SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Beechams Multi-symptom Relief Oral Solution

Beechams All in One Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 20 ml dose contains paracetamol 500 mg, guaifenesin 200 mg and phenylephrine hydrochloride 10 mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Oral Solution.
A clear, bright amber liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Short term symptomatic relief of colds, chills and influenza including chesty coughs.

4.2. Posology and Method of Administration

Adults and children 16 years and over
One 20 ml measured dose (or four 5 ml spoonfuls). Repeat every four hours as necessary. Do not exceed four doses per 24 hours.

Not to be given to children under 16 years except on

medical advice.

Elderly
The normal adult dose may be taken.

Do not take continuously for more than 5 days without medical advice

4.3 Contraindications

Hypersensitivity to paracetamol and/or other constituents.
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 and those patients who are taking or have taken, within the last two weeks, monoamine oxidase inhibitors (see section 4.5).

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe 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)

The amount of alcohol should be taken into account in children and high-risk groups.

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.

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

Special label warnings
Do not take with any other paracetamol-containing products. Do not take with other flu, cold or decongestant products.

Immediate medical advice should be sought in the event of an overdose, even if you feel well.
Contains ethanol, glycerol, sorbitol and Sunset Yellow, see leaflet for further information.

Special leaflet warnings
Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.
This medicinal product contains 19% v/v ethanol (alcohol) i.e. 3.8 ml per 20 ml dose, equivalent to 76
ml beer or 31.6 ml wine.
Harmful for those suffering from alcoholism.
To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy. Glycerol may cause headache, stomach upset and diarrhoea. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Contains sorbitol 4.7 g per dose, a source of 1.175 g fructose.
Sunset Yellow (E110) may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

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. 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 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

This product should not be used 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 guaiphenesin and phenylephrine during pregnancy has not been established.

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

The amount of alcohol in the product should be taken into account by pregnant or lactating women.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate machinery if affected by dizziness.
The amount of alcohol in this product may impair the ability to drive or use machines.

4.8 Undesirable effects

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, angiodema and Stevens Johnson syndrome, toxic epidermal necrolysis
Metabolism and nutrition disorders	High anion gap metabolic acidosis* (frequency not known)
Respiratory, thoracic and mediastinal disorders	Bronchospasm**
Hepatobiliary disorders	Hepatic dysfunction
Gastrointestinal disorders	Acute pancreatitis

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

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 those with bladder outlet obstruction, such as prostatic hypertrophy.

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

4.9 Overdose

Paracetamol

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g 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, phenobarbitone, 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 in accordance with established treatment guidelines, see BNF overdose section.
Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 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 8 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 24h from ingestion should be discussed with the NPIS or a liver unit.

Phenylephrine

Symptoms and signs
Phenylephrine overdosage is likely to result in effects similar to those listed under advserse reactions. Additional symptoms may include irritability, restless, hypertension and possibly reflux bradycardia. In severe cases confusion, hallucinations, seizures and arrythmias 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.

Guaifenesin

Symptoms and signs
Very large doses of guaifenesin cause nausea and vomiting.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: N02BE 51 Paracetamol combinations excluding psycholeptics.

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

Guaifenesin is rapidly absorbed after oral administration. It is rapidly metabolised by oxidation to ß-(2 methoxy-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 has reduced bioavailability. It is excreted in the urine almost entirely as the sulphate conjugate.

5.3 Preclinical safety data

Preclinical safety data on these active ingredients in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not already been mentioned elsewhere in this Summary.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol 70 per cent (crystallising) (E420), glycerol (E422), alcohol (96%), propylene glycol, sodium cyclamate (E952), acesulfame potassium (E950),

sodium citrate (E331), xanthan gum (E415), citric acid monohydrate (E330), coughsweet flavour, sunset yellow (E110), Patent Blue V (E131), water.

6.2 Incompatibilities

None known.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Bottle: amber flint glass with Child Resistant Closure: polypropylene/HDPE with polyester-coated aluminium faced boxboard wad. Contains 240 ml.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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Weybridge
Surrey
KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0020

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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