SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Flamingo Cold and Flu with Chesty Cough Relief 500mg/ 100mg/ 6.1mg hard capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard (capsule)

Size "0" hard gelatin capsules with, blue translucent cap & green translucent body, containing white to off-white granular powder or powder plug. The length of capsule is 21.38 mm.

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 mucous and provide relief from chesty coughs.

4.2 Posology and method of administration

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

Adults, the elderly and children aged 16 years and over:
Two capsules every four hours as required. Do not take more than 8 capsules (4 doses) in any 24 hour period.

Do not exceed the stated dose.

Minimum dosing interval: 4 hours.

The lowest dose necessary to achieve efficacy should be used for the shortest duration of treatment.

Maximum daily dose: Eight capsules (4000 mg paracetamol, 800 mg guaifenesin, 48.8 mg phenylephrine HCl) in any 24 hour period.

Not to be given to children under 16 years except on medical advice.

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

4.3 Contraindications

Known hypersensitivity to any of the ingredients.

Concomitant use of other sympathomimetic decongestants.

Phaeochromocytoma.

Closed angle glaucoma.

An enlargement of the prostate gland.

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

Contains paracetamol. Do not take with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which may require liver transplant or lead to death

Concomitant use of decongestants and other cough and cold medicines should be avoided.

Medical advice should be sought before taking this product in patients with:

- Occlusive vascular disease (e.g. Raynaud's Phenomenon)
- Glutathione depletion due to metabolic deficiencies
- Chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema.

Use with caution in patients taking the following medications (see Interactions)

- vasoconstrictor agents such as ergot alkaloids (e.g. ergotamine and methysergide)
- digoxin and cardiac glycosides

Do not take with a cough suppressant.

This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) (see section 4.5).

Special label warnings
If you are taking medication or are under medical care, consult your doctor before using this medicine.
Do not exceed the stated dose.
If symptoms persist consult your doctor. Keep out of the sight and reach of children.

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

Special leaflet warnings
Contains paracetamol.
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.

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 end 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.

Excipient-related

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

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding. The hepatotoxicity 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.

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
Warfarin and other coumarins	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.

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).

No significant interactions with other drugs have been noted for guaifenesin.
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)

4.6 Fertility, pregnancy and lactation

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

Human and animal studies with paracetamol have not identified any risk to pregnancy or embryo-foetal development.

No relevant data are available for products containing phenylephrine.

The safety of guaifenesin during pregnancy has not been established.

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

Human studies with paracetamol have not identified any risk to lactation or the breast-

fed offspring.

Paracetamol crosses the placental barrier and is excreted in breast milk. Phenylephrine may be excreted in breast milk.

No relevant data available for guaifenesin.

4.7 Effects on ability to drive and use machines

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

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.
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	Very rare cases of serious skin reactions have been reported. Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes and angioedema
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Hepatic dysfunction
Gastrointestinal disorders	Acute pancreatitis
Metabolism and nutrition disorders	High anion gap metabolic acidosis(Frequency-Not known)

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

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.

Body System	**Undesirable effect**
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 that cross- sensitivity may occur with other sympathomimetics
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

*Dyspnoea has been reported in association with other symptoms of hypersensitivity.

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 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, even if symptoms of overdose are not present. 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 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
Very large doses of guaifenesin can cause nausea and vomiting.

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

Phenylephrine
Symptoms
Phenylephrine overdosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include irritability, restlessness, 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 liver 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 ciliary 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 mucous, 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

There are no preclinical data of relevance to the prescriber additional to that already covered in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Sodium laurilsulfate
Povidone K-30
Croscarmellose Sodium
Magnesium Stearate
Purified Talc

Empty Hard Gelatin capsule"0" blue cap/green body

Capsule body contains:
Brilliant blue FCF (E 133)
Iron oxide black (E 172)
Patent blue V (E 131)
Iron oxide yellow (E 172)
Gelatin
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

This medicine is available in cartons containing child-resistant white opaque aluminium-PVC/PVDC blister packs of 8, 12 and 16 capsules.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Flamingo Pharma UK Ltd.
First floor, Kirkland House,
11-15 Peterborough Road,

Harrow, Middlesex,
HA12AX, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 43461/0159

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/04/2026

10 DATE OF REVISION OF THE TEXT

02/04/2026