

Eufan F.C. TABLET 10mg

"Standard"

(Dimemorfan Phosphate)

NAME AND STRENGTH OF ACTIVE INGREDIENT:

Each Eufan 10mg film coated tablet contains dimemorfan phosphate 10mg

Excipients: Mannitol, Potato starch, Polyvinylpyrrolidone K30, Sodium stearyl fumarate, HPMC, Polyethylene glycol 4000, Titanium dioxide

INDICATIONS:

Symptomatic control of cough due to upper respiratory inflammation, acute bronchitis, pneumonia.

DOSAGE & ADMINISTRATION:

Adult: 1-2 tablets tid,

Children: 8-14 yr 1 tablet tid.

CLINICAL PHARMACOLOGY:

The antitussive action of dimemorfan appears to be directly on the cough center in the medulla. Dimemorfan does not induce any significant physical or psychological dependence, and its antitussive action is not affected by the opioidreceptor blocker levallorphan. Dimemorfan is therefore considered as a non-narcotic antitussive. In contrast to the narcotic antitussive, dimemorfan caused no serious problems with the digestive system, such as constipation and disorder of the bile duct, and caused no dependence or tolerance, and was unlikely to have clinical analgesic effects.

Pharmacokinetics:

Absorption:

After oral administration of 90 mg of dimemorfan in healthy male volunteers, peak plasma levels were reached 1 to 2 hours after administration, with a concentration of 0.007 to 0.008 ug/mL.

Elimination:

In healthy male volunteers who fasted for 12 hours and then received 30mg of dimemorfan orally, about 60% of the drug was excreted into urine within 24 hours, and all metabolites found in urine resulted from oxidizing dealkyl reactions. The proportion of unmetabolized dimemorfan detected was $\leq 2.0\%$. No metabolites showed an antitussive effect.

PRECAUTIONS AND WARNINGS:

Diabetes mellitus

ADVERSE REACTIONS:

Infrequently, change in glucose tolerance, dizziness, drowsiness, dry mouth, nausea, vomiting.

Rarely, malaise, tachycardia, palpitation, hot flushes

TOXICOLOGY:

No teratogenic changes were detected in rats and mice. Administration of dimemorfan in the late stage of pregnancy in mice and rats did not affect dams and fetuses. No decrease in beta granules was found by histologic observation of the pancreas in rat neonates.

Like codeine and dextromethorphan, the toxicity of dimemorfan appeared to be associated with central excitatory effects, but dimemorfan showed a better safety margin and was not teratogenic.

PACKING AND PACK SIZES:

10's x 10/BOX

1000's/BOTTLE

CLASS OF DRUG:

Prescription only medicine

SHELF-LIFE:

24 months

STORAGE:

Store at temperature below 30°C.

NAME AND ADDRESS OF MANUFACTURER:

Standard Chem. & Pharm. Co., Ltd.

6-20 Tu Ku Li. Hsin-Ying (730)

Taiwan, Republic of China

Marketed by: STASON PHARMACEUTICAL - USA

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