SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Flu-Gone C+F Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:
Paracetamol.....600mg
Chlorpheniramine Maleate..... 4mg
Pseudoephedrine Hydrochloride..... 60mg

3. PHARMACEUTICAL FORM

White colored oblong shaped Tablets with "FLU-GONE CF" marking on one side and bisect reverse.

4. Clinical particulars

4.1 Therapeutic indications

Flu-Gone C&F provides effective relief from cold and flu symptoms including pain & fever, congestion or symptoms associated with allergies such as rhinitis, sinusitis, running nose and sneezing.

4.2 Posology and method of administration

Adults and children over 12 years:
1 Tablet3 times daily or as advised by the physician.
The dose should not be repeated before 6 hours. Do not exceed the recommended dose.

Method of administration
Oral

4.3 Contraindications

Hypersensitivity of any of the constituents of Flu-Gone C+F Tablets, hypertension, severe coronary artery disease or with monoamine oxidase inhibitor.

4.4 Special warnings and precautions for use

Paracetamol:

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 should be advised that paracetamol may cause severe skin reactions. If a skin reaction such as skin reddening, blisters, or rash occurs, they should stop use and seek medical assistance right away.

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

The concomitant use with other products containing paracetamol may lead to an overdose Underlying liver disease increases the risk of paracetamolrelated liver damage. Patients who have been diagnosed with hepatic or renal impairment must seek medical advice before taking this medication. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Cases of hepatic dysfunction/ failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index, dehydrated, are chronic heavy users of alcohol or have sepsis. In patients with glutathionedepleted states the use of paracetamol may increase the risk of metabolic acidosis

Chlorpheniramine Maleate:

Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion. The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients, which may seriously affect ability to drive and use machinery.

The effects of alcohol may be increased and therefore concurrent use should be avoided. Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Concurrent use with drugs, which cause sedation such as anxiolytics and hypnotics, may cause an increase in sedative effects; therefore, medical advice should be sought before taking chlorphenamine concurrently with these medicines

Pseudoephedrine Hydrochloride:

Flu-Gone C+F Tablets containing Pseudoephedrine Hydrochloride hence used with caution in patients with hypertension, heart disease, diabetes, hyperthyroidism, elevated intraocular pressure and prostatic enlargement.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol:
Colestyramine:
The speed of absorption of paracetamol is reduced by colestyramine. Therefore, the cholestyramine should not be taken within one hour if maximal analgesia is required.

Metoclopramide and Domperidone:
The absorption of paracetamol is increased by metoclopramide and domperidone. However, concurrent use need not be avoided.

Warfarin and other anticoagulants:
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.

Chloramphenicol: Increased plasma concentration of chloramphenicol.

Flucloxacillin:
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.

Chlorpheniramine Maleate:

Concurrent use of chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects; concurrent use of alcohol may have a similar effect therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines. Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity. The anticholinergic effects of chlorphenamine are intensified by MAOIs Pseudoephedrine Hydrochloride:

MAOIs and/or RIMAs: Pseudoephedrine exerts its vasoconstricting properties by stimulating
α -adrenergic receptors and displacing noradrenaline from neuronal storage sites. Since monoamine oxidase inhibitors (MAOIs) impede the metabolism of sympathomimetic amines and increase the store of releasable noradrenaline in adrenergic nerve endings, MAOIs may potentiate the pressor effect of pseudoephedrine. This product should not be used in patients taking monoamine inhibitors or within 14 days of stopping treatment as there is an increased risk of hypertensive crisis.

Moclobemide: Risk of hypertensive crisis.

Antihypertensives: Because of its pseudoephedrine content, this product may partially reverse the hypotensive action of antihypertensive drugs which interfere with sympathetic activity including bretylium, betanidine, guanethedine, debrisoquine, methyldopa, adrenergic neurone blockers and beta-blockers.

Cardiac glycosides: Increased risk of dysrhythmias.

Ergot alkaloids (ergotamine & methysergide): Increased risk of ergotism.

Appetite suppressants and amphetamine-like psychostimulants: Risk of hypertension.

Oxytocin: Risk of hypertension.

Anticholinergic drugs: Enhances effects of anticholinergic drugs (such as Tricyclic antidepressants).

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

4.6 Fertility, pregnancy, and lactation

Pregnancy 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.

Chlorpheniramine Maleate:
There are no adequate data from the use of Chlorpheniramine in pregnant women. The potential risk for humans is unknown, use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essential by a physician.
Pseudoephedrine Hydrochloride:

There are no adequate and well-controlled studies in pregnant women. This product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus.

Breastfeeding Paracetamol:
Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Chlorpheniramine Maleate:
Chlorpheniramine maleate and other antihistamines may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician.

Pseudoephedrine Hydrochloride:
This product should not be used during lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the breastfeeding infant.
Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breastfed infants is not known. It has been estimated that approximately 0.4 to 0.7% of a single 60 mg dose of pseudoephedrine ingested by a nursing mother will be excreted in the breast milk over 24 hours. Data from a study of lactating mothers taking 60 mg pseudoephedrine every 6 hours suggests that from 2.2 to 6.7% of the maximum daily dose (240 mg) may be available to the infant from a breastfeeding mother.

Fertility
There are no adequate data from the use of Flu-Gone C+F Tablet in humans regarding effects on fertility.

4.7 Effects on ability to drive and use machines

Paracetamol:
Paracetamol has no influence on the ability to drive and use machines.

Chlorpheniramine Maleate:
The anticholinergic properties of chlorpheniramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery.

Pseudoephedrine Hydrochloride: None known.

4.8 Undesirable effects

Mild side-effects, such as skin rashes, dry mouth and nausea may be experienced. If any unusual effects are noticed Flu-Gone should be stopped and your pharmacist or doctor should be consulted.

Paracetamol:
Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class and frequency.

The following convention has been utilised for the classification of the undesirable effects: very common (=1/10), common (=1/100 to <1/10), uncommon (=1/1000 to <1/100), rare (=1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).

Adverse event frequencies have been estimated from spontaneous reports received through postmarketing data.

Body System	Adverse Reaction	Frequency
Blood and lymphatic system disorders	Thrombocytopaenia	Very rare
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes,	Very rare
	angioedema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis	
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

Chlorpheniramine Maleate:
Chlorpheniramine may cause drowsiness, nausea, vomiting, headaches, blurred vision, anorexia and dryness of the mouth. The administration of antihistamines has also been associated with rash, angioedema, convulsions, paresthesias, dizziness and constipation.

Pseudoephedrine hydrochloride:

Pseudoephedrine may cause anxiety, tremor, cardiac arrhythmias, palpitations, tachycardia, hypertension, nausea, vomiting, and headache and may occasionally cause insomnia and urinary retention in men. Rarely sleep disturbance and hallucinations have been reported. There have been rare cases of psychosis following misuse of pseudoephedrine.

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system. https://pv.pharmacyboardkenya.org/

4.9 Overdose

Paracetamol:
Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.
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 postingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous Nacetylcysteine, 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.

Chlorpheniramine Maleate:
Symptoms and signs of overdose of Chlorphenamine includes include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment: Management should be as clinically indicated or as recommended by the national poisons centres where available.

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

Pseudoephedrine hydrochloride:
Overdose may result in:
Hyperglycaemia, hypokalaemia CNS stimulation, insomnia; irritability, restlessness, anxiety, agitation; confusion, delirium, hallucinations, psychoses, seizures, tremor, intracranial haemorrhage including intracerebral haemorrhage, drowsiness in children, mydriasis, palpitations, tachycardia, reflex bradycardia, supraventricular and ventricular arrhythmias, dysrhythmias, myocardial infarction, hypertension, vomiting, ischaemic bowel infarction, acute renal failure, difficulty in micturition.

Treatment: Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed if

indicated. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

Management

Necessary measures should be taken to maintain and support respiration and control convulsions. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-Opioid analgesics andantipyretics: Anilides ATC code: N02BE

Mechanism of action

Flu-Gone C+F Tablets is well tolerated and effective analgesic, decongestant and antihistaminic. The individual constituents act synergistically or alone to produce the desired pharmacological effects of Flu-Gone C+F Tablets.

Paracetamol:

Analgesic – the mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting 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 synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic- paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat – regulation 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.

Chlorpheniramine Maleate:

Antihistamines such as pheniramine appear to compete with histamine for histamine h1- receptor sites on effector cells. The antihistamines antagonize those pharmacological effects of histamine which are mediated through activation of h1- receptor sites and thereby reduce the intensity of allergic reactions and tissue injury response involving histamine release. Antihistamines suppress the histamine-induced wheal (swelling) and flare (vasodilation) response by blocking the binding of histamine to its receptors on nerves, vascular smooth muscle, glandular cells, endothelium, and mast

cells. They effectively exert competitive antagonism of histamine for h1receptors.

Pseudoephedrine hydrochloride:
Pseudoephedrine acts directly on both alpha- and, to a lesser degree, betaadrenergic receptors. Through direct action on alpha-adrenergic receptors in the mucosa of the respiratory tract, pseudoephedrine produces vasoconstriction. Pseudoephedrine relaxes bronchial smooth muscle by stimulating beta2-adrenergic receptors. Like ephedrine, pseudoephedrine releasing norepinephrine from its storage sites, an indirect effect. This is its main and direct mechanism of action. The displaced noradrenaline is released into the neuronal synapse where it is free to activate the postsynaptic adrenergic receptors

5.2 Pharmacokinetic properties

Paracetamol:
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 - 4 hours after therapeutic doses.

Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 30% may be bound at the concentrations encountered during acute intoxication. Following therapeutic doses 90 - 100% of the drug may be recovered in the urine within the first day. However, practically no paracetamol is excreted unchanged and the bulk is excreted after hepatic conjugation.

Panadol Advance 500 mg Tablets contain a disintegrant system which accelerates tablet dissolution compared to standard paracetamol tablets.

Human scintigraphy data demonstrate that Panadol Advance 500 mg Tablets generally start to disintegrate by 5 minutes post dose in the stomach. There is also less between-subject and less within- subject variability ($p<0.0001$) in early absorption of paracetamol from Panadol Advance 500 mg Tablets compared to standard paracetamol tablets.

Human pharmacokinetic data demonstrate that the time taken to reach plasma paracetamol therapeutic threshold (4-7mcg/ml) is at least 37% faster with Panadol Advance 500 mg Tablets compared to standard paracetamol tablets ($P<0.05$).

Total extent of absorption of paracetamol from Panadol Advance 500 mg Tablets is equivalent to that from standard paracetamol tablets.

Chlorpheniramine Maleate:

Chlorpheniramine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within I to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.
Chlorpheniramine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

Pseudoephedrine hydrochloride:
Pseudoephedrine is rapidly and completely absorbed after oral administration. After an oral dose of 180 mg to man, peak plasma concentrations of 500-900 ng/ml were obtained about 2 hours post dose. The plasma half-life was about 5.5 hours and was increased in subjects with alkaline urine and decreased in subjects with acid urine. The only metabolism was Ndemethylation which occurred to a small extent. Excretion was mainly via the urine.

5.3 Preclinical safety data Not

Available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Starch
- Soluble Starch
- Povidone K-25
- Sodium Benzoate
- Purified Talc
- Stearic Acid

Colloidal Anhydrous Silica (Aerosil 200)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years (36 months)

6.4 Special precautions for storage

Store below 30C.
Protect from light, heat and moisture.
Keep all medicines out of reach of children.
Do not use after expiry date mentioned on the package.
To be sold on the prescription of a regitsterd Medical practitioner only.

6.5 Nature and contents of container <and special equipment for use, administration or implantation

Flu-Gone C+F Tablets is available in (1x10's) 10's tablets in Alu/PVC blister packed in a printed unit carton along with package insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Marketing Authorization Holder (MAH): Company name: Globe Pharmacy Limited. Address: Globe House, Mazeras Rd, Kileleshwa P. O. Box 58171-00200 Nairobi – Kenya Country: Kenya
Telephone: 0775-222 333/0775-444 555/0701-944 444 E-Mail: globe@globe.co.ke

Manufacturing Site:
Name: Pharmatec Pakistan (Pvt.) Ltd.,
Address: D-86/A, S.I.T.E., Karachi-75700, Pakistan.
Telephone No.: 021-32561155-8
Fax No.: 32561330
Website: www.pharmatec.com
Email: info@pharmatec.com, hilal.ahmed@pharmatec.com

8. MARKETING AUTHORIZATION NUMBER

15270

9. RENEWAL OF THE REGISTRATION

29/07/2026

10. DATE OF REVISION OF THE TEXT

29/07/2026