Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

SUGAR-FREE FERVEX FOR ADULTS, granules for oral solution in sachet.

SUGAR-FREE FERVEX FOR CHILDREN, granules for oral solution in sachet.

2. Qualitative and quantitative composition

SUGAR-FREE FERVEX FOR ADULTS, granules for oral solution
Each sachet contains 500mg of Paracetamol, 200mg of Ascorbic acid (vitamin C) and 25 mg of Pheniramine maleate.

Excipients with known effect
Each 5g sachet contains 50 mg aspartame (E951) and trace amounts of ethanol in the flavoring.

SUGAR-FREE FERVEX FOR CHILDREN, granules for oral solution
Each sachet contains 0.2800 g of Paracetamol, 0.1000 g of Ascorbic acid (vitamin C) and 0.0100 g of Pheniramine maleate.

Excipients with known effect
Each 3g sachet contains: Benzyl alcohol, Allura red AC (E129), Sucrose acetate isobutyrate (E444), Sunset yellow FCF (E 110), Trace amounts of ethanol and Sodium benzoate (E 202) in the flavoring.

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

This medicine is in the form of granules for oral solution in sachet.

4. Clinical particulars

4.1 Therapeutic indications

Treatment of colds, rhinitis, rhinopharyngitis and flu states :
- Clear nasal discharge and lacrimation
- Sneezing
- Headache and/or fever.

4.2 Posology and method of administration

Posology
For adults and children over 15 years of age.

Age (weight)	Dose per administration	Administration interval	Maximum daily dose
Adults and children over 15 years of age (over 50 kg)	1 sachet (500 mg paracetamol 25 mg pheniramine	4 hours minimum	3 sachets (1500 mg paracetamol 75 mg

	200 mg vitamin C)		pheniramine 600 mg vitamin C)

The maximum recommended dose of paracetamol in adults and children weighing more than 50kg should not exceed 4g/day.

For children above 6 years of age.

Age (weight)	Dose per administration	Administration interval	Maximum daily dose
21 kg - 25 kg (approximately 6 to 10 years of age)	1 sachet (280 mg paracetamol 10 mg pheniramine 100 mg vitamin C)	12 hours minimum	2 sachets (560 mg paracetamol 20 mg pheniramine 200 mg vitamin C)
26 kg - 40 kg (approximately 10 to 12 years of age)	1 sachet (280 mg paracetamol 10 mg pheniramine 100 mg vitamin C)	8 hours minimum	3 sachets (840 mg paracetamol 30 mg pheniramine 300 mg vitamin C)
41 kg - 50 kg (approximately 12 to 15 years of age)	1 sachet (280 mg paracetamol 10 mg pheniramine 100 mg vitamin C)	6 hours minimum	4 sachets (1120 mg paracetamol 40 mg pheniramine 400 mg vitamin C)

The maximum daily dose of paracetamol in children more than 21 kg should not exceed 60 mg/kg/day.
To avoid a risk of overdose, check for the absence of paracetamol and/or pheniramine and/or vitamin C in the composition of other medicines, including for medicines obtained without a prescription.

Renal patients
In case of renal insufficiency and unless medical advice, it is recommended to reduce the dose and to increase the minimum interval between 2 doses, according to the following table:

Creatinine clearance	Minimum administration interval
≥50 mL/min	4 hours
10-50 mL/min	6 hours
<10 mL/min	8 hours

The total dose of paracetamol (taking into account all other drugs containing paracetamol in their formula) must not exceed 3 g/day.

Special clinical situations
The lowest effective daily dose of paracetamol should be considered, not exceeding 60 mg/kg/day (not exceeding 3 g/day) in the following situations:
- adults under 50 kg, adult
- mild to moderate hepatocellular impairment
- chronic alcoholism
- chronic malnutrition (low liver glutathione reserves)
- dehydration.

Method of administration
Oral use.

The sachets should be taken in a sufficient amount of water, cold or hot.
In the case of influenza, it is better to take this drug in warm water in the evening.

The maximum duration of treatment is 5 days

4.3 Contraindications

•Hypersensitivity to the active substances or to'one of the excipients listed in section 6.1, or
•In case of severe hepatocellular insufficiency,
•In case of risk of glaucoma by closing the angle,
•In case of risk of urinary retention related to urethro-prostatic disorders,
•In children under 6 years of age
•In people with phenylketonuria (PCU) due to the presence of aspartam (E951).

4.4 Special warnings and precautions for use

In case of high or persistent fever, or signs of superinfection or persistence of symptoms beyond 5 days, a re-evaluation of the treatment should be made.

The risk of essentially psychological dependence appears only for dosages higher than those recommended and for long-term treatments.

To avoid the risk of overdose:
-check for the absence of paracetamol, pheniramine, or other antihistamines in the composition of other concomitant treatments, (including whether they are drugs obtained with or without a prescription).
- follow the recommended maximum doses (see section 4.2).

Very rare cases of serious cutaneous adverse reactions have been reported. Patients should be informed of the early signs of these severe skin reactions, the appearance of a rash or any other sign of hypersensitivity requires that treatment be discontinued.

Precautions for use
Related to the presence of paracetamol:
Paracetamol should be used with caution in case of:
•weight < 50kg, weight
•mild to moderate hepatocellular insufficiency
•renal insufficiency (see table section 4.2),
•chronic alcoholism
•chronic malnutrition (low hepatic glutathione reserves)

•dehydration (see section 4.2).

If acute viral hepatitis is found, treatment should be discontinued
Alcohol consumption during treatment is not recommended.

Caution should be exercised when co-administered with paracetamol and flucloxacillin due to an increased risk of high anionic gap metabolic acidosis, especially in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g., chronic alcoholism), as well as in those using maximum daily doses of paracetamol.

Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Related to the presence of pheniramine maleate:
The absorption of alcoholic beverages, or sedatives (barbiturates in particular) which potentiate the sedative effect of antihistamines should be avoided during treatment (see section 4.5).

Related to Vitamin C:
Vitamin C should be used with caution in patients with iron metabolism disorders and in subjects with Glucose-6 deficiency Phosphate Dehydrogenase.

Related to excipients with known effect:
This medicine contains mannitol. Mannitol may have a mild laxative effect.

This medicine contains 50 mg of aspartame per sachet. Aspartame contains a source of phenylalanine. May be dangerous for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

4.5 Interaction with other medicinal products and other forms of interaction

Related to the presence of paracetamol:
Combinations requiring precautions for use
Vitamin K antagonists
Risk of increased oral anticoagulant effect and of haemorrhage if paracetamol is taken at maximum doses (4 g/day) for at least 4 days.
The INR should be regularly monitored. Potential adjustment of the oral anticoagulant posology during treatment with paracetamol and after its discontinuation.

Interactions with paraclinical examinations
Administration of paracetamol may distort the results of blood glucose assays using the glucose oxidase-peroxidase method in the case of abnormally high concentrations.

Administration of paracetamol may distort the results of blood uric acid assays using the phosphotungstic acid method.

Related to the presence of pheniramine maleate:
Inadvisable combinations
Alcohol (beverage or excipient):
Increased sedative effect of the H1 antihistamine via alcohol. Impaired alertness may make driving vehicles and using machines dangerous.
The consumption of alcoholic beverages or medicinal products containing alcohol should be avoided.

Sodium oxybate
Increased CNS depression. Impaired alertness may make driving vehicles and using machines dangerous.

Combinations to consider
Other sedatives (related to the presence of pheniramine): morphine derivatives (analgesics, antitussives and substitute treatments), neuroleptics, barbiturates, benzodiazepines, anxiolytics other than benzodiazepines (e.g. meprobamate), hypnotics, sedative antidepressants (amitriptyline, doxepin, mianserin, mirtazapine, trimipramine), sedative H1 antihistamines, centrally-acting antihypertensives, baclofen and thalidomide.

Increased CNS depression. Impaired alertness may make driving vehicles and using machines dangerous.
Other atropine drugs (related to the presence of pheniramine): imipramine antidepressants, most atropinic H1 antihistamines, anticholinergic antiparkinsonian agents, atropinic antispasmodics, disopyramide, phenothiazine neuroleptics and clozapine.

Addition of atropinic undesirable effects, such as urinary retention, constipation, dry mouth.

Anticholinesterases risk of reduced efficacy of anticholinesterases via acetylcholine receptor antagonism due to the pheniramine maleate.

Opioids significant risk of colic akinesia, with severe constipation.

4.6 Pregnancy and Lactation

Pregnancy
There are no clinical data available on' use of combination with vitamin C and pheniramine.

A large amount of data on pregnant women demonstrates the absence of any foetal/neonatal malformation or toxicity related to the use of paracetamol. Epidemiological studies on the neurodevelopment of children exposed to paracetamol in utero produce inconclusive results.

Therefore, as a precautionary measure, SUGAR-FREE FERVEX FOR ADULTS is not recommended in pregnant women.

Lactation
Due to the lack of animal studies and clinical data in humans, the risk to breast-fed children is not known.
It is therefore not recommended during breast-feeding.

Fertility
Due to the potential mechanism of action on cyclooxygenase and prostaglandin synthesis, paracetamol may impair fertility in women, affecting ovulation. This is reversible upon discontinuation of treatment. Its use is not recommended in women who wish to become pregnant.

Effects on male fertility were observed in one animal study. The relevance of these effects in humans is not known.

4.7 Effects on ability to drive and use machines

SUGAR-FREE FERVEX FOR ADULTS has influence on the ability to drive and use machines.

Attention is drawn, especially for those who drive or use a machine, to the risk of drowsiness related to this drug, especially at the beginning of treatment.

This effect is increased by the consumption of alcoholic beverages, medicinal products containing alcohol or sedative drugs.

4.8 Undesirable effects

Related to the presence of paracetamol:

Adverse effects are classified by system-organ. Their frequencies are defined as follows:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥1/10 000 to <1/1 000)
Very rare (<1/10 000)

Table 1: Adverse effects related to paracetamol

System-organ class	Frequency	Undesirable effect
Blood and lymphatic system disorders	Very rare	Thrombocytopenia, Neutropenia, and Leukopenia
Immune system disorders	Frequency not known	Anaphylactic shock Erythema

		Urticaria Angioedema
Metabolism and nutrition disorders	Frequency not known	Pyroglutamic acidosis in patients with factors predisposing to glutathione depletion
Gastrointestinal disorders	Frequency not known	Diarrhea Abdominal pain
Hepatobiliary disorders	Frequency not known	Increase in liver enzymes
Skin and subcutaneous tissue disorders	Rare	Urticaria Erythema Skin rash Purpura
	Very rare	Serious skin reactions
[1]The occurrence of these effects imposes the definitive cessation of this drug and related drugs. [2]The occurrence of this effect imposes the immediate cessation of this drug. The product can be reintroduced only on medical advice.		

Table 2: Adverse effects related to pheniramine maleate

The pharmacological characteristics of the molecule are responsible for adverse reactions of unequal intensity and dose related or not (see section 5.1) :

System-organ class	Undesirable effect
Blood and lymphatic system disorders	Leukopenia Neutropenia Thrombocytopenia Hemolytic anemia
Immune system disorders	Edema, more rarely angioedema (edema of Quincke) Anaphylactic shock
Nervous system disorders	Sedation or drowsiness, more marked at the beginning of treatment Anticholinergic effects such as dry mucous membranes, constipation, accommodation problems, mydriasis, palpitations, risk of urinary retention Orthostatic hypotension Balance disorders, dizziness, decreased memory or concentration, which are more

	common in the elderly, and Motor incoordination, Tremors Mental confusion, hallucinations More rarely, effects are excitation type: agitation, nervousness, insomnia.
Skin and subcutaneous tissue disorders	Erythema Pruritus Eczema Urticaria Purpura
[1]The occurrence of these effects imposes the definitive cessation of this drug and related drugs. [2]The occurrence of this effect imposes the immediate cessation of this drug. The product can be reintroduced only on medical advice	

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Related to the presence of paracetamol:

The risk of serious intoxication (therapeutic overdose or accidental intoxication) can be particularly high in elderly people, in young children, in patients with liver damage, in cases of chronic alcoholism, in patients with chronic malnutrition. In these cases, it can be fatal.

Symptoms

Nausea, vomiting, anorexia, pallor, abdominal pains usually appearing within the first 24 hours.

An overdose causes hepatic cytolysis that is likely to develop into complete and irreversible necrosis characterised by hepatocellular impairment, metabolic acidosis and encephalopathy that may lead to a coma and death.

At the same time, an increase in hepatic transaminases, lactic dehydrogenase and bilirubin, and a decrease in the prothrombin level may occur 12 to 48 hours after ingestion.

Management

- Discontinue treatment.
- Immediate transfer to hospital.

•A tube of blood should be collected to measure the initial paracetamol plasma concentration
•Rapid elimination of the ingested product by gastric lavage.
•The treatment of paracetamol overdose typically includes administration of the antidote N-acetyl cysteine intravenously or orally as early as possible, preferably before the tenth hour]
• Liver tests should be performed at the beginning of treatment and repeated every 24 hours. In most cases, liver transaminases return to normal within 1 to 2 weeks with full restoration of liver function. However, in very severe cases, liver transplantation may be necessary.

Related to the presence of pheniramine maleate:
Overdosage of pheniramine can lead to: convulsions (especially in children), disorders of consciousness, coma.

Related to the presence of vitamin C:
Overdosage of vitamin C can lead to digestive disorders (gastric irritation, diarrhea, abdominal pain).
At doses greater than 1 g/day of vitamin C, risk of hemolysis in subjects deficient in G6PD

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: OTHER COLD PREPARATIONS
ATC code: R05X
SUGAR-FREE FERVEX has 3 pharmacological actions:
•antihistamine action which reduces rhinorrhoea and often associated lacrimation and also reduces spasmodic phenomena such as episodes of sneezing.
•antipyretic analgesic action, which reduces fever and pain (headache, myalgia).
•compensation of ascorbic acid in the body

5.2 Pharmacokinetic properties

Paracetamol
Absorption
The absorption of paracetamol by mouth is complete and rapid. Peak plasma concentrations are reached 30 to 60 minutes after ingestion.

Distribution
Paracetamol is distributed rapidly in all tissues. Concentrations are comparable in blood, saliva and plasma. Plasma protein binding is low.

Metabolism
Paracetamol is metabolized primarily in the liver. The two major metabolic routes are conjugation with glucuronic acid and sulphate. The latter route can be rapidly saturated at posologies that exceed the therapeutic doses.

A minor pathway, catalysed by cytochrome P450, is the formation of a reactive intermediate (N-acetyl-p-benzoquinone imine), which, under normal conditions of use, is quickly detoxified by reduced glutathione and eliminated in urine after conjugation with cysteine and mercapturic acid. In contrast, during massive intoxications, the quantity of this toxic metabolite is increased.

Elimination
Elimination is primarily urinary. 90% of the ingested dose is eliminated by the kidneys within 24 hours, mostly in glucuro-conjugated (60 to 80%) and sulfo-conjugated (20 to 30%) forms.

Less than 5% is eliminated unchanged. The elimination half-life is around 2 hours.

Pathophysiological variations
Renal insufficiency: in case of severe renal impairment (see section 4.2), the elimination of paracetamol and its metabolites is delayed.

Elderly subject: the conjugation capacity is not modified.

Pheniramine maleate
It is well absorbed in the digestive tract. Its plasma half-life is approximately 1 hour to 1 hour 30 minutes.
It has a high tissue affinity and is eliminated mainly by the renal route.

Ascorbic acid
Gastrointestinal absorption is good. When intake exceeds requirements, the excess is eliminated in urine.

5.3 Preclinical safety data

Paracetamol
Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. Pharmaceutical Particulars

6.1 List of Excipients

SUGAR-FREE FERVEX FOR ADULTS
Mannitol
Anhydrous citric acid
Polyvidone, anhydrous magnesium citrate
Aspartame
Lemon flavouring containing trace amounts of ethanol.

SUGAR-FREE FERVEX FOR CHILDREN
Mannitol (E 421)
Anhydrous citric acid
Povidone
Anhydrous magnesium citrate

Acesulfame potassium
Sodium benzoate (E 202)
Raspberry flavouring containing sunset yellow FCF (E 110)
Allura red AC (E129)
Benzyl alcohol
Sodium benzoate
Ethanol
Sucrose acetate isobutyrate (E444).

6.2 Incompatibilities
Not applicable.

6.3 Shelf-Life
SUGAR-FREE FERVEX FOR ADULTS
24 months

SUGAR-FREE FERVEX FOR CHILDREN
36 months

6.4 Special Precautions for storage
No special requirements for disposal.

6.5 Nature and Content of container
SUGAR-FREE FERVEX FOR ADULTS
5 g in sachet (Paper/Aluminium/Polyethylene)

SUGAR-FREE FERVEX FOR CHILDREN
3 g in sachet (Paper/Aluminium/Polyethylene) Box of 8.

6.6 Special precautions for disposal and other handling
No special requirements for disposal.

7. Marketing Authorization Holder
UPSA SAS, 3 RUE JOSEPH MONIER

8. Marketing Authorization Number
SUGAR-FREE FERVEX FOR ADULTS
CTD10759

SUGAR-FREE FERVEX FOR CHILDREN
CTD10806

9. Date of first authorization/renewal of the authorization
SUGAR-FREE FERVEX FOR ADULTS
09/08/2024

SUGAR-FREE FERVEX FOR CHILDREN
03/10/2024

10. Date of revision of the text

18/05/2025