SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots All In One Max Strength Cold & Flu Relief Capsules, hard
Morrisons All in One Max Strength Cold & Flu Capsules, hard
Tesco Health Max Strength All-In-One Cold & Flu Relief Capsules
Olbas Max Strength All-In-One Cold and Flu Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	**mg/Capsule**
Paracetamol	500
Guaifenesin	100
Phenylephrine hydrochloride	6.1

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard (Capsules)

Dark blue/dark green hard gelatin capsules containing the drug product, an off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms associated with colds and flu and the pain and congestion of sinusitis, including aches and pains, headache, blocked nose and sore throat, chills, lowering of temperature, and to loosen stubborn mucus and provide relief from chesty coughs.

4.2 Posology and method of administration

Route of administration: Oral.
Swallow whole with water. Do not chew.

For all indications:

Adults, the elderly and children aged 16 years and over:
Two capsules every 4 to 6 hours when necessary to a maximum of 8 capsules (4 doses) in 24 hours.

Dosage should not be continued for longer than 3 days without consulting a doctor.

Children under 16 years:
Do not give to children under 16 years old.

4.3 Contraindications

Hypersensitivity to paracetamol and /or any of the 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).
Use in patients with glaucoma or urinary retention.

Use in patients who are currently receiving other sympathomimetic drugs.

Phaeochromocytoma.

Closed angle glaucoma.

Avoid in patients with prostatic enlargement.

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 Raynaud's Phenomenon and diabetes mellitus.

Patients with prostatic hypertrophy may have increased difficulty with micturition.

Sympathomimetic-containing products should be used with great care in patients suffering from angina.

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 with alcohol.

This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'.

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

Special label warnings
If you are taking medication or are under medical care, consult your doctor before using this medicine.

CONTAINS PARACETAMOL
Do not take anything else containing paracetamol while taking this medicine. Talk to a doctor at once if you take too much of this medicine, even if you feel well. Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.
Do not take with other flu, cold or decongestant products.
Keep out of the sight and reach of children.

Special leaflet warnings

Talk to a 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. Go to your nearest hospital casualty department. Take your medicine and this leaflet with

you.

If you are taking medication or are under medical care, consult your doctor before using this medicine.

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, although 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 receiving phenothiazines or tricylic antidepressants.

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

Concurrent use with halogenated 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 methysergide)	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

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

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.

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

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

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.

Very rare cases of serious skin reactions have been reported.

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 most 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: N02BE51

PARACETAMOL

Analgesic:

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting a prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic:

Paracetamol probably produces antipyresis by acting on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

GUAIFENESIN

Guaifenesin is a well known expectorant. Such expectorants are known to increase the volume of secretions in the respiratory tract and therefore to facilitate their removal by cilary action and coughing.

PHENYLEPHRINE HYDROCHLORIDE

Sympathomimetic amines, such as phenylephrine, act on alpha-adrenergic receptors of the respiratory tract to produce vasoconstriction, which temporarily reduces the swelling associated with inflammation of the mucous membranes lining the nasal and sinus passages. This allows the free drainage of the sinusoidal fluid from the sinuses.

In addition to reducing mucosal lining swelling, decongestants also suppress the production of mucus, therefore preventing a build up of fluid within the cavities which could otherwise lead to pressure and pain.

5.2 Pharmacokinetic properties

PARACETAMOL

Absorption and Fate

Paracetamol is rapidly absorbed from the gastro-intestinal tract with peak plasma concentrations occurring between 10 and 120 minutes after oral administration. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours.

Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdose and cause liver damage.

GUAIFENESIN

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

PHENYLEPHRINE HYDROCHLORIDE

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

Maize starch

Croscarmellose sodium

Sodium laurilsulfate

Magnesium stearate

Talc

Gelatin capsule:

Gelatin

Quinoline yellow E104

Indigo carmine E132

Erythrosine E127

Titanium dioxide E171

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Child Resistant blister comprising 250 micron PVC lidded with 35 gsm paper/9 micron aluminium foil.

Pack sizes of 8 and 16 capsules are available.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Limited
Braunton
Devon
EX33 2DL

8 MARKETING AUTHORISATION NUMBER(S)

PL 12063/0105

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/12/2024

10 DATE OF REVISION OF THE TEXT

16/04/2025