SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

VistaPrep 110g Powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains the following active substances:

Macrogol 3350	105.000 g
Sodium chloride	2.800 g
Sodium bicarbonate	1.430 g
Potassium chloride	0.370 g

The electrolyte ion content of one sachet after preparation of 1,000 mL solution is equivalent to:

Sodium	65 mmol/L
Chloride	53 mmol/L
Bicarbonate	17 mmol/L
Potassium	5 mmol/L

Excipients with known effect

- glucose
- sulphur dioxide

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Appearance: white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

VistaPrep is used for bowel cleansing in preparation for colonoscopy.

VistaPrep is indicated in adults over 18 years of age.

4.2 Posology and method of administration

Posology

For complete bowel cleansing, 3 up to a maximum of 4 litres of VistaPrep solution must be taken. 1 sachet corresponds to 1 L solution.

Paediatric population

VistaPrep should not be used in children because the safety has not been established in this patient group.

Method of administration

The route of administration is for oral use.

The solution is drunk in portions of 200 - 300 mL every 10 minutes until the rectal effluent is clear or 4 litres maximum have been drunk.

Administration takes place over a period of about 4 hours, generally on the examination day. The total amount required can also be taken on the evening before, or a part taken on the evening before and the remaining amount on the morning of the examination day.

Patients should consume no solid food for 2 to 3 hours prior to administration of VistaPrep until after the examination.

Precautions to be taken before handling or administering the medicinal product

For instructions on reconstitution of the medicinal product before administration, see section 6.6. For further directions for use see section 6.2 Incompatibilities.

4.3 Contraindications

Ileus and suspected ileus, gastrointestinal obstruction or perforation, risk of gastrointestinal perforation, hyperflorid colitis, toxic megacolon, gastric emptying disorders. Hypersensitivity to the active substances, other macrogols, sulphur dioxide, glucose, saccharin sodium, orange flavour, lemon-lime flavour, colloidal anhydrous silica, or to any of the excipients listed in section 6.1.

VistaPrep should not be administered to unconscious patients or those with impaired consciousness and patients prone to aspiration or regurgitation, general weakness or impaired swallowing reflex.

4.4 Special warnings and precautions for use

VistaPrep should be administered only under medical supervision in elderly patients and those with reflux oesophagitis or pre-existing cardiac arrhythmias, known or suspected SA block or sick sinus syndrome.

Use is possible in patients with chronic inflammatory bowel disease (exception: highly florid stages and toxic megacolon). However, VistaPrep must be administered with caution in these patients, preferably under medical supervision.

In patients with heart failure (NYHA class III and IV), renal insufficiency, liver disease or in patients with severe dehydration, VistaPrep should not be used, as the safety of use has not been sufficiently documented in these groups.

In certain patients at risk, e.g. elderly or debilitated patients, careful monitoring of the electrolyte and fluid balance is required.

Ischaemic colitis
Post-marketing cases of ischaemic colitis, including serious, have been reported in patients treated with macrogol for bowel preparation. Macrogol should be used with caution in patients with known risk factors for ischaemic colitis or in case of concomitant use of stimulant laxatives (such as bisacodyl or sodium picosulfate). Patients presenting with sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis should be evaluated promptly.

This medicine contains 20 mmol potassium and 260 mmol sodium per 4 litres of VistaPrep solution. This should be taken into consideration by patients on a controlled potassium or sodium diet and for patients with reduced kidney function.

4.5 Interaction with other medicinal products and other forms of interaction

Up to several hours before, during or up to one hour after taking VistaPrep, orally administered medicines may possibly be washed out of the gastrointestinal tract or may not, or only partially, be absorbed. In particular, this applies to delayed-release medicines. If administration of a medicine is absolutely necessary for a life-threatening indication shortly before or whilst taking VistaPrep, oral administration may have to be withheld and a switch made to an alternative.

In diagnostic tests of the discharged intestinal liquid using enzymatic assay procedures (e.g. ELISA), there may be interactions between macrogol 3350 and the enzymatic assays.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited amount of data from the use of VistaPrep in pregnant women. Studies in animals have shown no indirect reproductive toxicity (see section 5.3). Clinically, no effects during pregnancy are anticipated, since systemic exposure to macrogol 3350 is negligible.

Within the context of animal trials, no teratogenic effects were observed. Furthermore, as macrogol 3350 is barely absorbed, VistaPrep may be administered to pregnant women after careful risk-benefit assessment.

Breast-feeding

No human data are available on whether macrogol 3350 is excreted in human milk.

Macrogol 3350 is barely absorbed. VistaPrep can be taken by breast-feeding women if deemed necessary.

Fertility

There are no data on the effects of VistaPrep on fertility in humans. There were no effects on fertility in studies in male and female rats (see section 5.3).

4.7 Effects on ability to drive and use machines

VistaPrep has no or negligible effects on the ability to drive and use machines.

4.8 Undesirable effects

System organ class	*MedDRA frequency convention*	
	Common (≥1/100 to <1/10)	*Very common (≥ 1/10)*
Gastrointestinal disorders	Vomiting, stomach cramps, anal irritation	Nausea, feeling of fullness, flatulence

These phenomena are largely attributable to the drinking of relatively large amounts of liquid within a short period of time. Upon occurrence of gastrointestinal symptoms, administration of VistaPrep should be temporarily slowed down or discontinued until the symptoms subside.

System organ class	*MedDRA frequency convention*	
	Uncommon (≥1/1,000 to <1/100)	*Very rare (<1/10,000)*
General disorders and administration site conditions	General malaise, insomnia	
Cardiac disorders		Cardiac arrhythmias, tachycardia, pulmonary oedema
Investigations		Clinically relevant decrease in the serum levels of calcium, potassium and sodium
Nervous system disorders		Neurological effects ranging from mild disorientation up to generalised seizures as a consequence of altered serum levels of electrolytes (see “Investigations”)
Immune system disorders		Urticaria, rhinorrhoea, dermatitis, probably of allergic origin; anaphylactic shock

Note:

In the literature, cases have been documented where Mallory-Weiss syndrome occurred as a result of vomiting after administration of bowel lavage solutions containing macrogol.

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 www.mhra.gov.uk/yellowcard.

4.9 Overdose

Severe diarrhoea can be expected in the event of overdose. Shifts in the fluid and electrolyte balance, as well as in the acid-base balance, are to be expected only in cases of severe overdose. Sufficient fluid replacement and monitoring of serum electrolytes and pH values should be carried out.

In the event of shifts in the fluid and electrolyte balance and acid-base balance, electrolytes should also be replaced and care taken to correct the acid-base balance.

In the case of aspiration, a toxic pulmonary oedema may develop, requiring immediate intensive-care measures including positive pressure ventilation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: osmotically acting laxatives, macrogol combinations.

ATC code: A 06 AD 65.

VistaPrep is a mixture of different salts with macrogol to produce an isotonic bowel lavage solution.

The pharmacodynamic effect consists in the initiation of diarrhoea. The bowel is emptied and cleansed. The ready for use solution contains electrolytes balanced in such a way that fluid and electrolyte absorption and secretion in the gastrointestinal tract largely cancel each other out and the net flux is almost zero. With the addition of high-molecular macrogol, an iso-osmolar concentration is achieved which has a particle concentration comparable to plasma. This prevents any significant fluid shift between the intestinal lumen and the vascular space. Through this type of balancing and osmolarity, virtually no effect is exerted on the electrolyte and fluid balance in the body.

5.2 Pharmacokinetic properties

Macrogol 3350 itself is an inert compound which is only minimally absorbed during gastrointestinal passage and is not metabolised. A minimal amount of macrogol 3350, < 1% of the administered dose, is excreted via the urine.

5.3 Preclinical safety data

Preclinical studies have shown that macrogol 3350 has no specific toxicological potential.

Two teratogenicity studies, one in rats and one in rabbits, have been conducted. Macrogol 3350 was orally administered up to a dose of 2,000 mg/kg body weight; in rats between day 6 and day 16 of gestation and in rabbits between day 6 and day 18. Both studies showed no signs of a maternotoxic or teratogenic effect up to the maximum dose of up to 2,000 mg/kg body weight. Indirect embryofetal effects have been observed in rabbit studies at maternally toxic levels but rabbits are a sensitive animal test species to the effects of GI-acting substances and the studies were conducted under exaggerated conditions with high dose volumes administered, which are not clinically relevant.

There are long-term animal toxicity and carcinogenicity studies with macrogol 3350. Results from these and other toxicity studies using high levels of orally administered high molecular weight macrogols provide evidence of safety at the recommended dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Saccharin sodium
- Orange flavour
- Lemon-lime flavour
- Colloidal anhydrous silica
- Butylated hydroxytoluene (BHT)

Orange flavour

(Orange flavour contains: natural flavourings, glucose, maltodextrin, gum Arabic (E414), alpha-tocopherol (E307), sulphur dioxide (E220))

Lemon-lime flavour

(Lemon-lime flavour contains: natural flavourings and extracts, nature-identical flavourings, maltodextrin, gum arabic (E414), citric acid (E330), sulphur dioxide (E220)).

6.2 Incompatibilities

- Saccharin sodium
- Orange flavour
- Lemon-lime flavour
- Colloidal anhydrous silica
- Butylated hydroxytoluene (BHT)

Orange flavour

(Orange flavour contains: natural flavourings, glucose, maltodextrin, gum Arabic (E414), alpha-tocopherol (E307), sulphur dioxide (E220))

Lemon-lime flavour

(Lemon-lime flavour contains: natural flavourings and extracts, nature-identical flavourings, maltodextrin, gum arabic (E414), citric acid (E330), sulphur dioxide (E220)).

6.3 Shelf life

Powder: 3 years

Reconstituted solution: Store below 25°C for 3 hours or store in a refrigerator (2°C-8°C) for 48 hours.

Discard any remaining oral solution not consumed within 48 hours.

6.4 Special precautions for storage

Powder: no special storage instructions.

For storage conditions for the reconstituted solution, see section 6.3.

6.5 Nature and contents of container

Container material: sachet of surlyn/aluminium/PE -coated paper.

Packs of 4 sachets.

Multipacks containing 48 (12 x 4) sachets or 64 (16 X 4) sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Preparing the solution

Freshly prepare the almost colourless and slight opalescent solution before use. The contents of one sachet are dissolved in 1,000 mL of lukewarm water. The ready-to-use solution can be placed in the refrigerator after preparation to cool down as it is more pleasant to drink chilled.

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Tillotts Pharma UK Ltd.
Wellingore Hall, Wellingore,
Lincoln, LN5 0HX
UK
Telephone: +44 (0)1522 813500

8 MARKETING AUTHORISATION NUMBER(S)

PL 36633/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/11/2015

10 DATE OF REVISION OF THE TEXT

30/11/2020