Brofex® TS

Dextromethorphan Polistirex INN

COMPOSITION:

Extended Release Suspension: Each 5 mL contains Dextromethorphan Polistirex INN equivalent to Dextromethorphan Hydrobromide 30 mg.

PHARMACOLOGY:

Dextromethorphan Hydrobromide is a cough suppressant, which has a central action on the cough center in the medulla. Although structurally related to morphine, it has no analgesic properties and in general, it has little sedative activity. Addiction has not been observed after the administration of rather large doses for prolonged period. It is rapidly absorbed from the GI tract and exerts its effects in 15-30 minutes after oral administration. Polistirex forms a matrix around the Dextromethorphan particles, which slows down the dissolution of the Dextromethorphan in the gastrointestinal tract, leading to a gradual and prolonged release of Dextromethorphan into the bloodstream. The duration of action is 12 hours with extended release suspension dosage form. Dextromethorphan Hydrobromide is extensively metabolized in the liver and excreted in the urine as unchanged Dextromethorphan and de-methylated metabolites including Dextrophan, which has some cough suppressant activity. Urinary excretion of parent and metabolites accounts for up to 50% of the ingested dose over 24 hours. About 8% of the dose is excreted unchanged in the urine over the first 6 hours.

INDICATION:

Brofex® TS is indicated in

- Chronic dry cough/unproductive cough
- Acute dry cough, which is interfering with normal function or sleep.

DOSAGE AND ADMINISTRATION:

Adults and children 12 years of age and over: 10 mL every 12 hours. Do not exceed 20 mL in 24 hours.

Children (06-12 years): 5 mL every 12 hours. Do not exceed 10 mL in 24 hours.

Children (04-06 years): 2.5 mL every 12 hours. Do not exceed 5 mL in 24 hours.

Children under 04 years of age: Not Recommended

PREGNANCY & LACTATION:

There is little information on the use of this drug in pregnancy and therefore it should be avoided in the first three months of pregnancy. No information is available on secretion of dextromethorphan into breast milk, so nursing mothers should be advised not to take the drug.

CONTRAINDICATION AND PRECAUTION:

Concomitant use of monoamine oxidase inhibitors is contraindicated with **Brofex®** TS. Dextromethorphan is extensively metabolized in the liver and should be prescribed with caution to patients with liver disease.

SIDE EFFECT:

Adverse effects with Dextromethorphan are rare, but nausea and dizziness sometimes occur. The drug produces no analgesia or addiction and little or no CNS depression. Excitation, confusion and respiratory depression may occur after over dosage.

DRUG INTERACTION:

Two fatal interactions have been reported in patients taking therapeutic doses of phenelzine and dextromethorphan.

STORAGE:

Store below 30° C in dry place. Keep away from light . Keep out of reach of children.

HOW SUPPLIED:

Brofex® TS ER suspension: Each PET Bottle contains 100 mL suspension and a measuring cup .

Manufactured by-

SQUARE PHARMACEUTICALS PLC.

Salgaria, Pabna, Bangladesh

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