

PAC No.: PAC-2404-0005
Leaflet - Cough-en Linctus (MY)
Size: 195W x 170Hmm
Color: Black



Xepa-Soul Pattinson (Malaysia) Sdn Bhd

1-5 Cheng Industrial Estate 75250 Melaka, Malaysia

Important information. Please read carefully

Cough-en[®] Linctus

For the relief of resistant, dry and unproductive cough accompanied by nasal and respiratory congestion

COMPOSITION

Each 5ml linctus contains:

Tripolidine Hydrochloride	1.25mg
Dextromethorphan Hydrobromide.....	15mg
Pseudoephedrine Hydrochloride	30mg
Sodium Benzoate 0. 10% w/v as preservative	

Pharmacodynamics

Dextromethorphan is a cough suppressant. Its effectiveness in suppressing cough has been found to be about equal to codeine. Pseudoephedrine hydrochloride is used as a nasal and bronchial decongestant. It is said to have less pressor activity and CNS effects than ephedrine of which it is a stereoisomer. Tripolidine is a H₁-receptor blocking agent. In therapeutic dosages, tripolidine produces no significant effects on the cardiovascular system.

Pharmacokinetics

Dextromethorphan is rapidly absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextrorphan, which has some cough suppressant activity.

Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is excreted largely unchanged in the urine with small amounts of its hepatic metabolite. It has a half-life of about 5 to 8 hours; elimination is enhanced and half-life accordingly shorter in acid urine. Small amounts are distributed into breast milk.

After absorption from gastrointestinal tract, tripolidine is metabolised; a carboxylated derivative accounts for about half the dose excreted in the urine. Reported half-lives vary from 3 to 5 hours or more. Tripolidine is distributed into breast milk.

Indications

Cough-en Linctus is indicated for the symptomatic relief of dry irritating coughs such as those associated with common cold, upper respiratory tract infections, allergic (seasonal) rhinitis, vasomotor (perennial) rhinitis and hay fever.

Cough-en Linctus helps dry up running nose and opens congested bronchi to aid clear breathing.

Dosage and administration

- **Adults and children above 12 years:**
10ml 3 times a day;
- **Children 6-12 years:**
5ml 3 times daily;
- **Children 2-5 years:**
2.5ml 3 times daily;

Sip and swallow slowly, preferably taken without dilution.

Contraindications

Cough-en Linctus should not be taken for persistent or chronic cough (eg with smoking, emphysema, asthma) or when coughing is accompanied by excessive secretions unless directed by a physician.

It should be avoided in patients with liver disease or asthmatic patients and is contraindicated in patients taking monoamine oxidase inhibitors or within 2 weeks from stopping such treatment, known hypersensitivity to phenylephrine and during acute attacks of asthma.

Warnings/ Precautions

This preparation may cause drowsiness. If affected, do not drive motor vehicle or operate machinery. Avoid alcoholic drink while on this medication.

Use with caution in patients with epilepsy, prostatic hypertrophy, glaucoma, hepatic disease, hypertension, heart disease, diabetes, hyperthyroidism, patients with stenosing peptic ulcer, pyloroduodenal obstruction or bladder neck obstruction, unless under the medical advice and supervision.

If symptoms do not improve within one week or accompanied with high fever, consult a physician before continuing use.

As with any other drugs, use in pregnancy is best avoided.

Not to be used in children below 2 years old. To be used with cautions, and as advised by the physician/pharmacist for children age 2 to 6 years.

There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) observed with pseudoephedrine-containing medicines. Reported symptoms include sudden onset of severe headache, nausea, vomiting, visual disturbances and other neurological signs and symptoms such as seizure and altered mental status. Most cases have resolved within days following discontinuation of the medication and appropriate treatment. Pseudoephedrine-containing products must be discontinued, and medical advice sought immediately if signs or symptoms of PRES or RCVS develop.

SIDE EFFECTS

Cough-en Linctus may cause drowsiness, dizziness and constipation.

Other side effects that may occur include gastrointestinal tracts discomfort. No apparent evidence of physical dependence of the morphine type.

Other less common side effects may include transient hypertension, dry mouth, insomnia, restlessness, palpitations, allergic reactions such as rashes, tightness of chest, thickening of bronchial secretions, toxic psychosis and blood dyscrasia.

Drug Interactions

Possible reactions systemically may occur with betahistine, certain hypnotic and anxiolytic medication, metoclopramide and antiparkinson drugs.

Overdosage

In cases of overdosage, hospital admission is strongly advised. Overdosage may produce respiratory depression, paranoid psychosis, delusions, hallucinations, and convulsion.

Treatment should include emptying the stomach by aspiration or gastric lavage. Nervous stimulation and convulsions should be treated with a sedative such as diazepam intramuscularly. If marked excitation is present, a sedative such as diazepam or a short-acting barbiturate may be given.

Elimination of pseudoephedrine may be assisted by acidification of the urine with ammonium chloride. Other symptomatic and supportive treatments should be given.

Presentation

Red, clear syrup in packs of 90ml and 120ml.

Shelf Life

The expiry date is indicated on the packaging.

Storage

Store in a cool place below 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician

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Manufactured and Marketed by
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