BENYLIN FOUR FLU TABLETS

SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

Benylin Four Flu Tablets

COMPOSITION:

Each tablet contains:

Diphenhydramine hydrochloride	12,5 mg
Paracetamol	500,0 mg
Pseudoephedrine hydrochloride	22,5 mg

PHARMACOLOGICAL CLASSIFICATION:

A: 5.8 Preparations for the common cold including nasal decongestants and antihistaminics.

PHARMACOLOGICAL ACTION:

Benylin Four Flu tablets have antihistaminic, analgesic, decongestant and antipyretic properties.

INDICATIONS:

For the relief of symptoms associated with colds and flu; including coughing, fever, headache, minor aches and pains and nasal congestion.

CONTRA-INDICATIONS:

Known hypersensitivity to any of the ingredients.

Most types of cardiovascular disease, including angina and hypertension, and also in hyperthyroidism, hyperexcitability, phaeochromocytoma and closed angle glaucoma.

Concomitant use of monoamine oxidase inhibitors, or within 14 days of stopping treatment with this class of medicine.

Severe liver disease. Should be avoided in patients undergoing anaesthesia with cyclopropane, halothane, or other halogenated anaesthetics.

Pregnancy and lactation

Safety in pregnancy and lactation has not been established.

WARNINGS:

Do not use continuously for more than ten days; if symptoms persist, irrespective of therapy used, consult your doctor. Dosages in excess of those recommended may cause severe liver or kidney damage.

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned not to drive a motor vehicle, operate dangerous machinery, or climb dangerous heights, as impaired decision making could lead to accidents.

Do not use this product without consulting a doctor or pharmacist if you are presently taking monoamine oxidase inhibitors or other medicines for depression, psychiatric or emotional conditions or hypertension.

Do not take with any other paracetamol-containing products.

DOSAGE AND DIRECTIONS FOR USE:

Adults, the elderly and children

over 12 years: Two tablets four times daily. Do not exceed 8 tablets in 24 hours.

Children 6 to 12 years:	One tablet four times daily. Do not exceed 4 tablets in 24 hours
Children under 6 years:	Not recommended.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Diphenhydramine hydrochloride:

The most common side-effects are sedation, varying from slight drowsiness to deep sleep, and includes lassitude, dizziness and inco-ordination. Other side-effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite, and epigastric pain. Antimuscarinic effects include blurred vision, difficulty in micturition, dysuria, dryness of the mouth, and tightness of the chest. Other central effects include hypotension, muscular weakness, tinnitus, euphoria, and headache.

In infants and children it may act as a cerebral stimulant. Symptoms of stimulation include insomnia, nervousness, tachycardia, tremors and convulsions.

Large doses may precipitate fits in epileptics. Deepening coma, extrapyramidal effects and photosensitization of the skin may occur.

Elderly patients are more susceptible to the central nervous system depressant and hypotensive effects.

Allergic reactions and anaphylaxis may occur. Blood dyscrasias including agranulocytosis, leucopenia and haemolytic anaemia may occur. Diphenhydramine has been reported to cause thrombocytopenia.

The positive results of skin tests may be suppressed.

Paracetamol:

Patients with impaired kidney or liver function should take paracetamol under medical supervision only.

Paracetamol may cause pancreatitis and other allergic reactions in the form of a rash or blood disorders.

Sensitivity reactions resulting in skin rash, laryngeal oedema, angioedema and anaphylaxis have been reported less frequently. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions. Blood disorders such as neutropenia pancytopenia, leucopenia and thrombocytopenia have also been reported.

Pseudoephedrine hydrochloride:

Central effects include fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, and psychotic states. Appetite may be reduced and nausea and vomiting may occur.

Effects on the cardiovascular system include, hypertension, cerebral haemorrhage and pulmonary oedema, reflex bradycardia, tachycardia and cardiac arrhythmias, anginal pain, palpitations, and cardiac arrest. Hypotension with dizziness and fainting and flushing may occur. Hypokalaemia may occur. Other effects include headache, difficulty in micturition and urinary retention, dyspnoea, weakness altered metabolism, including changes in blood sugar levels, sweating, and hypersalivation.

Benylin Four Flu should not be used by patients with cardiovascular disease, hypertension, hyperthyroidism, liver disease, renal disease, glaucoma or diabetes. (see Contra-indications).

This preparation may cause urinary retention in patients with prostatic hypertrophy.

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.

Interactions

Diphenhydramine may potentiate the effects of other CNS depressants such as anti-depressants, minor tranquillisers, neuroleptics, barbiturates and alcohol, and other drugs with anti-cholinergic properties such as tricyclic anti-depressants.

Pseudoephedrine may reverse the effect of antihypertensive agents which modify sympathetic activity, and concomitant use with other sympathomimetic agents such as decongestants, tricyclic anti-depressants and appetite suppressants or with monoamine oxidase inhibitors, which interfere with the catabolism of sympathomimetic amines may cause a rise in blood pressure.

An increased risk of arrhythmias may also occur if sympathomimetic agents are given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Diphenhydramine hydrochloride:

Overdosage may be fatal especially in infants and children.

In infants & children CNS stimulation predominates over CNS depression causing ataxia, excitement, tremors, psychoses, hallucinations and convulsions; hyperpyrexia may also occur. Deepening coma and cardio-respiratory collapse may follow. In adults, CNS depression with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse.

Paracetamol:

Nausea, vomiting and anorexia. Liver damage which may be fatal, may only appear after a few days. Acute intoxication may cause kidney failure.

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person to a hospital directly. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5-10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazapine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage:

Any adult person who has had about 7,5 grams of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken.

An initial dose of 150 mg/kg N-acetylcysteine in 200 ml glucose injection given **intravenously** over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml glucose injection over the next four hours, and then 100 mg/kg in 1000 ml glucose injection over the next sixteen hours. The volume of intravenous fluid should be modified for children.

Orally (not the treatment of choice): 140 mg/kg as a 5% solution initially, followed by 70 mg/kg every four hours for seventeen doses. N-acetylcysteine is more likely to be effective if administered within 8 hours of overdosage.

A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours, unless high, may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-aetylcysteine, can be identified according to their plasma paracetamol level.

If N-acetylcysteine is not available, methionine 2,5 gram may be given immediately, followed by 2,5 g every four hours for three doses. Patients should however preferably be transferred to a facility where N-acetylcysteine can be given.

Monitor all patients with significant ingestions for at least ninety six hours.

Pseudoephedrine hydrochloride:

Convulsions and hyperpyrexia in children due to cerebral stimulation. In adults symptoms of stimulation include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Treatment: Symptomatic and supportive.

IDENTIFICATION:

An orange, oval, biconvex film-coated tablet.

PRESENTATION:

Blister packs of 24 tablets.

STORAGE INSTRUCTIONS:

Store at or below 25°C, in a dry place. Protect from light. Keep blisters in carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

33/5.8/0509

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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