

studies and provide you with complete prescription information for your guidance in the use of our TAO products in your practice

As you may recall, in October 1961, we advised the medical profession of two preliminary studies in which abnormal changes in liver function tests had been observed following the administration of TAO for 14 days or longer. These observations have been confirmed by further studies and appropriate changes have now been incorporated in our directions for use of our TAO product.

The effectiveness of TAO is such that prolonged therapy is seldom required in the treatment of most common susceptible infections for which it is recommended. It is therefore concluded that you may continue to employ TAO in your practice with full confidence in the treatment of acute bacterial infection including cases due to staphylococci resistant to other antibiotics, in accordance with the enclosed prescription information.

Sincerely yours,

JOHN L. WATTERS, M.D.,
Medical Director.

THE WM. S. MERRELL CO.,
Cincinnati, Ohio, December 5, 1961.

DRUG WARNING—KEVADON

DEAR DOCTOR: We have received information from abroad on the occurrence of congenital malformations in the offspring of a few mothers who had taken thalidomide (marketed in Canada as Kevadon) early in their pregnancies. It is impossible at this time to determine whether, in fact, there is any causal relationship.

However, until definitive information is available to us, as a precaution we are adding the following contraindication to the use of Kevadon:

Kevadon should not be administered to pregnant women nor to premenopausal women who may become pregnant.

We are actively following this matter and you will be advised when it is finally determined whether or not this precautionary step was necessary

Sincerely yours,

JOHN N. PREMI, M.D.,
Medical Director.

THE WM. S. MERRELL CO.,
Cincinnati, Ohio, December 1, 1961.

DRUG WARNING—MER/29 (TRIPARANOL)

DEAR DOCTOR: In cooperation with the United States Food and Drug Administration, we are writing to inform and caution you concerning adverse effects, including some unpublished reports, associated with the use of MER/29 (triparanol). Although comparatively few serious clinical injuries have been reported to date, their possible significance is emphasized by findings from animal studies.

Cataracts. Four cases of cataracts in humans are reported in patients who have received MER/29. One of these cases occurred in a patient receiving the recommended dosage of 250 mg. of MER/29 daily. Cataracts and corneal opacities have also been produced with MER/29 in animals. Slit lamp examinations are necessary for early detection of developing cataracts. For this reason such examinations are indicated prior to and periodically during therapy. Before this problem came to our attention, approximately one thousand persons being treated with MER/29 were patients of ophthalmologists. Most of them have had careful eye examinations, including use of the slit lamp, before and during drug therapy. Results on these patients will be reported to you as soon as they are available.

Hair Changes. There have been many cases of hair loss, either baldness or thinning of hair, changes in hair color and texture, and loss of body hair. Such hair changes may be related to the skin change discussed below as well as to the eye changes discussed above. It is recommended that MER/29 therapy be discontinued promptly at the first evidence of hair or skin changes to minimize progressive effects possible including eye injury.