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 HCl, 500mg Paracetamol and 22.5mg Pseudoephedrine HCl per tablet.

Uses:
Symptomatic relief of colds and flu.

Dosage:
Tablets: Adults and children over 16 years: Two tablets up to four times daily; Children aged 10 - 15 years: One tablet up to four times daily.

Contraindications:
Use in children under 10 years, known hypersensitivity to diphenhydramine, paracetamol, pseudoephedrine or to any of the excipients, hyperthyroidism, cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, closed-angle glaucoma, severe renal impairment, concomitant use of sympathomimetic decongestants, beta-blockers or MAOIs, or within 14 days of stopping MAOI treatment.

Precautions:
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. Benylin Four Flu Tablets should be stopped if hallucinations, restlessness or sleep disturbances occur. Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine containing products. 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. Pseudoephedrine should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop. Ischaemic optic neuropathy: Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. Rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) have been reported with sympathomimetic drugs, including pseudoephedrine. Pseudoephedrine should be discontinued, and medical advice sought immediately if signs or symptoms of PRES/RCVS develop. Patients with the following conditions should be advised to consult a physician before using this product: acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema or where cough is accompanied by excessive secretions, difficulty in urination,urinary retention and/or prostatic hyperplasia, or with thyroid disease who

are receiving thyroid hormones. Caution in patients with susceptibility to angle-closure, severe hepatic impairment, moderate to severe renal impairment, (particularly if accompanied by cardiovascular disease) or occlusive vascular disease. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin. Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with 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. Taking this product with other paracetamol-containing products could lead to overdose and should therefore be avoided. May cause drowsiness - If patients are affected they should not drive or use machinery. This product should not be used to sedate a child.

Pregnancy and lactation:

Pregnancy: This medicine, like most medicines should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs any possible risk to the developing foetus. Paracetamol, pseudoephedrine and diphenhydramine have been in widespread use for many years without any apparent ill consequence. A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. 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.

Breast-feeding: Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. It has been estimated that approximately 0.4 to 0.7% of a single 60mg dose of pseudoephedrine ingested by a nursing mother will be excreted in the breast milk over 24 hours. Data from a study of lactating mothers taking 60 mg pseudoephedrine every 6 hours suggests that from 2.2 to 6.7% of the maximum daily dose (240 mg) may be available to the infant from a breastfeeding mother. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding. A pharmacokinetic study of paracetamol in 12 nursing mothers revealed that less than 1% of a 650mg oral dose of paracetamol appeared in the breast-milk. Similar findings have been reported in other studies, therefore 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 may occur 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, 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, ischaemic optic neuropathy. Very rare cases of serious skin reactions have been reported with paracetamol.
RRP (ex-VAT): 24 Tabs: £6.16.
Legal category: P.
PL holder: McNeil Products Ltd, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK
PL Number: 15513/0058.
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