SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Beechams Max Strength All in One Hot Cranberry and Blackcurrant, powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single-dose sachet contains paracetamol 1000 mg, guaifenesin 200 mg and phenylephrine hydrochloride 12.2 mg.

Excipients:
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.
Grey to purple fine powder with a cranberry odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This product is indicated in adults and children aged 16 years and older for the short-term relief of the symptoms of influenza, feverishness, chills and colds including headache, chesty cough, sore throat pain, aches and pains, nasal congestion, sinusitis and its associated pain, and acute nasal catarrh.

4.2 Posology and method of administration

Posology

Adults (including the elderly) and children aged 16 years and over:
One sachet, dissolved in a standard mug of hot water but not boiling water (approximately 250 ml), to be taken every four to six hours, up to a maximum of four sachets in any 24 hours.

Minimum dosing interval: four hours

Do not exceed the stated dose.

Maximum duration of continued use without medical advice: 7 days.

Paediatric population
Children under 16 years of age:
Not to be given to children under 16 years of age, except under medical advice.
The safety of this product in children aged from birth to 16 years of age has not been established (see section 5.1). No data are available.

Populations

Patients with hepatic impairment:
Patients who have been diagnosed with hepatic impairment must seek medical advice before taking this medicine. The restrictions related to the use of such combinations in patients with hepatic impairment are primarily a consequence of the paracetamol content of the product (see Section 4.4 Special Warnings and Precautions for Use).

Patients with renal impairment:
Patients who have been diagnosed with renal impairment must seek medical advice before taking this medicine. The restrictions related to the use of such combinations in patients with renal impairment are primarily a consequence of the paracetamol content of the product (see Section 4.4 Special Warnings and Precautions for Use).

Method of administration
For oral use. Dissolve one sachet in a standard mug of hot water but not boiling water (approximately 250 ml). A purple solution slightly cloudy with an odour of cranberry will be obtained.
To be taken as a warm drink.

4.3 Contraindications

- Hypersensitivity to any of the drug substances or to any of the excipients.
- Use in patients who are taking, or have taken, within the last two weeks, monoamine oxidase inhibitors (MAOIs) (see Section 4.5 Interaction with other medicinal products and other forms of interaction).
- Concomitant use of other sympathomimetic decongestants.
- Phaeochromocytoma.
- Closed angle glaucoma.
- Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease or those taking tricyclic antidepressants or beta-blocking drugs.

Contains sucrose: Patients with rare hereditary problems of fructose intolerance, glucose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains a source of phenylalanine. May be harmful to people with phenylketonuria.

4.4 Special warnings and precautions for use

Medical advice should be sought before taking this product in patients with the following conditions: hypertension, cardiovascular disease, diabetes, hyperthyroidism, angle closure glaucoma, phaeochromocytoma, an enlargement of the prostate gland, occlusive vascular disease (e.g. Raynaud's Phenomenon).

Patients suffering from chronic cough or asthma should consult a physician before taking this product. Do not take with a cough suppressant.

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. Underlying liver disease increases the risk of paracetamol related liver damage.

Use with caution in patients taking beta-blockers and other antihypertensive drugs or tricyclic antidepressants (see Section 4.5 Interaction with other Medicaments and other forms of interaction).

This product should not be used by patients taking other sympathomimetics (e.g. decongestants, appetite suppressants and amphetamine-like psychostimulants) (see Section 4.5 Interaction with other Medicaments and other forms of interaction).

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.

Contains paracetamol.

If symptoms persist or are accompanied by a fever, rash or persistent headache. consult your doctor. Prolonged use of this product, except under medical supervision, may be harmful. Maximum duration of use without medical advice is 7 days.

Do not take other medicines containing paracetamol, decongestants or cough and cold products while using 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.

This product should only be used when clearly necessary.

Do not exceed the stated dose.

This medicinal product contains 117 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Paediatric Population

For children aged 16 years and over:

See above.

Keep all medicines out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Paediatric Population
No interaction studies have been performed.

Paracetamol:

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged, regular, daily 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. The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. 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.

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 risks factors (see section 4.4).

Phenylephrine Hydrochloride:

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

Monoamine oxidase inhibitors	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine hydrochloride and monoamine oxidase inhibitors (see Section 4.3 Contraindications).

Sympathomimetic amines	Concomitant use of phenylephrine hydrochloride with other sympathomimetic amines can increase the risk of cardiovascular side effects (see Section 4.4 Special Warnings and Precautions for Use).
Beta-blockers, and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa	Phenylephrine hydrochloride may reduce the efficacy of beta-blocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased (see Section 4.4 Special Warnings and Precautions for Use).
Tricyclic antidepressants (e.g. amitriptyline	May increase the risk of cardiovascular side effects with phenylephrine hydrochloride (see Section 4.4 Special Warnings and Precautions for Use).
Ergot alkaloids (ergotamine and methylsergide)	Increased risk of ergotism
Digoxin and cardiac glycoside	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).

Guaifenesin

No significant interactions with other drugs have been noted for Guaifenesin.

4.6 Fertility, Pregnancy and lactation

Pregnancy:

There are limited data from the use of paracetamol, phenylephrine hydrochloride and guaifenesin in pregnant women.

Beechams Ultra All in One Hot Cranberry is not recommended during pregnancy without medical advice.

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. The safety of phenylephrine during pregnancy has not been established.

Breastfeeding:
Physiochemical data suggest excretion of paracetamol, phenylephrine hydrochloride or guaifenesin and their metabolites in human milk.

A risk to the newborn/infants cannot be excluded.

Paracetamol and Phenylephrine hydrochloride may be excreted in breast milk.

Beechams Ultra All in One Hot Cranberry should not be used during breast-feeding without medical advice.

4.7 Effects on ability to drive and use machines

Beechams Ultra All in One Hot Cranberry and Blackcurrant may have a moderate influence on the ability to drive and use machines. Patients should be advised not to drive or use machines if affected by dizziness.

4.8 Undesirable effects

The drug substances paracetamol, phenylephrine hydrochloride and guaifenesin are usually well tolerated in normal use.

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.

Paracetamol

The frequency of these paracetamol-related adverse reactions is unknown but based on estimate from post-marketing data are likely to be 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.
Metabolism and nutrition disorders	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). (Frequency not known).
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs.
Hepatobiliary disorders	Hepatic dysfunction
Gastrointestinal disorders	Acute pancreatitis

Guaifenesin

The frequency of these guaifenesin-related adverse reactions is unknown but based on estimate from post-marketing data are 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

*dyspnoea has been reported in association with other symptoms of hypersensitivity

Phenylephrine hydrochloride:

The following adverse events have been observed in clinical studies involving phenylephrine hydrochloride and are considered to be the most commonly occurring. Adverse events are listed below by MedDRA System Organ Class.

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.

Body System	**Undesirable effect**
Eye disorders	Mydriasis, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma (see Section 4.3 Contraindications and Section 4.4 Special Warnings and Precautions for Use).
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 those with bladder outlet obstruction such as prostatic hypertrophy.

Paediatric population

See above.

4.9 Overdose

Paracetamol

Immediate medical attention (in-hospital, if possible) is required in the event of overdose, even if there are no significant early symptoms. There may be no early symptoms following a life-threatening overdose.

Ingestion of more than 12 g paracetamol (24 standard 500 mg tablets, or 12 sachets) or more than 150 mg paracetamol per kg body weight (9 g of paracetamol in a 60 kg individual), whichever is the smaller, can cause severe liver damage. Liver damage (as demonstrated by a rise in plasma transaminase levels) may be apparent between 8 and 36 hours following overdose. Biochemical evidence of maximal damage, however, may not be attained until 72-96 hours after ingestion of the overdose.

Intravenous N-acetylcysteine (NAC) is effective when initiated within 8 hours of the overdose. Efficacy declines progressively after this time, but NAC may provide some benefit up to and possibly beyond 24 hours. Oral methionine is

also effective provided that it is given within 10 to 12 hours of the overdose. Activated charcoal should be considered if the dose of paracetamol ingested exceeds 12 g or 150 mg/kg, whichever is the smaller, and the procedure can be undertaken within one hour of the overdose. There is little evidence that undertaking gastric lavage will be of benefit to a patient in whom paracetamol is known to have been the only substance ingested.

Symptoms of paracetamol overdose in the first 24 hours may include pallor, nausea, vomiting, anorexia and abdominal pain. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Liver damage results when excess quantities pf a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrythmias and pancreatitis have been reported.

Phenylephrine hydrochloride
Phenylephrine hydrochloride overdosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms of phenylephrine hydrochloride overdose include headache, an increase in blood pressure and possibly associated reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur.

Treatment should be as clinically appropriate. Raised blood pressure should be treated with an alpha receptor antagonist such as intravenous phentolamine. Reduction of blood pressure should, by reflex mechanism, increase the heart rate but if necessary this can be facilitated by the administration of atropine.

Guaifenesin
Very large doses of guaifenesin cause nausea and vomiting. Vomiting would be treated by fluid replacement and monitoring of electrolytes if indicated.

Paediatric population
See above.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics, paracetamol, combinations excluding psycholeptics.

ATC Code: N02BE51.

Paracetamol
Paracetamol is an analgesic, antipyretic drug substance.

The antipyretic activity of paracetamol is thought to be mediated by its ability to selectively inhibit prostaglandin synthesis in the central nervous system.

The precise mechanism for the analgesic properties of paracetamol remains to be established. Data suggest that central prostaglandin synthetase inhibition is likely to be of primary importance. Paracetamol is a weak inhibitor of COX-1 and COX-2 leading to the suggestion that there may be another form of COX which is more sensitive to inhibition by paracetamol.

Paracetamol does not appear to inhibit the peripheral generation of prostaglandins, e.g., it does not alter the gastric mucosal generation of prostaglandins and serious gastro-intestinal adverse events associated with paracetamol are rare. Paracetamol is, therefore, particularly suitable for patients with a history of acid peptic disease or on concomitant medication where peripheral prostaglandin inhibition would be undesirable, e.g. with gastro-intestinal bleeding, cardiovascular disease or in the elderly.

Guaifenesin
Guaifenesin has an expectorant action. It is thought to reduce sputum viscosity by increasing the volume and water content of the bronchial secretion, thereby facilitating the expectoration of sputum.

Phenylephrine hydrochloride
Phenylephrine hydrochloride is a sympathomimetic post-synaptic α-receptor agonist with low cardioselective β-receptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

5.2 Pharmacokinetic properties

Paracetamol

Absorption and Distribution
Oral paracetamol is readily absorbed from the upper small intestine to give peak plasma concentrations of 15-20 mcg/ml in 30 to 120 minutes after oral administration of a 1000 mg dose in adults. The speed of gastric emptying modifies the rate of absorption. Plasma protein binding is minimal and there is distribution to all tissues.

Metabolism and Excretion
There is limited first-pass metabolism of paracetamol after oral administration and about 80% of a 1000 mg dose is bioavailable. Paracetamol is metabolised primarily in the liver. After a 1000 mg oral dose in adults, 50-60% is recovered in the urine as the glucuronide conjugate, 25-35% as the sulphate conjugate, up to 5% as unchanged paracetamol and 2-5% as the cysteine or mercapturate metabolites.

The latter are formed from the combination of glutathione with the oxidation

metabolite of paracetamol, N-acetyl-p-benzoquinoneimine (NAPQI). Excretion via the urine is rapid and the plasma half-life after oral administration is 1-4 hours.

Guaifenesin
Guaifenesin is well-absorbed after oral administration. Guaifenesin had a plasma half-life of approx 1 hour and was not detectable in the blood after 8 hours. No information is available on the distribution of guaifenesin in humans. It appears to undergo both oxidation and demethylation. It is excreted in urine.

Phenylephrine hydrochloride
Phenylephrine hydrochloride is irregularly absorbed from the gastro-intestinal tract after oral administration. It is subject to extensive presystemic metabolism in the gut wall and therefore has a systemic bioavailability of approximately 40% relative to intravenous dosing. Following oral administration, peak plasma concentrations are achieved in 1 - 2 hours. The mean plasma half-life is in the range 2 - 3 hours.
The volume of distribution is large (200 to 500 litres). Penetration of the brain and excretion in breast milk appear to be minimal. Phenylephrine hydrochloride does not cross the placenta. The extent of protein binding is unknown.
Phenylephrine hydrochloride is extensively metabolised in the gut wall and liver. The principal routes of metabolism are sulphation and glucuronidation of the 3-hydroxyl group and oxidative deamination by monoamine oxidase to 3-hydroxymandelic acid and 3-hydroxyphenylglycol. Sulphate conjugates are formed from the metabolites. Excretion is via the kidneys.

Paediatric population
The pharmacokinetic profile of oral paracetamol in children is similar to that seen in adults, whereas in neonates clearance of paracetamol is significantly reduced with a longer half-life seen. Infants have usually developed similar clearances of paracetamol to older children by the age of one year.

5.3 Preclinical safety data

Nonclinical data [*published in the literature]* reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Nonclinical safety data on the drug substances in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product, which have not already been mentioned elsewhere in the SPC.

The toxicity of paracetamol is well documented.
Effects of chronic toxicity in rats and mice include gastrointestinal lesions, blood count changes, degeneration and necrotic changes in testicular and

lymphoid tissue in addition to hepatic and renal necrosis.

Long-term studies in rats and mice give no conclusive evidence of carcinogenic effects. There is no evidence of embryo- or foeto-toxicity from paracetamol in animal studies.
Paracetamol hepatotoxicity is directly dependent on the plasma concentration in relation to time. In man, plasma concentrations above 1.2 mmol/l at 4 hours, 0.6 mmol/l at 8 hours and 0.3 mmol/l at 12 hours are criteria for immediate antidote treatment to prevent irreversible damage.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica, Colloidal Anhydrous
Maize Starch
Sucrose
Sodium Citrate
Citric Acid
Aspartame (E951)
Saccharin Sodium (E954)
Cranberry Blackcurrant Flavour
Natural Grapeskin Red Colour

6.2 Incompatibilities

Not applicable.

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

Individual single dose paper/PE/aluminium foil laminate sachets containing 6.6 g of Beechams Ultra All in One Hot Cranberry and Blackcurrant.

Supplied in packs of five or ten sachets.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
The Heights
Weybridge
Surrey
KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/11/2024

10 DATE OF REVISION OF THE TEXT

18/02/2025