1.3.1.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

FLUEXPRIN C COLD & FLU LEMON 800 mg/50 mg/45 mg powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 800 mg aspirin (acetylsalicylic acid), 50 mg caffeine and 45 mg Vitamin C (ascorbic acid).

Contains sugar: Sucrose 4 789,50 mg per sachet.

Contains sweetener: Sucralose 8 mg per sachet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

FLUEXPRIN C COLD & FLU LEMON is a fine, pale yellow, granular powder, free from caking or lumps.

For appearance of the powder dissolved in water, see section 4.2.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

FLUEXPRIN C COLD & FLU LEMON is indicated for the symptomatic treatment of aches, pains, fever, and headache associated with the common cold and influenza.

4.2. Posology and method of administration

Posology

Use the lowest effective dose for the shortest possible duration of treatment.

Adults and adolescents over 16 years of age

One sachet morning and night.

A dose at midday may be taken if desired.

Do not exceed 3 doses every 24 hours.

Do not use continuously for more than 10 days without consulting a doctor.

Paediatric population

FLUEXPRIN C COLD & FLU LEMON should not be given to children and adolescents under the age of 16 years except on medical advice (see section 4.4).

Method of administration

For oral administration.

Directions for use:

Empty contents of sachet into a tumbler. Half fill with very hot water. Stir. Add cold water if necessary, but drink as hot as possible.

Appearance of the powder dissolved in water: An opalescent, yellow solution.

4.3. Contraindications

FLUEXPRIN C COLD & FLU LEMON is contraindicated in:

- Patients with hypersensitivity to aspirin (acetylsalicylic acid), other salicylates, caffeine, ascorbic acid or to any excipients in FLUEXPRIN C COLD & FLU LEMON (see section 6.1).

- A history of hypersensitivity reactions (e.g., asthma, bronchospasm, rhinitis, urticaria, nasal polyps) in response to aspirin or nonsteroidal anti-inflammatory medicines (NSAIDs).
- Patients taking anticoagulants.
- History of gastrointestinal perforation, ulceration, or bleeding (PUBs) related to previous NSAIDs, including FLUEXPRIN C COLD & FLU LEMON.
- Active or a history of recurrent ulcer/ haemorrhage/perforations.
- Haemophilia, hypothrombinaemia or other clotting disorders.
- Heart failure.
- History of gout.
- Hyperoxaluria.
- Severe hepatic failure or kidney failure.

Safety in pregnancy and lactation has not been established.

4.4. Special warnings and precautions for use

In the event of overdosage and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Control Centre must be contacted immediately.

Do not exceed the recommended daily dose.

Excessive and prolonged use of FLUEXPRIN C COLD & FLU LEMON may be dangerous.

Drug reaction with eosinophilia and systemic symptoms

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported in patients taking NSAIDs such as FLUEXPRIN C COLD & FLU LEMON. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Other clinical manifestations may include hepatitis, nephritis, haematological abnormalities, myocarditis, or myositis. Sometimes symptoms of

DRESS may resemble an acute viral infection. Eosinophilia is often present. Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or lymphadenopathy, may be present even though rash is not evident. If such signs or symptoms are present, discontinue FLUEXPRIN C COLD & FLU LEMON and evaluate the patient immediately.

Aspirin

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported. FLUEXPRIN C COLD & FLU LEMON should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with aspirin therapy.
In view of the inherent potential of FLUEXPRIN C COLD & FLU LEMON to cause sodium and fluid retention, heart failure may be precipitated in some compromised patients and congestive heart failure and renal impairment may be exacerbated.

Patients who suffer from asthma should consult a doctor before taking FLUEXPRIN C COLD & FLU LEMON.

FLUEXPRIN C COLD & FLU LEMON should be used with caution in patients with mild to moderate renal or hepatic impairment, or in patients who are dehydrated. Aspirin, as contained in FLUEXPRIN C COLD & FLU LEMON, decreases platelet adhesiveness and increases bleeding time.

Haematological and haemorrhagic effects can occur, and may be severe. Patients should report any unusual bleeding symptoms to their medical practitioner. Due to its inhibitory effect on platelet aggregation, FLUEXPRIN C COLD & FLU LEMON may cause increased bleeding during and after surgery.

FLUEXPRIN C COLD & FLU LEMON may precipitate acute haemolytic anaemia in patients with G6PDH deficiency.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation (PUBs) which may be fatal.

The risk of gastrointestinal bleeding or perforation (PUBs) is higher with increasing doses of FLUEXPRIN C COLD & FLU LEMON, in patients with a history of ulcers, and the elderly.

When gastrointestinal bleeding or ulceration occurs in patients receiving FLUEXPRIN C COLD & FLU LEMON, treatment with FLUEXPRIN C COLD & FLU LEMON should be stopped.

FLUEXPRIN C COLD & FLU LEMON should be given with caution to patients with a history of gastrointestinal disease (e.g., ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.

Use in pregnancy

FLUEXPRIN C COLD & FLU LEMON is contraindicated and should not be used in pregnancy (see section 4.3 and 4.6).

Caffeine

Excessive intake of caffeine (e.g., coffee, tea, and some canned drinks) should be avoided while taking FLUEXPRIN C COLD & FLU LEMON.

Ascorbic acid

Increased intake of ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON, over a prolonged period may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).

Interference with serological testing

Ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON, may interfere with tests and assays for urinary glucose, giving false-negative results with methods utilising glucose oxidase with indicator (e.g., Labstix, Tes-Tape) and false-positive results with neocuproine methods.

Estimation of uric acid by phosphotungstate or uricase with copper reduction and measurement of creatinine in non-deproteinised serum may also be affected.

High doses of ascorbic acid may give false-negative reading in faecal occult blood tests (see section 4.5).

Excipients

Patients with the rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take FLUEXPRIN C COLD & FLU LEMON.

FLUEXPRIN C COLD & FLU LEMON contains 4 789,50 mg sucrose per sachet. This should be taken into account in patients with diabetes mellitus.

Paediatric population

Aspirin, as contained in FLUEXPRIN C COLD & FLU LEMON, has been implicated in Reye's Syndrome, a rare but serious illness in children and teenagers below the age of 16 years with chickenpox and influenza. A doctor should be consulted before FLUEXPRIN C COLD & FLU LEMON is used in such patients (see section 4.2).

4.5. Interaction with other medicines and other forms of interaction

Aspirin

NSAIDs

Use of two or more NSAIDs concomitantly could result in an increase in side effects.

Corticosteroids

Increased risk of gastrointestinal ulceration or bleeding (PUBs). Plasma salicylate concentrations may be reduced by concurrent use of corticosteroids, and salicylate toxicity may occur following withdrawal of the corticosteroids.

Anticoagulants

Aspirin may enhance the effects of anticoagulants such as warfarin.

Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs)

Increased risk of gastrointestinal bleeding.

Alcohol

Co-administration of alcohol and FLUEXPRIN C COLD & FLU LEMON increases the risk of gastrointestinal haemorrhage.

Angiotensin-converting enzyme inhibitors (ACE inhibitors)

Aspirin can diminish the effects of ACE inhibitors.

Antacids

Antacids may increase the excretion of aspirin, as contained in FLUEXPRIN C COLD & FLU LEMON, by alkalinisation of the urine.

Anticonvulsants

Aspirin may enhance the activity of phenytoin and valproate.

Beta-blockers

Aspirin can reduce the antihypertensive effect of beta-blockers.

Carbonic anhydrase inhibitors

There is an increased risk of salicylate toxicity when high dose aspirin is co-administered with carbonic anhydrase inhibitors (such as acetazolamide).

Diuretics

There is a risk of a reduced diuretic effect especially in patients with existing renal or cardiovascular disease.

Hypoglycaemic medicine (oral)

Aspirin may enhance the effects of oral hypoglycaemic medicine of the sulfonylurea type.

Methotrexate

The toxicity of methotrexate may be enhanced by concomitant use of FLUEXPRIN C COLD & FLU LEMON.

Uricosuric medicine

Aspirin diminishes the action of uricosurics such as probenecid and sulfinpyrazone.

Ascorbic acid

Amphetamine

Ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON, increases the renal excretion of amphetamine.

Smoking

The plasma concentration of ascorbate, as contained in FLUEXPRIN C COLD & FLU LEMON, is decreased by smoking.

Oral contraceptives

The plasma concentration of ascorbate, as contained in FLUEXPRIN C COLD & FLU LEMON, is decreased by oral contraceptives.

Iron

Ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON, increases the absorption of iron.

Antacids

Concomitant administration of aluminium-containing antacids may increase urinary aluminium elimination. Concurrent administration of antacids and FLUEXPRIN C COLD & FLU LEMON is not recommended, especially in patients with renal insufficiency.

Amygdalin

Co-administration with amygdalin (a complementary medicine) can cause cyanide toxicity.

Desferrioxamine

Concurrent administration of ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON, with desferrioxamine enhances urinary iron excretion. Cases of cardiomyopathy and congestive heart failure have been reported in patients with idiopathic haemochromatosis and thalassaemias receiving desferrioxamine who were subsequently given ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON.

FLUEXPRIN C COLD & FLU LEMON should be used with caution in these patients and cardiac function monitored.

Blood, urine and skin tests

Ascorbic acid as contained in FLUEXPRIN C COLD & FLU LEMON may interfere with biochemical determinations of creatinine, uric acid and glucose in samples of blood and urine.

4.6. Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established (see sections 4.3 and 4.4).

Pregnancy

FLUEXPRIN C COLD & FLU LEMON should not be used during pregnancy.

Aspirin, as contained in FLUEXPRIN C COLD & FLU LEMON, increases the risk of peripartum haemorrhage.

Regular use of non-steroidal anti-inflammatory drugs, such as aspirin may result in:

First trimester

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies raise concern about an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1 %, up to approximately 1,5 %. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

Second and Third trimester.

During the third trimester of pregnancy, prostaglandin synthesis inhibitors, may expose the foetus to: cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension); renal dysfunction, which may progress to renal failure with oligo-hydroamniosis.

At the end of pregnancy, the mother and the neonate may be exposed to: possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses; inhibition of uterine contractions resulting in delayed or prolonged labour.

FLUEXPRIN C COLD & FLU LEMON is contraindicated for use during pregnancy due to the possible increased risk of spontaneous abortion and low birth weight associated with total caffeine consumption above 200 mg per day.

For ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON, no clinical data on exposed pregnancies are available.

Breastfeeding

FLUEXPRIN C COLD & FLU LEMON should not be used while breastfeeding.

Aspirin, as contained in FLUEXPRIN C COLD & FLU LEMON, is secreted into breast milk in low concentration and should, therefore, be avoided during lactation because of the possible risk of Reye's Syndrome and the fact that high doses could potentially impair platelet function.

Caffeine, as contained in FLUEXPRIN C COLD & FLU LEMON, in breast milk may potentially have a stimulating effect on breastfed infants but significantly toxicity has not been observed.

Ascorbic acid, as contained in FLUEXPRIN C COLD & FLU LEMON, is excreted in breast milk. Caution should be exercised, though no evidence exists suggesting such excretion is hazardous to the infant.

Fertility

No data available.

4.7. Effects on ability to drive and use machines

FLUEXPRIN C COLD & FLU LEMON has moderate influence on the ability to drive and use machinery.

Since adverse reactions such as dizziness have been reported in patients receiving FLUEXPRIN C COLD & FLU LEMON, patients should not drive, use machinery or perform any

tasks that require concentration, until they are certain that FLUEXPRIN C COLD & FLU LEMON does not adversely affect their ability to do so (see section 4.8).

4.8. Undesirable effects

a) Tabulated list of adverse reactions

Aspirin

System organ class	**Frequent**	**Frequency unknown** (cannot be estimated from the available data)
Blood and the lymphatic system disorders		Prolonged bleeding time, thrombocytopenia, ecchymosis, anaemia
Immune system disorders		Hypersensitivity reactions e.g., rhinitis, angioedema, urticaria, bronchospasm, skin reactions and anaphylaxis
Metabolism and nutrition disorders		Sodium and fluid retention
Nervous system disorders		Dizziness
Ear and labyrinth disorders		Tinnitus, temporary hearing loss
Cardiac disorders		Oedema, hypertension, cardiac failure
Respiratory, thoracic and mediastinal disorders		Bronchospasm and dyspnoea in patients sensitive to aspirin and other NSAIDs

Gastrointestinal disorders	Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis	
Hepato-biliary disorders		Elevation in aminotransferase levels
Skin and subcutaneous tissue disorders		Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS) (see section 4.4).
Renal and urinary disorders		Renal dysfunction, increased blood uric acid levels, renal papillary necrosis

Caffeine

System organ class	**Frequency unknown** (cannot be estimated from the available data)
Psychiatric disorders	Insomnia
Nervous system disorders	Headache,
	nervousness, dizziness

Cardiac disorders	Palpitations
Gastrointestinal disorders	Nausea (queasiness), increased gastric secretions, gastric ulceration, Diuresis (increased urine secretion),

Ascorbic acid

System organ class	**Frequency unknown** (cannot be estimated from the available data)
Nervous system disorders	Headache
Vascular disorders	Flushing
Gastrointestinal disorders	Nausea, vomiting and stomach cramps. Large doses of ascorbic acid may cause diarrhoea.
Skin and subcutaneous tissue disorders	Redness of skin
Renal and urinary disorders	Increased urinary oxalate excretion

b) *Description of selected adverse reactions*

Aspirin

Some persons, especially asthmatics, exhibit notable sensitivity to aspirin which may provoke various hypersensitivity (abnormal or allergic) reactions which may include skin eruptions, paroxysmal bronchospasm and dyspnoea (difficulty in breathing). FLUEXPRIN C COLD & FLU LEMON should be administered with caution to patients with impaired renal (kidney) function, dyspepsia (heartburn), anaemia (decreased number of red blood cells) and when the patient is dehydrated. Aspirin may enhance the activity of coumarin anticoagulants and oral antidiabetic medicines and sulfonamides. Aspirin diminishes the effects of antigout medicines such as probenecid and sulfinpyrazone. Barbiturates and other sedatives may mask the respiratory symptoms of aspirin overdosage and have been reported to enhance its toxicity. Prolonged use of high doses may lead to anaemia (decreased number of red blood cells), blood dyscrasias

(serious blood disorders), gastrointestinal (affecting the stomach and intestines) haemorrhage, peptic ulceration and renal (kidney) papillary necrosis (death of tissues).

Caffeine

When the recommended aspirin-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Vitamin C (ascorbic acid)

Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid doses exceeding 1 g daily as there may be increased urinary oxalate excretion. However, such risk has not been demonstrated in normal, non-hyper oxaluric individuals. Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase. Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600 mg daily have a diuretic effect.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

Aspirin

Symptoms

These include dizziness, deafness, dehydration, tinnitus (ringing in the ears), vertigo, sweating, nausea, vomiting, headache, mental confusion, hyperventilation, fever, restlessness, respiratory alkalosis, metabolic acidosis, ketosis (elevated concentration of ketones in body fluids) and depression of the central nervous system which may lead to coma, cardiovascular collapse, and respiratory failure.

In children serious signs of overdosage may develop rapidly. Drowsiness and metabolic acidosis occur commonly. Hypoglycaemia may be severe.

Treatment

Symptomatic and supportive.

Give activated charcoal if an adult present within one hour of ingestion of more than 250 mg/kg.

The plasma salicylate concentration should be measured, although the severity of poisoning cannot be determined from this alone and the clinical and biochemical features must be taken into account.

Elimination is increased by urinary alkalinisation, which is achieved by the administration of sodium bicarbonate. The urine pH should be monitored.

Haemodialysis is the treatment of choice for severe poisoning and should be considered in patients with plasma salicylate concentrations >700 mg/L (5,1 mmol/L), or lower concentrations associated with severe clinical or metabolic features. Patients under 10 years or over 70 have increased risk of salicylate toxicity and may require dialysis at an earlier stage.

Caffeine

Symptoms

Large doses may cause restlessness, excitement, anxiety neuroses, muscle tremor, tinnitus (ringing in the ears), scintillating scotoma (visual spot disturbances), tachycardia (increased rate of heartbeat) and extrasystoles (abnormal heartbeats).

Symptoms may include gastrointestinal disturbance, epigastric pain, vomiting, diuresis, cardiac dysrhythmia, “rambling” flow of thought and speech, psychomotor agitation, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors, and convulsions) or periods of inexhaustibility.

Treatment

Symptomatic and supportive.

No specific antidote is available, but supportive measures such as beta adrenoceptor antagonists to reverse the cardiotoxic effects may be used.

Ascorbic acid

Symptoms

Large doses may cause diarrhoea and the formation of renal oxalate calculi. Ascorbic acid may cause acidosis or haemolytic anaemia in certain individuals with a deficiency of glucose 6-phosphate dehydrogenase. Renal failure can occur with massive ascorbic acid overdosage. In cases of overdosage, consult a doctor immediately.

Treatment

Symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A 5.8 Preparations for the common cold, including nasal decongestants and antihistaminics

Pharmacotherapeutic group: Cough and cold preparations, other cold preparations

ATC code: R05X

Mechanism of action

FLUEXPRIN C COLD & FLU LEMON has analgesic and antipyretic properties.

5.2. Pharmacokinetic properties

Aspirin

Absorption

Aspirin is rapidly absorbed from the upper gastrointestinal tract after oral administration.

Distribution

Aspirin is rapidly distributed throughout the whole body.

Biotransformation

It is hydrolysed to its active primary metabolite salicylic acid.

Salicylates are extensively bound to plasma proteins. Maximum plasma concentrations are reached after 10 to 40 minutes (acetylsalicylic acid) and 0,3 to 2 hours (total salicylate) depending on dosage form. The elimination half-life of acetylsalicylic acid is dose-dependent, typically two hours after a single dose of 0,5 g aspirin, 4 hours after 1 g and 20 hours after 5 g.

Elimination

Aspirin is completely excreted in the urine, principally as glucuronic acid and glycine conjugates of salicylic acid, but also as salicylic acid itself.

Following administration of acetylsalicylic acid, salicylic acid can be detected in breast milk, cerebral spinal fluid, and synovial fluid. The substance crosses the placenta.

Ascorbic acid

Absorption

Ascorbic acid is well absorbed from the gastrointestinal tract.

Distribution

Ascorbic acid is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1,5 g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma.

Elimination

Ascorbic acid additional to the body's needs, generally amounts above 200 mg daily, is rapidly eliminated; un-metabolised ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Menthol, Quinoline Yellow W.S. (E104), sucralose, sucrose, Trusil Lemon Special.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

The product must be consumed within 60 minutes after dissolving the powder in water.

6.4. Special precautions for storage

Store at or below 30 °C.

6.5. Nature and contents of container

Paper/low density polyethylene/aluminium/low density polyethylene individual sachets containing 6,1 g powder. Pack sizes of 8 or 24 sachets in a carton.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

8. REGISTRATION NUMBER

47/5.8/0322

9. DATE OF FIRST AUTHORISATION

25 November 2025

10. DATE OF REVISION OF TEXT

25 November 2025

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.