycin can be administered safely to patients who are hypersensitive to penicillin.

For further details, including dosage, consult the package insert.

*"Trobicin", The Upjohn Company.