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 500mg Paracetamol and 25mg Diphenhydramine HCl. White (Day) Tablet containing 500mg Paracetamol and 60mg Pseudoephedrine HCl.

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

Dosage: Adults and children over 12 years: One white tablet every 4 – 6 hours (max 3 per day) during the day, one blue tablet at night. Under 12 years: not recommended.

Contraindications: Contraindicated in individuals with known hypersensitivity to diphenhydramine paracetamol, pseudoephedrine or to any of the product's excipients. Concomitant use of other sympathomimetic decongestants, beta-blockers or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. The concomitant use of MAOIs may cause a rise in blood pressure and/or hypertensive crisis. Patients with cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, closed angle glaucoma, hyperthyroidism, and severe renal impairment.

Precautions:

May cause drowsiness. This product should not be used to sedate a child.

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.

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.

There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with

sympathomimetic drugs, including pseudoephedrine. Symptoms reported include sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. 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, patients with thyroid disease who are receiving thyroid hormones.

This product should be used with caution in patients with susceptibility to angle-closure, severe hepatic impairment or moderate to severe renal impairment (particularly if accompanied by cardiovascular disease), or occlusive vascular disease. 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.

Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin. Taking this product with other paracetamol-containing products, could lead to overdose and should therefore be avoided. 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.

Breast-feeding: 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 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 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, 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): 16 tablets £5.32.

Legal category: P.

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

PL Number: 15513/0108.
Date of preparation: 17 June 2022