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 Day and Night Tablets (paracetamol, diphenhydramine hydrochloride, pseudoephedrine hydrochloride) Product Information

Presentation:
Blue (Night) Tablet containing 500 mg paracetamol and 25 mg diphenhydramine hydrochloride. White (Day) Tablet containing 500 mg paracetamol and 60 mg pseudoephedrine hydrochloride.

Uses:
Relief of the symptoms associated with colds and influenza.

Dosage:
Adults and children over 12 years: one white tablet every 4 to 6 hours (maximum of 3 tablets per day) during the day, one blue tablet at night. Do not take the nighttime tablets during the day.
Under 12 years: not recommended.

Contraindications:
Benylin Day and Night Tablets is contraindicated in individuals with known hypersensitivity to paracetamol, diphenhydramine, 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 Day and Night 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 Day and Night Tablets unless directed by a physician. Patients with acute or chronic asthma, 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, 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. Pseudoephedrine 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. Pseudoephedrine 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 Day and Night 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 or 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 less than 1 mmol sodium (23 mg) per dose, 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 secretion, 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) have been reported following paracetamol use but were not necessarily causally related to the drug, hypersensitivity (cross-sensitivity with other sympathomimetics), depression, sleep disorder, extrapyramidal disorder, seizure, tremor, palpitation, 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): 16's £5.33.

Legal category: P.

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

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