NEXAVIR- liver derivative complex injection
Nexco Pharma

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DESCRIPTION:

NEXAVIR ® Injection (liver derivative complex) is a sterile solution containing 25.5mg liver derivative complex per ml in sterile water for injection.

NEXAVIR ® Injection is composed of peptides and amino acids. The product contains no protein and does not exhibit anti-anemia activity.

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

CLINICAL PHARMACOI.OGY:

The specific action of NEXAVIR ® is to enhance the resolution of inflammation and edema. In the late 1920's, it was demonstrated that liver was of benefit to patients suffering from acne vulgaris. [1] As a consequence, various techniques were employed for isolating the active "factor" from liver. Studies published in the late 1930's and early 1940's [2,3,4] showed activity in a specially purified liver fraction. During subsequent years, refinements in the isolation of the active material led to the marketing of NEXAVIR ®.

Initially it was thought that the primary action of NEXAVIR ® 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 NEXAVIR ® is in response to injury at the cellular level. The capillary changes observed following administration of NEXAVIR ® appear to be part of a more fundamental anti-inflammatory effect. In the normal animal, no consistent pharmacodynamic action has been demonstrated for NEXAVIR ®. In particular, there is no effect on 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 range of dermatological clinical conditions benefit from NEXAVIR ® therapy. The common denominator in these varied conditions is the presence of inflammation and edema. Favourable responses to the administration of NEXAVIR ® in patients with acne vulgaris [5,6,7,8,] herpes zoster, "poison ivy" dermatitis, pityriasis rosea, seborrheic dermatitis, urticaria and eczema [9,10,11], severe sunburn [12] and rosacea [13] 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.

PRECAUTIONS:

Drug Interactions:
NEXAVIR ® contains tyramine and should not be administered to patients taking MAO inhibitors because hypertensive crisis may occur.

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

Pregnancy- Pregnancy Category C:
Animal reproduction studies have not been conducted with NEXAVIR ®. It is also not known whether NEXAVIR ® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. NEXAVIR ® 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 NEXAVIR ® is administered to a nursing woman.

ADVERSE REACTIONS:

As with all Injectable medications, local reactions may occur. Local reactions may include pain. rash, stinging, 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 NEXAVIR ® Injection.

DOSAGE AND ADMINISTRATION:

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

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

HOW SUPPLIED:

NEXAVIR ® Injection (liver derivative complex, 25.5 mg/mL) is a sterile, brown solution
20 ml multiple dose vial NDC 10530-319-07

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

Manufactured for: Nexco Pharma, 10072 S. Ocean Drive, Suite 7N, Jensen Beach, Florida, 34957 (34957-2556)
Manufactured By: Maitland Labs, Florida, USA

Other information

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REFERENCES:

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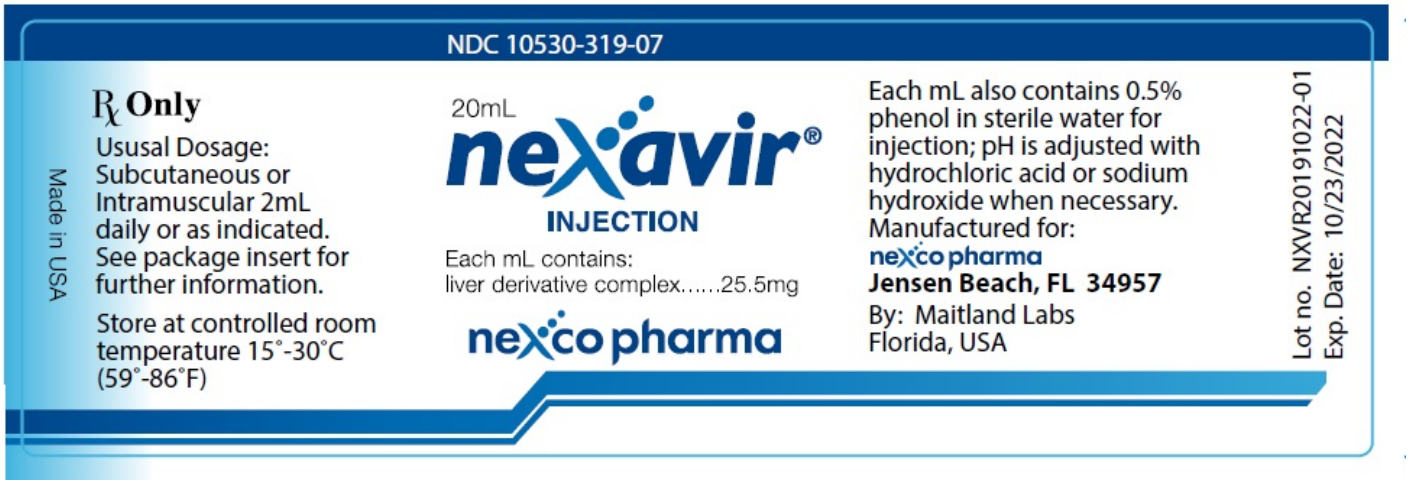
NDC 10530-319-07

Nexavir Injection

20 mL multiple dose vial

Rx only



NEXAVIR

liver derivative complex injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:10530-319

Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PORK LIVER (UNII: 6EC706HI7F) (PORK LIVER - UNII:6EC706HI7F)	PORK LIVER	25.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	brown (brown solution)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10530-319-07	20 mL in 1 VIAL, MULTI-DOSE; Type 0: Not a Combination Product	02/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/19/2020	

Labeler - Nexco Pharma (023524538)

Registrant - Nexco Pharma (023524538)

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