Decetri

Company name:

Averroes pharma for pharmaceutical industries.

Trade Name: Decetri

Generic Name:

Paracetamol, Pseudoephedrine Hydrochloride, Dextromethorphan Hydrobromide.

Dosage Form:

Oral Syrup

Composition:

Active Ingredients

Each 5 ml syrup contain : Paracetamol 160mg, Pseudoephedrine Hydrochloride 15mg, Dextromethorphan Hydrobromide 7.5 mg.

Inactive Ingredients

Polyethylene glycol 6000,Glycerin,Saccharin sodium, Sodium benzoate, Sodium citrate, Anhydrous Citric acid, Sodium chloride,Edetate disodium, Cherry flavor(W.S),Tutti fruity flavor (W.S),Ponceaus 4R(C.I.16255),sucrose, Purified water to.

Indication:

For the symptomatic relief of symptoms of cold and influenza including feverishness, aches and pains ,headache ;decongestant for the relief of catarrh and blocked sinuses associated with nasal congestion and congestion of mucous membranes of the upper respiratory tract associated with the common cold.

For the relief of allergic rhinitis.

Posology and methods of administration

Adults and children over 12 years: two 5 ml spoonfuls to be taken every 4 to 6 hours daily .

Elderly:the normal adult dose is appropriate in the elderly.

Children 6-12 years : one 5 ml spoonful to be taken every 4-6 hours daily .

The medicine is contraindicated in children under 6years of age .

Children of 6-12 years of age : not to be used for more than 5 days without the advice of a doctor .

Parents and carers should seek medical attention if the child`s condition deteriorates during treatment.

Administration in those with hepatic disorders

Care should be taken in administering this product to patients with severe hepatic impairment.

Administration in those with renal disorders

Care should be taken in administering this product to patients with moderate to severe renal impairment.

Warning: Do not exceed the stated dose.

Keep out of the sight and reach of children.

Contraindications

Hypersensitivity to the active substances or any of the excipients.

severe renal impairment.

Severe liver disease.

Cardiovascular disease including hypertension and peripheral vascular disease.

Diabetes mellitus.

Phaeochromocytoma.

Hyperthyroidism.

Closed angle glaucoma or where intraocular pressure is raised.

Prostatic enlargement.

Patients with chronic or persistent cough such as occurs with asthma, if you are suffering from an acute asthma attack, or where cough is accompanied by excessive secretions.

Dextromethorphan should not be given to subjects in, or at risk of developing respiratory failure.

Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.

Patients taking selective serotonin reuptake inhibitors.

Beta-blockers .

Concomitant use of other sympathomimetic decongestants.

Not to be use in children under the age of 6 years.

Contra-indicated in epileptics because of the antihistamine content.

Contra-indicated in hypertension or in patients receiving antihypertensive therapy.

Special warnings and precautions for use

Dextromethorphan

Should be used with caution in patients with liver disease.

Should be used with caution in atopic children due to histamine release.

Use of Dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses.

Cases of Dextromethorphan abuse have been reported .cautions is particularly recommended for adolescents and young adults as well as in patients with a history of drug abuse or psychoactive substances.

Dextromethorphan is metabolized by hepatic cytochrome P450 2D6. The activity of this enzyme is genetically determined. About 10% of the general population are poor metabolizers of CYP2D6. Poor metabolizers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated and\or prolonged effects of dextromethorphan. Caution should therefore be exercised in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors.

Pseudoephedrine

Caution in moderate to severe renal impairment.

Asthmatics should consult a medical practitioner before using this product.

Caution should be exercised in patients with renal impairment ,urinary retention ,diabetes ,hyperthyroidism , glaucoma, hepatic impairment or cardiovascular disease and those taking other sympathomimetic agents ,such as decongestant, amphetamine- like psychostimulants and appetite suppressants.

The effect of single dose of decerti on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment. As with other sympathomimetic agents, caution should be exercised in patients with prostatic enlargement or bladder dysfunction.

Others

In severe hepatic or renal dysfunction, a single dose of decetri should be given, and the patient`s response used as guide to the dosage requirement for further administration.

If symptoms persist consult your doctor.

Do not exceed the stated dose.

Do not take with other cough or cold medicines.

Should be taken with caution by patients with alcohol dependence.

If any of the following occur, the product should be stopped:

Hallucinations

Restlessness

Sleep disturbances

Not to be given to children under 6 years.

Do not take for longer than five days ,unless your doctor agrees.

If symptoms persist ,consult your doctor.

Do not take with any other decongestant-containing products.

Do not take with any other paracetamol-containing products.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

Interaction with other medicinal products and other forms of interaction

Pseudoephedrine

MAOIs and/or RIMAs: should not be given to patients treated with MAOIs or within 14 days of stopping treatment: increased risk of hypertensive crisis.

Moclobemide: risk of hypertensive crisis.

Antihypertensives(including adrenergic neuron blockers &beta-blockers):this product may block the hypotensive effects.

Cardiac glycosides :increased risk of dysrhythmias .

Ergot alkaloids (ergotamine &methysergide): increased risk of ergotism.

Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension.

Oxytocin-risk of hypertension.

Enhances effect of anticholinergic drugs (such as TCAs).

Concomitant use of this medicine with tricyclic antidepressants and sympathomimetic agents such as decongestants may cause a rise in blood pressure.

The antibacterial agent furazolidone is known to cause progressive inhibition of monoamine oxidase and although there are no reports of a hypertensive crisis having occurred, it should not be administered concurrently with decetri.

Paracetamol

Drugs which induce hepatic microsomal enzymes, such as anticonvulsants and oral contraceptive steroids, may increase the rate at which paracetamol is metabolized, leading to a reduced plasma concentration of the drug.

Alcohol may reduce the capacity of the liver to metabolize paracetamol.

Chronic use of paracetamol enhances the effects of anticoagulants.

Concurrent use of paracetamol with NSAIDs may increase the risk of adverse renal effects. The prolonged combined use of these compounds may increase the risk of renal damage.

Dextromethorphan

Not to be used in patients taking monoamine oxidase inhibitors or within 14 days of stopping treatment as there is a risk of serotonin syndrome (pyrexia, hypertension, arrhythmias) when MAOIs are taken in combination with dextromethorphan.

Dextromethorphan might inhibit additives CNS depressant effects when co-administered with alcohol, antihistamines, psychotropic, and other CNS depressant drugs.

CYP2D6 inhibitors

Dextromethorphan is metabolized by CYP2D6 and has an extensive first-pass metabolism.

Concomitant use of potent CYP2D6 enzyme inhibitors can increase the dextromethorphan concentrations in the body to levels multifold higher than normal. This increases the patient`s risk for toxic effects of dextromethorphan (agitation, confusion, tremor, lonsomnia, diarrhea and respiratory depression) and development of serotonin syndrome. Potent CYP2D6 enzyme inhibitors include fluoxetine, paroxetine, quinidine and terbinafine in concomitant use with quinidine, plasma concentrations of dextromethorphan have increased up to 20-fold which has increased the CNS adverse effects of the agent. Amiodarone, flecainide and propafenone, sertraline, bupropion, methadone, cinacalcet, haloperidol,

perphenazine and thioridazine also have similar effects on the metabolism of dextromethorphan. If concomitant use of CYP2D6 inhibitors and dextromethorphan is necessary, the patient should be monitored and the dextromethorphan dose may need to be reduced.

Fertility, pregnancy and lactation

The use of the product during pregnancy should be avoided.

Use of this product during lactation should be avoided.

Effects on ability to drive and use machines

May cause drowsiness, if affected do not drive or operate machinery. The drowsiness may be potentiated by alcohol or other central sedatives.

The patients should be know:

-the medicine is likely to affect your ability to drive.

-Do not drive until you know how the medicine affects you.

Undesirable effects

Dextromethorphan

The following side effects may be associated with the use of dextromethorphan:

Gastrointestinal disorders: vomiting, gastrointestinal disturbances (nausea and diarrhea).

Nervous system disorder: drowsiness (occasional), dizziness, convulsion.

Psychiatric disorders: excitation, mental confusion.

Respiratory, thoracic and mediastinal disorders :respiratory depression.

Skin and subcutaneous tissue disorders: skin reactions including rash.

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Cardiovascular disorders: tachycardia, palpitations, other cardiac dysrhythmias.

Gastrointestinal disorders: nausea and/or vomiting.

General disorders and administration site conditions: irritability.

Immune system disorders: hypersensitivity reactions, including cross-sensitivity that may occur with other sympathomimetics.

Nervous system disorders: headache, anxiety, restlessness, excitability, insomnia, hallucinations (particularly in children) and paranoid delusions.

Psychiatric disorders: sleep disturbance.

Renal and urinary disorders: difficulty in micturition including urinary retention.

Skin and subcutaneous tissue disorders: skin reactions including rash.

Vascular disorders: hypertension.

Paracetamol

Blood and lymphatic disorders: there have rarely been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

Overdose

Paracetamol

immediate symptoms of overdosage in the first 24 hours include pollar, nausea, vomiting, anorexia, abdominal pain, irritability, restlessness, palpitations, hypertension, difficulty in micturition, thirst and convulsions.

Liver damage may become apparent 12 to 48 hours after ingestion. Though hepatic enzymes may become elevated and prothrombin time prolonged within 10-12 hours of paracetamol overdosage, clinical symptoms may not be apparent for 1 to 6 days following ingestion.

Abnormalities of glucose metabolism and metabolic acidosis may occur in severe poisoning , hepatic failure may progress to encephalopathy , coma, and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

In paracetamol overdosage with hepatic damage, paracetamol half-life is often prolonged from around 2 hours in normal adult to 4 hours or longer.

Liver damage and nephrotoxic effects have been reported after the daily ingestion of excessive amounts of paracetamol. Liver damage is likely in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested); become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of overdosage. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who has ingested around 7.5g or more of paracetamol in the preceding 4 hours

Should undergo gastric lavage and activated charcoal administered to reduce paracetamol absorption. As peak plasma concentrations may be delayed by up to 4 hours following overdose, to accurately assess the risk of hepatotoxicity, plasma paracetamol levels should be measured at least 4 hours post-ingestion.

Generally treatment is required if the blood-paracetamol concentration is higher than a line drawn on semi-log/linear paper joining to points 200mg per liter (1.32mmol/liter) at 4 hours and 30mg per liter(0.2mmol/liter) at 15 hours following ingestion. Administration of oral methionine or intravenous N-acetylcysteine, which may have a beneficial effect up to at least 48 hours after overdose, may be required. It has been proposed that the threshold for treatment with N-acetylcysteine should be reduced by 30-50% in patients taking drugs which induce hepatic enzymes, who abuse alcohol long- term or who are chronically malnourished. These patients may be more susceptible to toxic effects of paracetamol.

Dextromethorphan

It is thought to be of low toxicity, but the effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms: these include nausea and vomiting, CNS depression, dizziness, dysarthria (slurred speech), nystagmus, somnolence (drowsiness), excitation, mental confusion, psychotic disorder (psychosis), and respiratory depression, convulsions.

Management: Treatment of overdose should be symptomatic and supportive. Gastric lavage may be of use. Convulsions should be controlled with intravenous diazepam. The specific narcotic antagonist naloxone can be used to reverse the effects of dextromethorphan.

Information for children

Naloxone has been used successfully to reverse control or peripheral opioid effects of dextromethorphan in children (0.01mg\kg body weight).

Pseudoephedrine

Symptoms: symptoms of overdosage include abdominal discomfort, excitation, confusion, hallucinations, ataxia, irritability, restlessness, palpitations, hypertension, difficulty in micturition and thirst.

Management: In severe overdosage gastric lavage aspiration should be performed.

Symptomatic and supportive measures should be undertaken, particularly with regard to the cardiovascular and respiratory symptoms. Chlorpromazine may be used to control marked excitement and hallucinations. Severe hypertension may need to be treated with an alpha-adrenoreceptor blocking drug, such as phentolamine. A beta-blocker may be required to control cardiac arrhythmias.

Store &package

Store below 30°C.

Carton box printed with product information contains amber glass bottle (Type]]) contains 120 ml syrup with white HDPE plastic closure cap contains white anti-tamper strip (firm rip) (LDPE) and cap is connected to bottle neck by (HDPE) seal off (red colour) and the cap contain foam linear (poly olefin) material and labeled with the product label +inner leaflet.

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