Xepa[sp] Xepa-Soul Pattinson (Malaysia) Sdn Bhd 1-5, Cheng Industrial Estate, 75250 Melaka, Malaysia.

Important information. Please read carefully.

Sedilix®-Rx
Linctus

COMPOSITION

Each 5ml linctus contains:

Dextromethorphan Hydrobromide	15mg
Phenylephrine Hydrochloride	5mg
Promethazine Hydrochloride	3.125mg

Sodium Benzoate 0.10% w/v as preservative
Ethanol 90% 0.19ml/5ml

PHARMACODYNAMICS

Dextromethorphan is a non-narcotic cough suppressant which acts centrally to raise the threshold for coughing. Its effectiveness in suppressing cough has been found to be about equal to codeine. Phenylephrine is used as a nasal and bronchial decongestant. It is a direct selective alpha-adrenergic receptor agonist, and thus it does not cause the release of endogenous noradrenaline like pseudoephedrine does. Promethazine is a H1- receptor blocking agent. In therapeutic dosages, promethazine produces no significant effects on the cardiovascular system.

PHARMACOKINETICS

Dextromethorphan is well absorbed following oral administration, with peak plasma levels (after a 30 mg dose) being seen after 2 hours. Metabolism in the liver by N- and O- demethylation is followed by sulphate or glucuronic acid conjugation. It is excreted in the urine, up to 56% as metabolites and remainder as unchanged drug. Phenylephrine has reduced bioavailability from the gastrointestinal tract owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver. Promethazine is distributed widely in the body. It enters the brain and crosses the placenta. Promethazine is slowly excreted via urine and bile.

INDICATIONS

Sedilix-Rx is indicated for the relief of dry irritating coughs such as those associated with common cold or upper respiratory tract infections.

Sedilix-Rx helps to relieve nasal congestion, sneezing and rhinorrhoea associated with allergy and the common cold.

DOSAGE AND ADMINISTRATION

Adults and children above 12 years: 10ml every 6 hours
Children 6 to 12 years: 5ml every 6 hours
Children 2 to 5 years: 2.5ml every 6 hours

CONTRAINDICATIONS

Sedilix-Rx 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 AND 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, pyloro-duodenal 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.

This product contains promethazine hydrochloride. It should not be used in pediatric patients less than 2 years of age because of the potential for fatal respiratory depression.

To be used with cautions, and as advised by the physician/pharmacist for children age 2 to 6 years.

This preparation contains sodium metabisulphite that may cause serious allergic type reactions in certain susceptible patients. Do not use if known to be hypersensitive to bisulphites.

DRUG INTERACTIONS

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

PREGNANCY AND LACTATION

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

SIDE EFFECTS

Sedilix-Rx may cause drowsiness, dizziness and constipation.

Other side effects that may occur include GIT 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.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE

In cases of overdosage, hospital admission is strongly advice. 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.

Severe overdosage of phenylephrine may produce hypertension and associated reflex bradycardia. Treatment measures include early gastric lavage and symptomatic and supportive measures. The hypertensive effects may be treated with an alpha-receptor blocking agent (such as phentolamine mesilate 6-10 mg) given intravenously, and the bradycardia treated with atropine, preferable only after the pressure has been controlled.

STORAGE CONDITION : Store below 30ºC.

SHELF-LIFE

The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION

Brown, clear syrup with cherry flavour in packs of 90ml and 120ml.

Revision Date : 8-Jun-2017

Manufactured and Marketed by
Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia.