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 biconvex film coated tablets containing 12.5 mg diphenhydramine hydrochloride, 500 mg paracetamol, and 22.5 mg pseudoephedrine hydrochloride per tablet.

Uses:
Symptomatic relief of symptoms associated with colds and flu, including relief of nasal congestion and congestion of mucous membranes of the upper respiratory tract, sneezing, runny nose, coughing, fever, headache, muscular aches and pains.

Dosage:
Adults and children over 16 years: two tablets up to four times daily (maximum of 8 tablets per day). Do not take more frequently than every 4 hours.
Children aged 10 to 15 years: one tablet up to four times daily (maximum of 4 tablets per day). Do not take more frequently than every 4 hours.

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 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.
Pseudoephedrine carries the risk of abuse and increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. Do not exceed the recommended maximum dose and treatment duration. 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.
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. If any of the following occur, this product should be stopped: hallucinations, restlessness & sleep 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.
Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. Avoid taking this product with other paracetamol-containing products as this could lead to overdose.
This medicine contains Sunset yellow (E110), which may cause allergic reactions. It also contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium-free’.
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. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. The safety of pseudoephedrine in pregnancy has not been established. Diphenhydramine is known to cross the placenta and, therefore should only be used during pregnancy if considered essential by a doctor. Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. Paracetamol is also excreted in breast milk but not in a clinically significant amount. Maternal ingestion of therapeutic doses of paracetamol does not appear to present a risk to the infant. Diphenhydramine is excreted into human breast milk, but levels have not been reported. Although the levels are not thought to be sufficiently high enough after therapeutic doses to affect the infant, the use of diphenhydramine during breast-feeding 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, high anion gap metabolic acidosis.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 24's £6.16.

Legal category: P.

PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG

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