165mm

155mm

Tussolve

(Levocloperastine fendizoate)

Oral suspension 708mg/100ml

ٹیوسولو

(لیووکلوپیراسٹین فنڈیزویٹ)

اورل سسپنشن ۷۰۸ ملی گرام/۱۰۰ ملی لیٹر

DESCRIPTION:
Tussolve is an antitussive medicine that contains the active ingredient levocloperastine fendizoate, which belongs to a group of medicines called cough suppressants that relieve cough by acting on the central nervous system. This medicine is used as a cough suppressant. Consult your doctor if you do not feel better or if you feel worse after 7 days.

COMPOSITION:
Each 100ml contains:
Levocloperastine Fendizoate 708mg Eq. to Cloperastine Hydrochloride ……..400mg

CLINICAL PHARMACOLOGY
Pharmacodynamics:
ATC Code: R05DB21
Therapeutic group: Cough suppressant.
Mechanism of action: Selective inhibitory action on the bulbar cough center. Sedative action on peripheral stimuli that induce the cough reflex, through inhibition of mediators of the inflammatory process and an anti-bronchospastic effect.

PHARMACOKINETICS
The product is absorbed through the intestines and mostly excreted via the urine, primarily in a degraded form. The maximum plasma peak is reached in 90-120 minutes, followed by wide distribution in tissue areas, especially in the lungs.

Preclinical safety data:
Preclinical data indicate no risks to humans based on conventional studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity.

THERAPEUTIC INDICATIONS
Cough sedative.

ROUTE OF ADMINISTRATION
Oral use.

ADVERSE REACTIONS
Tussolve 708 mg/100 ml Oral Suspension is generally well tolerated, with gastrolintestinal disorders being the most commonly reported adverse effects, which are usually mild, transient, and rare. The active ingredient's safety profile includes uncommon hypersensitivity reactions such as anaphylactic or anaphylactoid responses, as well as rare skin reactions like urticaria and erythema. Dry mouth has

also been noted as a rare side effect. Clinical trials have not observed any central nervous system-related sedative or excitatory symptoms at therapeutic doses, and overall, adverse reactions tend to be infrequent and of low severity.

CONTRAINDICATIONS
Hypersensitivity to any component of the product or to any of the excipients. Due to the lack of studies in the age group between 0 and 2 years, the use of the drug in early infancy is not recommended. Generally contraindicated during pregnancy.

Pregnancy
Although toxicity studies conducted during pregnancy in animals have not shown teratogenic activity or fetal toxicity, it is prudent as a precautionary measure not to take the medication during the first months of pregnancy and thereafter only if truly necessary under the direct supervision of a doctor.

Breastfeeding
It is not known whether the medicine and/or its metabolites are excreted in breast milk; since the risk to the infant cannot be excluded, it is preferable to avoid the use of cloperastine while breastfeeding.

PRECAUTIONS
Caution is advised when using in patients with intraocular hypertension, bladder hypertrophy, or obstruction.

DRUG INTERACTIONS
No interaction studies have been conducted.

Although the central side effects of levocloperastine are significantly reduced, the drug can interact with substances that are either depressants or stimulants of the central nervous system. It should be noted that there is a possibility of enhancing the effect of substances with antihistaminic/antiserotonergic action and, to a lesser degree, papaverine-type muscle relaxants. The ingestion of alcohol may enhance the undesirable effects of the medication.

OVERDOSAGE
In clinical trials, generally with dosages of levocloperastine higher than the authorized doses, episodes of drowsiness have been observed. In case of overdose, it is recommended to follow standard procedures (gastric lavage, activated charcoal, etc.) and to monitor for any signs of overstimulation.

DOSAGE AND ADMINISTRATION:
Adults: 5 ml three times a day.

Children:
Between 2 and 4 years: 2 ml twice a day;
Between 4 and 7 years: 3 ml twice a day;
Between 7 and 15 years: 5 ml twice a day.

Duration of treatment:
7 days.
If no noticeable results are observed, it is recommended to consult a doctor.

INSTRUCTIONS:
- To be dispensed on the prescription of a registered medical practitioner only.
- Store below 30°C in a dry place, protect from light.
- Keep out of the reach of children.
- Shake well before use. Keep bottle tightly closed.

How Supplied:
Extuss oral suspension 708mg/100ml is available in bottle of 100ml, 120ml and 200ml.

Dosage:
As directed by the physician.

خوراک : ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات : دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
ڈھکن کو اچھی طرح بند رکھیں۔ بچوں کی پہنچ سے دور رکھیں۔
استعمال سے پہلے اچھی طرح ہلائیں۔

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