1993
Physicians' Desk Reference®

**KUTAPRESSIN® Injection**
**(liver derivative complex)**

## DESCRIPTION

KUTAPRESSIN® Injection (liver derivative complex) is a sterile solution containing 25.5 mg liver derivative complex per mL in water for injection. KUTAPRESSIN Injection is composed of peptides and amino acids. The product contains no protein, is virtually non-allergenic, and does not exhibit anti-anemia activity.

KUTAPRESSIN Injection also contains as inactive ingredients: phenol 0.5%, water for injection, pH is adjusted with hydrochloric acid or sodium hydroxide when necessary.

## CLINICAL PHARMACOLOGY

The specific action of KUTAPRESSIN is to enhance the resolution of inflammation and edema. In the late 1920s it was demonstrated that liver was of benefit to patients suffering from acne vulgaris. As a consequence, various techniques were employed for isolating the active "factor" from liver. Studies published in the late 1930s and early 1940s showed activity in a specially purified liver fraction. During subsequent years refinements in the isolation of the active material led to the marketing of KUTAPRESSIN.

Initially it was thought that the primary action of KUTAPRESSIN was on the capillaries and precapillary sphincters. However, it is now believed that this effect is a secondary one and that the primary action of KUTAPRESSIN is in response to injury at the cellular level. The capillary changes observed following administration of KUTAPRESSIN appear to be part of a more fundamental anti-inflammatory effect. In the normal animal no consistent pharmacodynamic action has been demonstrated for KUTAPRESSIN. In particular there is no effect on the systemic blood pressure, no action on the autonomic nervous system and no alteration in prothrombin, coagulation or bleeding times. It is concluded that the specific action of the product is only apparent when tissues have been subjected to injury and when inflammation and edema are present.

## INDICATIONS AND USAGE

A wide variety of dermatological clinical conditions benefit from KUTAPRESSIN therapy. The common denominator in these varied conditions is the presence of inflammation and edema. Favorable response to administration of KUTAPRESSIN in patients with acne vulgaris, herpes zoster, "poison ivy" dermatitis, pityriasis rosea, seborrheic dermatitis, urticaria and eczema, severe sunburn, and rosacea have been reported.

## CONTRAINDICATIONS

Contraindicated in patients with hypersensitivity or intolerance to liver or pork products.

## WARNING

Use with caution in patients suspected of being hypersensitive to liver or with other allergic diatheses.

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## Schwarz Pharma—Cont.

## PRECAUTIONS

*Drug Interactions:*
No clinically significant drug interactions have been reported.

*Carcinogenesis, Mutagenesis, Impairment of Fertility:*
No long-term animal studies have examined the carcinogenic or mutagenic potential of KUTAPRESSIN. KUTAPRESSIN's effect upon reproductive capacity is similarly unknown.

*Pregnancy—Pregnancy Category C:*
Animal reproduction studies have not been conducted with KUTAPRESSIN. It is also not known whether KUTAPRESSIN can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. KUTAPRESSIN should be given to a pregnant woman only if clearly needed.

*Nursing Mothers:*
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when KUTAPRESSIN is administered to a nursing woman.

## ADVERSE REACTIONS

As with all injectable medications, local reactions may occur. Local reactions may include pain, swelling, and erythema.

## DRUG ABUSE AND DEPENDENCE

The information on drug abuse and dependence is limited to uncontrolled data derived from marketing experience. Such experience has revealed no evidence of drug abuse and dependence associated with KUTAPRESSIN Injection .

## DOSAGE AND ADMINISTRATION

For the management of skin disorders the usual dose of KUTAPRESSIN is 2 mL administered daily or as indicated. The product is given by intramuscular or subcutaneous injection only.

As with all parenteral drug products, KUTAPRESSIN should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

## HOW SUPPLIED

KUTAPRESSIN Injection (liver derivative complex, 25.5 mg/mL) is a sterile, brown solution.

20 mL multiple-dose vial NDC 0091-1510-21

Store at controlled room temperature 15°–30°C (59°–86°F).

CAUTION: Federal law prohibits dispensing without prescription.

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