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Pharmaceutical Research and Manufacturers of America
Retire Safe
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The AIDS Institute
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Shown in Product Identification Guide, page 309

COLD-fX Pharmaceuticals (USA) Inc.

5600 NORTH RIVER ROAD, SUITE 800
CHICAGO, IL, USA, 60018

Direct Inquiries to:
1-877-490-3300

COLD-fX™/† **OTC**
Strengthens the Immune System*

Supplement Facts

Serving Size 1 Capsule

Amount Per Serving	**% Daily Value**
CVT-E002 is a proprietary and patented natural extract containing poly-furanosyl-pyranosyl-saccharides derived from *Panax quinquefolius* (North American Ginseng, root) 200 mg**	

** *Daily Value not established*

Other ingredients: Gelatin

DIRECTIONS

Recommended for Short-Term Use

Day 1, take 3 capsules 3 times during the day (total = 9 capsules)
Day 2, take 2 capsules 3 times during the day (total = 6 capsules)
Day 3, take 1 capsule 3 times during the day (total = 3 capsules)

Recommended for Long-Term Use

Take 1 capsule 2 times each day

Recommended use for adults and children ages 12 years and older.

WARNINGS

Individuals with serious health conditions or taking medications, or pregnant or lactating women, should consult a health care professional before taking COLD-fX™ extract. As COLD-fX extract is a derivative of North American ginseng, it is not recommended for individuals with allergies to ginseng. Do not exceed the recommended daily dose.

OTHER INFORMATION

Each capsule is a ChemBioPrint™ product, made with a patented technology that is used to identify the active components of CVT-E002, a proprietary and patented natural extract, to prove the health benefit of CVT-E002, and to ensure that the product is consistently made from batch to batch.

For more information on COLD-fX, visit **www.cold-fx.com**

HOW SUPPLIED

Available in bottles of 30, 60 and 150 capsules as well as an 18 capsule blister package.

*** This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

7. Wang M *et al*. A proprietary extract from North American ginseng (*Panax quinquefolium*) enhances IL-2 and IFN-γ productions in murine spleen cells induced by Con-A. International Immunopharmacology 2004; 4:311-315.
8. Wang M *et al*. Immunomodulating activity of CVT-E002, a proprietary extract from North American ginseng (*Panax quinquefolium*). Journal of Pharmacy and Pharmacology 2001, 53: 1515-1523.
9. Ueng Y and C Chen. Effects of CVT-E002, a proprietary extract from North American ginseng (*Panax quinquefolium*) on drug metabolizing enzymes. Journal of Chinese Medicine 2002, 13(2): 89-96.
10. Yang JC *et al*. Effects of American ginseng extract (*Panax quinquefolius*) on formalin-induced nociception in mice. American Journal of Chinese Medicine 2001, 29(1): 149-154.

Shown in Product Identification Guide, page 309

CollaGenex Pharmaceuticals, Inc.

41 UNIVERSITY DRIVE, SUITE 200
NEWTOWN, PA 18940

Direct inquiries to:
888-339-5678

ORACEA™ ℞
[*or-RAY-sha*]
(doxycycline, USP)
Capsules 40 mg*

*30 mg Immediate Release & 10 mg Delayed Release beads

Rx Only

KEEP OUT OF REACH OF CHILDREN

The dosage of ORACEA differs from that of doxycycline used to treat infections. To reduce the development of resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, ORACEA should be used only as indicated.

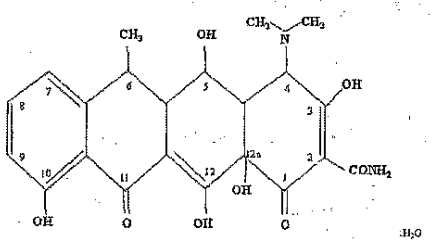
ORACEA is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.

This formulation of doxycycline has not been evaluated as an antibacterial in the treatment of infections.

DESCRIPTION

ORACEA (doxycycline, USP) capsules 40 mg are hard gelatin capsule shells filled with two types of doxycycline beads (30 mg immediate release and 10 mg delayed-release) that together provide a dose of 40 mg of anhydrous doxycycline ($C_{22}H_{24}N_2O_8$).

The structural formula of doxycycline, USP is:



Information will be superseded by supplements and subsequent editions

papules or pustules) when compared to the placebo group in both Phase 3 studies
[See table 2 above]
Patients treated with ORACEA did not demonstrate significant improvement in erythema when compared to those treated with placebo.

INDICATIONS AND USAGE

ORACEA is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. No meaningful effect was demonstrated for generalized erythema (redness) of rosacea. ORACEA has not been evaluated for the treatment of the erythematous, telangiectatic, or ocular components of rosacea. Efficacy of ORACEA beyond 16 weeks and safety beyond 9 months have not been established.
This formulation of doxycycline has not been evaluated in the treatment or prevention of infections. ORACEA should not be used for treating bacterial infections, providing antibacterial prophylaxis, or reducing the numbers or eliminating microorganisms associated with any bacterial disease.
To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, ORACEA should be used only as indicated.

CONTRAINDICATIONS

This drug is contraindicated in persons who have shown hypersensitivity to doxycycline or any of the other tetracyclines.

WARNINGS

Teratogenic effects

1) Doxycycline, like other tetracycline-class antibiotics, can cause fetal harm when administered to a pregnant woman. If any tetracycline is used during pregnancy or if the patient becomes pregnant while taking these drugs, the patient should be informed of the potential hazard to the fetus and treatment stopped immediately.
ORACEA should not be used during pregnancy (see PRECAUTIONS: Pregnancy).
2) The use of drugs of the tetracycline class during tooth development (last half of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of the drug but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. **Tetracycline drugs, therefore, should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated.**
3) All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.
Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can cause retardation of skeletal development on the developing fetus. Evidence of embryotoxicity has been noted in animals treated early in pregnancy (see PRECAUTIONS: Pregnancy section).

Gastrointestinal effects

Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.
Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of "antibiotic-associated colitis".
If a diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis.

Metabolic effects

The anti-anabolic action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline-class antibiotics may lead to azotemia, hyperphosphatemia, and acidosis. If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulations of the drug and possible liver toxicity. Under such conditions, lower than usual total doses are indicated, and if therapy is prolonged, serum level determinations of the drug may be advisable.

Photosensitivity

Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. Although this was not observed during the duration of the clinical studies with ORACEA, patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using ORACEA. If patients need to be outdoors while using ORACEA, they should wear loose-fitting clothes that protect skin from sun exposure and discuss other sun protection measures with their physician.

PRECAUTIONS

General

Safety of ORACEA beyond 9 months has not been established.
As with other antibiotic preparations, use of ORACEA may result in overgrowth of non-susceptible microorganisms, including fungi. If superinfection occurs, ORACEA should be discontinued and appropriate therapy instituted. Although not observed in clinical trials with ORACEA, the use of tetracyclines may increase the incidence of vaginal candidiasis.
ORACEA should be used with caution in patients with a history of or predisposition to candidiasis overgrowth.
Bacterial resistance to tetracyclines may develop in patients using ORACEA. Because of the potential for drug-resistant bacteria to develop during the use of ORACEA, it should be used only as indicated.

Autoimmune Syndromes

Tetracyclines have been associated with the development of autoimmune syndromes. Symptoms may be manifested by fever, rash, arthralgia, and malaise. In symptomatic patients, liver function tests, ANA, CBC, and other appropriate tests should be performed to evaluate the patients. Use of all tetracycline-class drugs should be discontinued immediately.

Tissue Hyperpigmentation

Tetracycline class antibiotics are known to cause hyperpigmentation. Tetracycline therapy may induce hyperpigmentation in many organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (teeth, mucosa, alveolar bone), sclerae and heart valves. Skin and oral pigmentation has been reported to occur independently of time or amount of drug administration, whereas other pigmentation has been reported to occur upon prolonged administration. Skin pigmentation includes diffuse pigmentation as well as over sites of scars or injury.

Pseudotumor cerebri

Bulging fontanels in infants and benign intracranial hypertension in adults have been reported in individuals receiving tetracyclines. These conditions disappeared when the drug was discontinued.

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