

# Vistaprep®

Powder for oral solution.

Macrogol 3350, sodium chloride, sodium bicarbonate and potassium chloride.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

## What is in this leaflet

1. What Vistaprep is and what it is used for
2. What you need to know before you take Vistaprep
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### 1. What Vistaprep is and what it is used for

Vistaprep is a white powder for oral solution with a laxative effect.

Vistaprep is used for bowel cleansing in preparation for the examination of the colon (colonoscopy) in adults over 18 years of age.

### 2. What you need to know before you take Vistaprep

#### Do not take Vistaprep

- if you are allergic to macrogol 3350, sodium chloride, sodium bicarbonate, potassium chloride saccharin sodium, orange flavour, lemon-lime flavour, colloidal anhydrous silica or any of the other ingredients of this medicine (listed in section 6);
- if you have a bowel obstruction or suspected bowel obstruction, strictures or perforations in the gastrointestinal area, or if you are at risk of perforations in the gastrointestinal area;
- if you suffer from problems emptying your stomach or have a severe, highly inflammatory form of colitis (colon inflammation) and a severe, abnormally enlarged colon due to this colitis (toxic megacolon);
- if you have an impaired swallowing and gag reflex, or suffer from general weakness.

Vistaprep should not be administered to patients with impaired consciousness and patients prone to choking or swallowing the wrong way (aspiration) with liquids.

#### Warnings and precautions

Contact your doctor:

- if you are an elderly patient
- if you have reflux disease (“heartburn”, reflux oesophagitis)
- if you have existing problems with your heart rhythm (SA block or sick sinus syndrome)
- if your heart does not pump efficiently (a condition called “heart failure”), and you have discomfort when performing light to moderate exercise or while resting
- if your kidneys and/or liver are not working efficiently (renal and hepatic insufficiency)
- if you have kidney failure or liver disease
- if you have severe dehydration
- if you have severe colitis, diverticulitis or chronic inflammatory bowel disease

In these cases Vistaprep can only be used under the supervision of a doctor who will check your electrolytes and fluid balance.

#### Children

There is no adequate experience for use in children. Vistaprep should therefore not be used in children.

## Other medicines and Vistaprep

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you take other medicines just before, during or up to 1 hour after taking Vistaprep, these may possibly be flushed out during the bowel irrigation and/or may not be effective. However, if it is essential that you must take these other medicines, ask your doctor in advance about an alternative option. This also applies to oral contraceptives (the “Pill”).

Macrogol 3350 may influence results of tests done using intestinal fluids.

#### Vistaprep with food and drink

You should not eat any solid food for 2 to 3 hours before drinking Vistaprep and until after the examination.

#### Pregnancy, breast-feeding, and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is no experience with use in pregnancy. If you are pregnant, your doctor will perform a careful benefit-risk assessment before using Vistaprep.

If necessary, you can also take Vistaprep during breast-feeding.

#### Driving and using machines

No special precautions are required.

#### Vistaprep contains sodium and potassium

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

### 3. How to take Vistaprep

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### Dosage for adults (over 18 years of age)

For complete bowel cleansing, you must take 3 up to a maximum of 4 litres of Vistaprep solution.

1 sachet corresponds to 1 L solution.

Drink the solution in portions of 200-300 mL every 10 minutes, until you notice that the discharge from the anus is clear or 4 litres maximum have been drunk.

Take it over a period of about 4 hours, generally on the examination day. You can take the entire required amount on the evening before, or some on the evening before and the remaining amount on the morning of the examination day. Please agree the procedure with your doctor.

#### Duration of use:

Vistaprep is for single use before a scheduled bowel examination.

#### Preparing the solution:

Please prepare the almost colourless and slightly cloudy solution freshly before use. The contents of one sachet are dissolved in one litre of

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lukewarm water. Make up 3-4 litres of solution in this way. As 1 sachet of Vistaprep corresponds to 1 litre of solution, you will need 3 to 4 sachets to produce 3-4 litres of solution. You can place the ready-to-use solution in the fridge to cool down after preparation. The chilled solution is more pleasant to drink.

You must not add any other solutions or additives (especially sugar or flavourings not compatible with Vistaprep solution) to the Vistaprep oral solution, as this, among other things, can result in a change in the electrolyte composition in your blood. Furthermore, explosive gas mixtures may develop in the intestines when the added substances are broken down by intestinal bacteria.

Please talk to your doctor if you have the impression that the effect of Vistaprep is too strong or too weak.

#### If you take more Vistaprep than you should

Diarrhoea or watery stools is the goal of treatment with Vistaprep. However, if you have taken much more Vistaprep than you should, severe symptoms of diarrhoea will occur.

In this case, you should drink plenty of liquid and always consult your doctor for advice.

#### If you forget to take Vistaprep

If you drink much less than the recommended amount, your bowel may not be thoroughly emptied. In this case, the examination cannot be carried out as planned. Therefore, please keep to the dosage recommended by your doctor or as recommended in this leaflet.

#### If you stop taking Vistaprep

If you stop taking Vistaprep or discontinue it too soon, your bowel may not be thoroughly emptied. In this case, the examination cannot be carried out as planned.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### Significant side effects or signs you should look out for and what to do if affected:

All medicines can cause allergic reactions. However, severe allergic reactions are very rare. If you are affected by any of the following side effects, do not take any more VistaPrep and tell your doctor as soon as possible:

- Allergic skin rash
- Circulatory disorders
- Shortness of breath
- Outbreaks of sweating with nausea

### The following side effects have also been observed:

#### Very common side effects (may affect more than 1 in 10 people):

- Nausea, feeling full and flatulence

#### Common side effects (may affect up to 1 in 10 people):

- Vomiting, stomach cramps and anal irritation.

These phenomena are largely due to drinking a relatively large amount of liquid within a short space of time. If symptoms occur in the gastrointestinal tract, administration of Vistaprep should be temporarily slowed down or stopped until the symptoms subside.

#### Uncommon side effects (may affect up to 1 in 100 people):

- General malaise and insomnia.

#### Very rare side effects (may affect up to 1 in 10,000 people):

- Irregular or rapid heartbeat (heart rhythm disorders, tachycardia) and fluid accumulation in the lungs (pulmonary oedema).
- Drop in blood calcium, potassium and sodium levels with tangible signs of illness.
- Neurological symptoms resulting from an electrolyte imbalance in the blood, which can range from mild disorientation to general seizures.

- Hives (urticaria), nasal discharge, runny nose (rhinorrhoea) or acute inflammation of the skin (dermatitis) which are probably allergic in nature, anaphylactic shock.

#### Note:

There have been cases described where vomiting has occurred followed by bleeding due to tearing of the gullet (Mallory-Weiss syndrome) after swallowing solutions containing macrogol.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971, Fax: +353 1 6762517; website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Vistaprep

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

Do not use this medicine after the expiry date which is stated on the sachet and carton. The expiry date refers to the last day of that month.

#### Storage conditions:

Powder: no special storage instructions.

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

Discard any remaining oral solution if not consumed within 48 hours.

## 6. Contents of the pack and other information

### What Vistaprep contains

The active substances are (per sachet):

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

– The other ingredients are:

Saccharin sodium, colloidal anhydrous silica, orange flavouring (orange flavouring contains flavouring preparations flavouring substances, natural flavouring substances, maltodextrin, gum Arabic (E414), alpha-tocopherol (E307)) and lemon-lime flavouring (lemon-lime flavouring contains: natural flavouring preparations, natural flavouring substances, maltodextrin, gum Arabic (E414), citric acid (E330)).

### What Vistaprep looks like and contents of the pack

Vistaprep is a white powder for oral solution.

Vistaprep is available in packages of 4 or 64 sachets and in multipacks comprising 12 cartons, each containing 4 sachets of powder for oral solution.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

Tillotts Pharma GmbH  
Warmbacher Str. 80  
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### Manufacturer

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Strassburger Str. 77  
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