SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benylin Mucus Cough & Cold All in One Relief Tablets

Sudafed Mucus Relief Triple Action Cold & Flu Tablets

Benylin Chesty Cough & Cold Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	**mg/Tablet**
Paracetamol	250
Guaifenesin	100
Phenylephrine Hydrochloride	5

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

White capsule shaped tablet, embossed with "PGP", free from specks and blemishes.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms associated with colds and flu, including aches and pains, headache, blocked nose and sore throat, chills and chesty cough.

4.2 Posology and method of administration

For oral use. Take tablets with water. Swallow whole, do not chew.

Adults, the Elderly and children aged 12 years and over:

Two tablets. Repeat every four hours as required. Do not take more than 8 tablets (4 doses) in any 24 hour period.

Do not give to children under 12 years, except on medical advice.

Do not take more medicine than the label tells you to.

4.3 Contradictions

Hypersensitivity to paracetamol or any of the other ingredients.

Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease or those taking tricyclic antidepressants or beta-blocking drugs and those patients who are taking or have taken, within the last two weeks, monoamine oxidase inhibitors (see section 4.5). Avoid in patients with prostatic enlargement.

Use in patients with glaucoma or urinary retention.

Use in patients who are currently receiving other sympathomimetic drugs.

Phaeochromocytoma.

Closed angle glaucoma.

4.4 Special warnings and precautions for use

The physician or pharmacist should check that sympathomimetic containing preparations are not simultaneously administered by several routes i.e. orally and topically (nasal, aural and eye preparations).

Care is advised in the administration of paracetamol to patients with severe renal or hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
Patients suffering from chronic cough or asthma should consult a physician before taking this product.

Patients should stop using the product and consult a health care professional if cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache.

Do not take with a cough suppressant.

Medical advice should be sought before taking this product in patients with these conditions: An enlargement of the prostate gland
Occlusive vascular disease (e.g. Raynaud's
Phenomenon) Cardiovascular disease
This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants).

Concomitant use of other paracetamol-containing products should be avoided. If symptoms persist consult your doctor.

Use with caution in patients with circulatory disorders such as Raynaud's Phenomenon.

Patients with prostatic hypertrophy may have increased difficulty with micturition.

Sympathomimetic-containing products may act as cerebral stimulants giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions.

Long term use of the product is not recommended.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Keep out of the sight and reach of children.
Do not take with any other flu, cold or decongestant products.
Contains paracetamol. Do not take anything else containing paracetamol while taking this medicine.
Talk to your doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.

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. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

4.5 Interaction with other medicinal products and other forms of interaction

PARACETAMOL

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of Paracetamol with increased risk of bleeding, occasional doses have no significant effect. The hepato-toxicity of paracetamol may be potentiated by excessive intake of alcohol. Pharmacological interactions involving paracetamol with a number of other drugs have been reported. These are considered to be of unlikely clinical significance in acute use at the dosage

regimen proposed.

Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol particularly after overdosage. Contraindicated in

patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors because of a risk of hypertensive crisis.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risk factors (see section 4.4)

PHENYLEPHRINE HYDROCHLORIDE

Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta blockers.

Sympathomimetic-containing products should be used with great care in patients suffering from angina and in patients receiving phenothiazines or tricyclic antidepressants.

Sympathomimetic-containing products should be used in caution in patients receiving digitalis, beta-adrenergic blockers, guanethidine, reserpine, methyldopa or anti- hypertensive agents

Concurrent use with halogentated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane may provoke or worsen ventricular arrhythmias.

Phenylephrine should be used with caution in combination with the following drugs as interactions have been reported:

Monoamine oxidase inhibitors (including moclobemide)	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors (see contraindications).
Sympathomimetic amines	Concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects.

Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa)	Phenylephrine may reduce the efficacy of beta- blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased.
Tricyclic antidepressants (e.g. amitriptyline)	May increase the risk of cardiovascular side effects with phenylephrine.
Ergot alkaloids (ergotamine and methylsergide)	Increased risk of ergotism
Digoxin and cardiac glycosides	Increase the risk of irregular heartbeat or heart attack

If urine is collected within 24 hours of a dose of this product, a metabolite may cause a colour interference with laboratory determinations of 5 hydroxyindoleacetic acid (5- HIAA) and vanillymandelic acid (VMA).

4.6 Fertility, pregnancy and lactation

PARACETAMOL

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.

This product should not be used during pregnancy without medical advice.

Paracetamol is excreted in breast milk but not in a clinically significant amount. This product should not be used whilst breast feeding without medical advice

GUAIFENESIN

The safety of guaifenesin in pregnancy and lactation has not been fully established but this constituent is not thought to be hazardous. However the product should only be used in pregnancy when considered essential by the doctor.

PHENYLEPHRINE HYDROCHLORIDE

Due to the vasconstrictive properties of Phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce

placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.
The safety of phenylephrine during pregnancy has not been established.
Phenylephrine is excreted in breast milk but not in a clinically significant amount.

This product should not be used whilst breast feeding without medical advice.

4.7 Effects on ability to drive and use machines

None known.

Patients should be advised not to drive or operate machinery if affected by dizziness.

4.8 Undesirable effects

The active ingredients are usually well tolerated in normal use.

PARACETAMOL

Very rare cases of serious skin reactions have been reported.

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by MedDRA System Organ Class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

Body System	Undesirable effect
Blood and lymphatic system disorders	Thrombocytopenia
	Agranulocytosis
	These are not necessarily causally related to paracetamol
Immune system disorders	Anaphylaxis
	Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome, toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction
Gastrointestinal disorders	Acute pancreatitis

Metabolism and nutrition disorders	High anion gap metabolic acidosis**

* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

** Frequency “Not known” (cannot be estimated from the available data)

Description of selected adverse reactions

High anion gap metabolic acidosis

Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

GUAIFENESIN

The frequency of these events is unknown but considered likely to be rare.

Body System	Undesirable effect
Immune system disorders	Allergic reactions, angioedema, anaphylactic reactions
Respiratory, thoracic and mediastinal disorders	Dyspnoea*
Gastrointestinal disorders	Nausea, vomiting, abdominal discomfort,
Skin and subcutaneous disorders	Rash, urticaria

PHENYLEPHRINE HYDROCHLORIDE

The following adverse events have been observed in clinical trials with phenylephrine and may therefore represent the most commonly occurring adverse events.

Body System	**Undesirable effect**
Psychiatric disorders	Nervousness, irritability, restlessness, and excitability
Nervous system disorders	Headache, dizziness, insomnia
Cardiac disorders	Increased blood pressure
Gastrointestinal disorders	Nausea, Vomiting, diarrhoea

Adverse reactions identified during post-marketing use are listed below. The

frequency of these reactions is unknown but likely to be rare.

Eye disorders	Mydriasis, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma
Cardiac disorders	Tachycardia, palpitations

Skin and subcutaneous disorders	Allergic reactions (e.g. rash, urticaria, allergic dermatitis). Hypersensitivity reactions including cross-sensitivity with other sympathomimetics may occur.
Renal and urinary disorders	Dysuria. Urinary retention. This is more likely to occur in men with an enlarged prostate.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

PARACETAMOL

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors

If the patient

a) is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

or

b) Regularly consumes ethanol in excess of recommended amounts.

or

c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with

acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be accordance with established treatment guidelines, see British National Formulary (BNF) overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within one hour. Plasma paracetamol concentration should be measured at four hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine, may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to eight hours post-ingestion.

The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the National Poisons Information Service (NPIS) or a liver unit.

GUAIFENESIN

Symptoms and signs

Very large doses of guaifenesin can cause nausea and vomiting.

Treatment

Vomiting should be treated by fluid replacement and monitoring of electrolytes if indicated.

PHENYLEPHRINE HYDROCHLORIDE

Symptoms and signsPhenylephrine overdosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include hypertension and possibly reflux bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However the amount required to produce serious phenylephrine toxicity would be greater than required to cause paracetamol-related toxicity.

Treatment

Treatment should be as clinically appropriate. Severe hypertension may need to be treated with an alpha blocking drug such as phentolamine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other analgesics and antipyretics &
Other cold combination preparations

ATC code: N02B E51

Paracetamol is an analgesic and antipyretic.

Guaifenesin is an expectorant.

Phenylephrine Hydrochloride is a sympathomimetic decongestant.

The active ingredients are not known to cause sedation.

5.2 Pharmacokinetic properties

Paracetamol is rapidly absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine, mainly as the glucuronide and sulphate conjugates.

Guaifenesin is rapidly absorbed after oral administration. It is rapidly metabolised by oxidation to β-(2 methyoxy-phenoxy) lactic acid, which is excreted in the urine.

Phenylephrine hydrochloride is irregularly absorbed from the gastrointestinal tract and undergoes first-pass metabolism by monoamine oxidase in the gut and liver; orally administered phenylephrine thus has reduced bioavailability. It is excreted in the urine almost entirely as the sulphate conjugate.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Microcrystalline cellulose
Stearic acid
Povidone

Film Coat:
Hypromellose
Polyethylene glycol

6.2 Incompatibilities

None known

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Child Resistant PVC/Al blister.

Pack sizes: 8, 12 and 16 tablets.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Limited (T/A Perrigo)

Braunton

Devon

EX33 2DL

8 MARKETING AUTHORISATION NUMBER(S)

PL 12063/0112

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/11/2024

10 DATE OF REVISION OF THE TEXT

14/06/2025