# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Resolve

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 8.09g sachet of granules contains:

| | |
|---|---|
| Paracetamol Ph.Eur. | 1000mg |
| Anhydrous citric acid Ph.Eur. | 1185mg |
| Sodium bicarbonate Ph.Eur. | 808mg |
| Potassium bicarbonate BPC | 715mg |
| Anhydrous sodium carbonate Ph.Eur. | 153mg |
| Ascorbic Acid (Vitamin C) Ph.Eur. | 30mg |

in a base containing glucose (4g)

Excipients with known effect:
Sucrose
Glucose

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Effervescent granules

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Recommended for the relief of headache with gastric upset, particularly associated with over-indulgence in food or drink or both.

### 4.2 Posology and method of administration

Posology
For oral administration

Method of administration:

Dissolve the contents of the sachet in a glass of water (150 - 200 ml) before taking.

*Adults and children aged 16 years and over:*
One sachet every 4 hours as required. Do not take more than 4 sachets in any 24 hours.

Not to be given to children under 16 years of age.
The elderly may take the normal adult dose.

## 4.3 Contraindications

Hypersensitivity to paracetamol, potassium bicarbonate, sodium bicarbonate, sodium carbonate, citric acid, ascorbic acid (vitamin C) or to any of the excipients listed in section 6.1
Hepatic or severe renal impairment. Patients on sodium - or potassium - restricted diets.
Patients with hypochloraemia and hyperkalaemia.
Patients with cardiac disease.

## 4.4 Special warnings and precautions for use

Concomitant use of other paracetamol containing medicines should be avoided.
Consult your doctor if you are taking warfarin.
Care is advised in the administration of this product to patients with renal or severe hepatic impairment. The hazards of overdose with paracetamol are greater in those with non-cirrhotic, alcoholic liver disease.
Resolve® includes 4 g of glucose per sachet. This should be taken into account in patients with diabetes mellitus.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption of sucrase-isomaltase insufficiency should not take this medicine.
Potassium-containing salts should be given with considerable care to the elderly, patients with diabetes or any other conditions that may predispose to them to hyperkalaemia.
Resolve® contains 290mg of sodium per sachet, equivalent to 12% of the WHO recommended maximum daily intake of 2g sodium for an adult.

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 and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at a 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.
Do not exceed the recommended dose.
If symptoms persist, consult your doctor.

Keep this medicine out of the sight and reach of children.

## 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 cholestyramine.
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.
The hepatotoxicity of paracetamol may be potentiated by excessive intake of alcohol.
These interactions are considered to be of unlikely clinical significance in acute use at the dosage regimen proposed.
The acid neutralising capacity of the product may alter the absorption profile of pH specific drugs given concomitantly.
Antihypertensives (ACE inhibitors and Angiotensin II Antagonists): Hyperkalaemia might develop if Ace inhibitors and angiotensin II receptor antagonists are given with potassium supplements or potassium-containing salt substitutes.
Ciclosporin or tacrolimus: There is a increased risk of Hyperkalaemia when potassium salts are given with Ciclosporin or tacrolimus.
Potassium-sparing diuretics and Aldosterone Antagonists: There is an increased risk of increased risk of hyperkalaemia when potassium salts given with potassium-sparing diuretics and aldosterone antagonist.
Medicinal products which induce hepatic microsomal enzymes, such as, barbiturates may increase the hepatotoxicity of paracetamol, particularly after overdose.
As this product contains sodium bicarbonate and potassium bicarbonate, which have antacid properties, it is recommended that Resolve® should not be taken simultaneously with other medications, but should be taken two hours later, as Resolve® may impair drug absorption.
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

Pregnancy:
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, and hence paracetamol is not contraindicated during pregnancy. However patients should follow the advice of their doctor regarding its use

Breast feeding:
Paracetamol is excreted in breast milk but not in clinically significant amounts. Available published data do not contraindicate breast feeding.

Fertility:
There is no information on the effects of the product on fertility.

## 4.7 Effects on ability to drive and use machines

None stated.

## 4.8 Undesirable effects

The active ingredients are usually well tolerated in normal use. Adverse effects of paracetamol are rare, but hypersensitivity including skin rashes and other allergies may occur.
There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these are not necessarily causally related to paracetamol.
Frequency not known:
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.
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

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:

- Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes
- Regularly consumes ethanol in excess of recommended amounts.
- Is likely to be glutathione depleted 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, coma 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 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 NPIS or a liver unit.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

ATC Code: N02BE51

| | | |
|---|---|---|
| Paracetamol - | | analgesic |
| Ascorbic acid - | | replaces lost vitamin C |
| Citric acid | } | Sodium and potassium citrates are formed by |
| Sodium bicarbonate | } | effervescent reaction with water. These |
| Potassium bicarbonate | } | provide acid neutralising and buffering actions |
| Sodium carbonate | } | against acidic gastric contents. |

## 5.2 Pharmacokinetic properties

*Paracetamol* is readily and rapidly absorbed from the gastro-intestinal 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 gastro-intestinal 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

*Antacid Combination* provides an immediately available, local buffering effect in the stomach. Absorbed sodium, potassium and citrate ions will be handled and excreted by normal metabolic routes.

### 5.3 Preclinical safety data

Preclinical safety data on these active ingredients in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product and which have not already been mentioned elsewhere in this summary.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sucrose
Povidone 30
Anhydrous glucose
Polyethylene glycol 6000
Lemon flavour
Saccharin sodium
Sodium cyclamate
Quinoline yellow (E104)

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

Three years

### 6.4 Special precautions for storage

Not applicable

### 6.5 Nature and contents of container

The product is packed in laminate sachets comprising paper/polythene/aluminium foil/polythene.

A trial size sample consists of a single attached to a cardboard backing. Two, three, four, five or ten sachets may be contained in a boxboard carton.

### 6.6 Special precautions for disposal

Not applicable.

## 7 MARKETING AUTHORISATION HOLDER

Risolv Health Limited
Clifton House
Bunnian Place
Basingstoke
RG21 7JE

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 58255/0001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/05/1998

## 10 DATE OF REVISION OF THE TEXT

05/02/2025