Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Benylin Four Flu Tablets (Diphenhydramine Hydrochloride, Paracetamol, Pseudoephedrine Hydrochloride) Product Information

Presentation:
Orange, oval tablets containing 12.5mg diphenhydramine hydrochloride, 500mg paracetamol, and 22.5mg pseudoephedrine hydrochloride per tablet.
Uses:
Symptomatic relief of colds and flu.
Dosage:
Adults and children over 16 years: two tablets up to four times daily (maximum of 8 tablets per day); Children aged 10 to 15 years: one tablet up to four times daily (maximum of 4 tablets per day).
Contraindications:
Benylin Four Flu Tablets should not be used in children under 10 years of age. This product is contraindicated in individuals with known hypersensitivity to diphenhydramine, paracetamol, pseudoephedrine, or to any of the product's excipients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product should not be used by individuals who are concomitantly taking beta blockers, or other sympathomimetic decongestants, and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. The concomitant use of MAOIs and pseudoephedrine-containing products may result in a rise in blood pressure and/or hypertensive crisis.
Precautions:
Benylin Four Flu Tablets may cause drowsiness. This product should not be used to sedate a child. Caution should be exercised in the presence of hepatic impairment (particularly if accompanied by cardiovascular disease), moderate to severe renal impairment, or occlusive vascular disease. The hazards of overdose are greater in individuals with non-cirrhotic alcoholic liver disease. Patients with thyroid disease who are receiving thyroid hormones should not take Benylin Four Flu Tablets unless directed by a physician. Patients with acute or chronic asthma, persistent or chronic cough such as in chronic bronchitis or emphysema, cough that is accompanied by excessive secretions, urinary retention, prostatic hyperplasia, and susceptibility to

angle closure are advised to consult a physician before using this product. Benylin Four Flu Tablets should be discontinued if hallucinations, restlessness, or sleep disturbances occur.
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of this medicine should be discontinued, and appropriate measures taken if needed.
Some cases of ischaemic colitis have been reported with pseudoephedrine. This product should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding, or other symptoms of ischaemic colitis develop.
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. This product should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.
Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.
Do not use Benylin Four Flu Tablets with any other product containing diphenhydramine, including topical formulations used on large areas of skin. Both diphenhydramine and pseudoephedrine have been associated with central nervous system adverse events. Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, opioid analgesics, antipsychotics, and tranquilizers. Alcoholic beverages should be avoided while taking this product. Avoid taking this product with other paracetamol-containing products as this could lead to overdose. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as this has been associated with high anion gap metabolic acidosis (HAGMA), especially in patients with risks factors such as severe renal impairment, sepsis, malnutrition, and other sources of glutathione deficiency (e.g., chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Pregnancy and lactation:

This product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs any possible risk to the developing foetus. Use during lactation is not recommended.

Side effects:

Very Common: headache, somnolence, sedation.
Common: insomnia, nervousness, dizziness, paradoxical stimulation, psychomotor impairment, vision blurred, increased viscosity of bronchial secretions, dry mouth,

gastrointestinal disorder, nausea, urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor), asthenia.
Uncommon: confusional state, irritability, tinnitus, rash.
Rare: blood disorders, blood dyscrasias (including thrombocytopenia and agranulocytosis), hypersensitivity (cross-sensitivity with other sympathomimetics), depression, sleep disorder, extrapyramidal disorder, seizure, tremor, palpitations, hypotension, liver disorder.
Not Known: anxiety, euphoric mood, excitability, hallucinations, paranoid delusions restlessness, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, ischaemic optic neuropathy, dysrhythmias, myocardial infarction/myocardial ischaemia, tachycardia, hypertension, dyspnoea, nasal dryness, ischaemic colitis, vomiting, angioedema, erythema, fixed eruption, pruritus, rash pruritic, serious skin reactions including acute generalised exanthematous pustulosis (AGEP), urticaria, dysuria, chest discomfort..
RRP (ex-VAT): 24 Tabs: £6.16.
Legal category: P.
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PL Number: 15513/0058.
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