SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Haleon Flu Relief 1000mg/10mg/70mg Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**mg / 7.605 g powder**
Paracetamol	1000
Ascorbic Acid	70
Phenylephrine Hydrochloride	10
Excipients of known effect	
Sucrose	
Sodium	

3 PHARMACEUTICAL FORM

Powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Short term symptomatic relief of symptoms of influenza, feverishness, chills and colds including headache, sore throat pain, aches and pains, nasal congestion, sinusitis and its associated pain and acute nasal catarrh.

4.2 Posology and method of administration

Directions for use

Empty contents of sachet into a beaker. Half fill with very hot water. Stir well. Add cold water as necessary and sugar if desired.

Recommended Dose and Dosage Schedule

Adults (including elderly) and children aged 16 years and over:

The contents of one sachet to be taken every four to six hours as necessary, up to a maximum of four sachets in any 24 hours.

The product should not be used continuously for more than seven days without medical advice.

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

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

4.3 Contraindications

Known hypersensitivity to paracetamol or any of the other constituents.

Concomitant use of other sympathomimetic decongestants

Phaeochromocytoma

Closed angle glaucoma

An enlargement of the prostate gland

Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, and heart disease.

Patients taking tricyclic antidepressants, or beta blocking drugs and those who are taking or who have taken within the last two weeks monoamine oxidase inhibitors (see section 4.5).

4.4 Special warnings and precautions for use

Contains paracetamol. Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. 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. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

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

- Occlusive Vascular disease (e.g. Raynaud’s Phenomenon)
- Cardiovascular disease
- Glutathione depletion due to metabolic deficiencies

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

- digoxin and cardiac glycosides
- ergot alkaloids (e.g. ergotamine and methysergide)

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

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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.

Contains 5 g sucrose per dose. This should be taken into account in patients with diabetes.

This medicinal product contains 118 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Do not exceed the stated dose.

Patients should be advised not to take other paracetamol-containing or other cold, flu or decongestant products concurrently.

If symptoms persist consult your doctor.

Keep out of the reach and sight of children.

Medical advice should be sought if symptoms worsen, persist for longer than 7 days, or are accompanied by high fever, skin rash or persistent headache.

Consult your doctor if you are taking warfarin.

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.

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**.**

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine. 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.

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

4.6 Fertility, Pregnancy and lactation

Due to the phenylephrine content this product should not be used in pregnancy or whilst breast-feeding without medical advice. This product should not be used during pregnancy or lactation unless the expected benefit to the mother justifies the potential risk to the foetus or newborn. The lowest effective dose and shortest duration of treatment should be considered Phenylephrine may be excreted in breast milk.

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

Paracetamol

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive postmarketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system 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 casually related to paracetamol.
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis Very rare cases of serious skin reactions have been reported.
Metabolism and nutrition disorders	High anion gap metabolic acidosis*
Respiratory, thoracic and mediastinal disorders	Bromchospasm**
Hepatobiliary disorders	Hepatic dysfunction

* 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.

Phenylephrine

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 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continue monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reaction via the Yellow Card Scheme, 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 10 g or more of paracetamol. Ingestion of 5 g 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 overdose 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 arrythmias 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 the 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 24 h from ingestion should be discussed with the NPIS or a liver unit.

<u>Phenylephrine</u>

<u>Symptoms and signs</u>

Phenylephrine overdosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include 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.

Ascorbic acid

Symptoms and signs

High doses of ascorbic acid (>3000 mg) may cause transient osmotic diarrhoea and gastrointestinal effects such as nausea and abdominal discomfort. Effects of overdose of ascorbic acid would be subsumed by severe liver toxicity caused by paracetamol overdose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: N02BE51

Paracetamol: An analgesic and antipyretic.

Ascorbic acid: a common ingredient of cold and influenza combination products included to compensate for Vitamin C losses which may occur in the initial stages of acute viral infections.

Phenylephrine hydrochloride: 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.

Ascorbic Acid: is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic Acid in excess of the body's needs is eliminated in the urine as metabolites.

Phenylephrine Hydrochloride: is readily 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 pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartaric acid
Sodium citrate anhydrous
Aspartame (E951)
Euroblend blackcurrant
Berry fruit flavourburst
Sucrose

6.2 Incompatibilities

None known

6.3 Shelf life

Three years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

The product is packed in laminate sachets comprising paper / polyethylene / foil / ethylene-methacrylic acid copolymer (EMAA). Five or ten sachets may be contained in a box board carton.

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
The Heights
Weybridge
Surrey
KT13 0NY
U.K.

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0219

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/05/2024

10 DATE OF REVISION OF THE TEXT

10/02/2025