

Public Assessment Report

SoLo Prep

PL 11847/0013

SOLO PREP

PL 11847/0013

UKPAR

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SOLO PREP

PL 11847/0013

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted E-Z-EM Limited a Marketing Authorisation (licence) for the medicinal product SoLo Prep (PL 11847/0013). This is a pharmacy [P] medicine used to cleanse the bowel before surgery, radiography or procedures involving an examination of the bowel.

SoLo Prep contains the active ingredients heavy magnesium carbonate, anhydrous citric acid and potassium citrate. When added to water, SoLo Prep becomes a solution of magnesium citrate, which encourages bowel movement.

No new or unexpected safety concerns arose from this application and it was decided that the benefits of using SoLo Prep outweigh the risks, hence a Marketing Authorisation has been granted.

SOLO PREP

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SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product SoLo Prep (PL 11847/0013) to E-Z-EM Limited on 12 April 2006. The product is a pharmacy medicine.

The application was submitted as an abridged application according to Article 10.1(a)(ii) of Directive 2001/83/EC (bibliographic application).

SoLo Prep contains the active ingredients heavy magnesium carbonate, anhydrous citric acid and potassium citrate. It is indicated for use in the evacuation of the bowel before exploratory procedures, surgery or radiography.

A common use for high doses of oral magnesium salts is to produce a laxative effect. In the intestinal lumen the poorly absorbable magnesium ions exert an osmotic effect and cause water to be retained in the intestinal lumen. This increases the fluidity of the intraluminal contents and results in a laxative action.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 11847/0013
PROPRIETARY NAME:	SoLo Prep
ACTIVE(S):	Heavy Magnesium Carbonate Anhydrous Citric Acid Potassium Citrate
COMPANY NAME:	E-Z-EM
E.C. ARTICLE:	10.1(a)(ii) bibliographic
LEGAL STATUS:	P

INTRODUCTION & BACKGROUND

This standard, bibliographic, abridged application for effervescent powder containing Magnesium Carbonate, Citric Acid and Potassium Citrate is submitted under Article 10.1(a)(ii) of Directive 2001/83/EC.

The actives are currently used in a number of UK products as osmotic laxatives. It is acceptable for such applications to be bibliographic.

DRUG SUBSTANCES

General information

Magnesium carbonate, anhydrous citric acid and potassium citrate are the actives in the formulation. The reaction between magnesium carbonate and citric acid forms the active, magnesium citrate. The active acts as an osmotic laxative. About 15-30% of the magnesium content is absorbed and excreted in urine.

Manufacture of active substances

A suitable active ingredient manufacturer (AIM) is proposed for anhydrous citric acid and potassium citrate. Both actives are received with Certificates of Analysis from the supplier and it is stated that the actives comply with the USP and Ph.Eur. monographs. Satisfactory supplier and in-house (finished product manufacturer) Certificates of Analysis are provided.

A suitable AIM is proposed for magnesium carbonate. The active is received with Certificates of Analysis from the supplier and it is stated that the active complies with the USP and Ph.Eur. monographs. Satisfactory supplier and in-house (finished product manufacturer) Certificates of Analysis are provided.

Control of active substance

It is stated that all three actives comply with the Ph.Eur. specifications, and are commonly used in the food and pharmaceutical industry and no development chemistry is provided. It is also stated that impurities comply with the US, BP and Ph.Eur. requirements.

Containers and closures for the actives

Satisfactory details of the containers used for routine packaging of the active substances are provided.

Stability tests on drug substances

Stability data is not provided for the drug substances and no formal stability studies have been conducted. The applicant has stated that the active ingredients are in common use in the food and pharmaceutical industry and conduct of the stability trials is not seen as necessary. However, an assurance has been provided by the applicant that before use, each batch of raw material will be fully tested in-house according to Ph.Eur. specifications.

DRUG PRODUCT

Composition

The product is described as a white coarse powder.

Names of ingredients	g per sachet	Reference standards
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Active substances		
Heavy Magnesium Carbonate	10.380	Ph.Eur.
Anhydrous Citric Acid	22.071	Ph.Eur.
Potassium Citrate	1.025	Ph.Eur.
Excipients		
Saccharin Sodium		Ph.Eur.
PEG 8000		NF

Clinical trial formula

Not applicable. It is stated that the product is currently on the market in USA, with the trade name of "LoSo Prep".

Development pharmaceuticals

Magnesium carbonate is insoluble in water. However, it will dissolve upon reaction with an aqueous acid solution, forming magnesium citrate. The carbonic acid formed decomposes to yield carbon dioxide, resulting in the effervescent reaction.

The formulation contains excipients commonly used in the preparation of oral pharmaceutical products and does not contain any new excipient. Data has been provided to support the reconstitution time of the powder mix.

Method of preparation

A suitable site is named for the control of starting material, manufacturing, assembly, QC and batch release of the product. It is stated that the premises was inspected by an EU regulatory agency and found to be satisfactory. A manufacturing licence is provided.

The manufacturing process is adequately summarised and a flow diagram is provided.

Satisfactory in-process controls are provided.

Process validation/qualification protocols and reports are also provided.

Other ingredients

Saccharin sodium is Ph.Eur. grade and PEG 8000 is NF. Satisfactory supplier's and in-house Certificates of Analysis are provided for typical batches.

Container and closure system

PET/LDPE/Aluminium foil/LDPE /Linear LDPE sachets. The linear LDPE is the product contact material and is stated to be of suitable quality for food contact. SoLo Prep is presented in bulk packs containing 10 sachets per pack.

Control tests on the finished medicinal product

Specifications and routine tests

A satisfactory finished product specification is provided.

Analytical methods and validation

Analytical methods are described and validation data provided where necessary.

Batch data

Satisfactory batch analysis data have been supplied for three batches of products as per specification. All three batches fully comply with the proposed finished product specification.

Stability of drug product

Stability data are provided for three batches of products in sachets proposed for marketing. The analytical methods used for assessment of the stability of the finished product were as described for routine batch release.

Storage conditions for testing: 25°C/60%RH, 30°C/60%RH and 40°C/75%RH .

The stability data provided is adequate to support the proposed shelf life of 36 months.

BIOAVAILABILITY/BIOEQUIVALENCE

No trials are required for this bibliographic application.

OTHER INFORMATION

TSE status

The applicant declares that no material of animal origin is used in the preparation of the products.

The applicant has provided satisfactory declarations from the manufacturers/suppliers of actives and excipients regarding the TSE risk status of the materials. None are of animal origin.

Genetically Modified Organisms (GMO)

The applicant declares that no GMO material is used in the preparation of the product.

PRODUCT PARTICULARS

Product name and appearance

The proposed product name is acceptable.

Marketing Authorisation Application (MAA) forms

Satisfactory.

SPC, PIL and Labelling

Satisfactory.

PHARMACEUTICAL EXPERT REPORT

The pharmaceutical expert is named. The expert report is a good summary of the data presented.

DISCUSSION

There are no major pharmaceutical issues in this application.

CONCLUSION

A marketing authorisation may be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required.

CLINICAL ASSESSMENT

LICENCE NO:	PL 11847/0013
PROPRIETARY NAME:	SoLo Prep
ACTIVE(S):	Heavy Magnesium Carbonate Anyhdrous Citric acid Potasium citrate
COMPANY NAME:	E-Z-EM Ltd
E.C. ARTICLE:	10.1(a)(ii)
LEGAL STATUS:	P

INTRODUCTION

This is a standard abridged national application for the use of SoLo Prep as a bowel cleansing agent prior to an investigative procedure. The application is submitted in accordance with Article 10.1(a)(ii) of Directive 2001/83/EC, based on bibliography.

BACKGROUND

The main active ingredient of SoLo Prep is magnesium carbonate. It is an osmotic laxative and acts by retaining fluid in the bowel by osmosis or by changing the pattern of water distribution in the faeces.

INDICATIONS

For the evacuation of the bowel before exploratory procedures, surgery or radiography.

Assessor's comment

This indication is appropriate.

DOSE & DOSE SCHEDULE

These are satisfactory.

TOXICOLOGY

This has been assessed separately.

CLINICAL PHARMACOLOGY

Pharmacodynamics

In the intestinal lumen the poorly absorbable magnesium ions exert an osmotic effect and cause water to be retained in the intestinal lumen. This increases the fluidity of the intraluminal contents and results in a laxative action.

Pharmacokinetics

Magnesium metabolism depends mainly on gastrointestinal absorption and renal excretion. Magnesium absorption occurs by saturable transport system and passive diffusion. When oral osmotic laxatives containing magnesium are administered, approximately 15 – 30% may be absorbed, with excretion being handled by the kidney.

EFFICACY

The applicant has provided 11 copies of publications and a comprehensive literature review which confirm the effectiveness of SoLo Prep.

SAFETY

The applicant has provided publications or literature reviews which confirm the safety of SoLo Prep.

EXPERT REPORT

A satisfactory clinical expert report has been provided with an appropriate CV.

SUMMARY OF PRODUCT CHARACTERISTICS

Satisfactory.

PATIENT INFORMATION LEAFLET

Satisfactory.

LABELLING

Full colour mock-ups have been provided.

DISCUSSION

Osmotic laxatives containing magnesium carbonate have been available in the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

CONCLUSION

A marketing authorisation may be granted.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of SoLo Prep are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

Osmotic laxatives containing magnesium carbonate have been available in the UK for more than ten years. Their use is well established with recognised efficacy and acceptable safety.

No new or unexpected safety concerns arise from this application.

RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The efficacy of the active ingredients in SoLo Prep for use as osmotic laxatives is established. The risk-benefit assessment is therefore considered to be favourable.

SOLO PREP

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for SoLo Prep on 15 July 2003.
2	The MHRA's assessment of the submitted clinical data was completed on 21 November 2003.
3	Further information (clinical) was requested from the company on 27 November 2003.
4	The applicant's response to further information request (clinical) was received on 12 December 2003.
5	The MHRA's assessment of the submitted quality data was completed on 18 December 2003.
5	Further information (quality) was requested from the company on 7 January 2004, 29 July 2005 and 18 January 2006.
6	The MHRA completed its assessment of the application on 15 March 2006.
7	The application was determined on 12 April 2006.

SOLO PREP

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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SoLo Prep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Heavy Magnesium Carbonate	Ph Eur	10.380 g/sachet
Anhydrous Citric Acid	Ph Eur	22.071 g/sachet
Potassium Citrate	Ph Eur	1.025 g/sachet

For excipients see Section 6.1.

3. Pharmaceutical Form

Effervescent Powder.

White coarse powder which effervesce in water with a tart flavour.

For preparation as a solution following the addition of water as directed in section 6.6

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the evacuation of the bowel before exploratory procedures, surgery or radiography.

4.2. Posology and method of administration

For oral administration.

Adults and Elderly:

First dose: The contents of one sachet reconstituted at 8:00am on the day prior to the examination.

Second dose: The contents of one sachet, reconstituted between 2:00 and 4:00pm on the day prior to the examination.

The dose may be reduced to half a sachet for very ill or very thin, elderly patients who may tolerate vigorous bowel cleansing poorly.

Children over 10 years: Half the adult a dose, timing as for adults.

Children 5 –9 years: A third of the adult dose, timing as for adults.

The examination may be preceded by a low residue or fluid only diet according to the instructions of the treating physician. Plenty of clear fluids, at least 8 glasses of water, should be consumed between taking SoLo Prep and the examination.

4.3. Contra-indications

SoLo Prep should not be used in patients with severely reduced renal function, acute gastro-intestinal conditions such as intestinal perforation or obstruction, paralytic ileus, severe inflammatory conditions of the intestinal tract (e.g. Crohn's disease, ulcerative colitis, and toxic megacolon).

4.4. Special Warnings and Precautions for Use

SoLo Prep should not be used in patients suffering from nausea, vomiting, or abdominal pain unless directed by the treating physician. The risk of toxic hypermagnesaemia indicates the need for caution in the administration of magnesium citrate to patients with renal impairment. Caution should be taken when administered to patients with hepatic impairment, elderly and debilitated patients.

SoLo Prep should be used with caution in which hyperkalaemia can occur, such as Addison's disease, selective hypoaldosteronism, and treatment with spironolactone, triamterene or amiloride.

SoLo Prep contains on average 275mg of potassium per sachet. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet

4.5. Interactions with other medicinal products and other forms of interaction

None known

4.6. Pregnancy and lactation

SoLo Prep should only be used in pregnancy or nursing mothers at the discretion of the treating physician.

4.7. Effects on ability to drive and use machines

None known

4.8. Undesirable Effects

Colic has been reported following oral administration of magnesium salts.

4.9. Overdose

Treat symptomatically.

In the rare circumstances, extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbance.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other laxatives

ATC code: A06AX

A common use for high doses of oral magnesium salts is to produce a laxative effect. In the intestinal lumen the poorly absorbable magnesium ions exert an osmotic effect and cause water to be retained in the intestinal lumen. This increases the fluidity of the intraluminal contents and results in a laxative action.

5.2. Pharmacokinetic properties

Magnesium metabolism depends mainly on gastrointestinal absorption and renal excretion. Magnesium absorption occurs by saturable transport system and passive diffusion. When oral osmotic laxative containing magnesium are administered approximately 15 – 30% may be absorbed, with excretion being handled by the kidney.

5.3. Preclinical safety data

There is no additional data other than that already provided in other sections of this Summary of Product Characteristics

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Saccharin Sodium
Polyethylene Glycol 8000

6.2. Incompatibilities

Not applicable

6.3. Shelf Life

6.3.1. Shelf life as packaged for sale

The shelf life of the medicinal product as packaged for sale is 36 months when stored unopened below 30°C.

6.3.2. Shelf life after reconstitution according to directions

The solution product should be administered immediately after reconstitution as directed and must not be stored.

6.3.3. Shelf life after first opening of the sachet

Not applicable: SoLo Prep is presented as a single-dose per sachet, which allows for preparation by the patient as required. Any unused product should be discarded immediately.

6.4. Special precautions for storage

No special precautions for storage. Store in original package.

6.5. Nature and Contents of Container

SoLo Prep granules is provided in a single-dose sachet. The sachet material is multi-layer comprising PET/LDPE/aluminium foil/LDPE/Linear LDPE and the linear LDPE is the product contact material. Each sachet contains 34g of SoLo Prep granules.

SoLo Prep is presented in bulk packs containing 10 sachets per pack.

6.6. Instructions for Use/Handling

Slowly add the contents of the sachet to 200ml (8fl. oz) of cold water into a large glass. Stir gently. After effervescence stops, stir until dissolved

7. MARKETING AUTHORISATION HOLDER

E-Z-EM Limited
Avonbury Business Park
Howes Lane
Bicester
OX26 2UB
United Kingdom.

8. MARKETING AUTHORISATION NUMBER

PL 11847/0013

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/04/2006

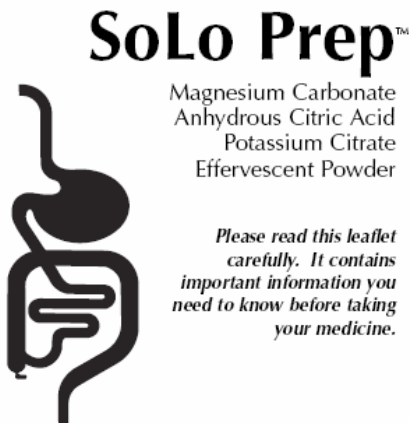
10 DATE OF REVISION OF THE TEXT

12/04/2006

Patient Information Leaflet

SOLO PREP

PL 11847/0013



SoLo Prep™

Magnesium Carbonate
Anhydrous Citric Acid
Potassium Citrate
Effervescent Powder

*Please read this leaflet
carefully. It contains
important information you
need to know before taking
your medicine.*

WHAT IS SOLO PREP?

SoLo Prep contains the active ingredients magnesium carbonate 10.38g, anhydrous citric acid 22.07g, and potassium citrate 1.025g in each sachet. In addition, SoLo Prep also contains: saccharin sodium, and polyethylene glycol 8000. SoLo Prep is dispensed in sachets containing 34g of effervescent powder. When added to water SoLo Prep becomes a solution of magnesium citrate, which is a strong laxative.

WHAT IS SOLO PREP USED FOR?

SoLo Prep is used to cleanse the bowel prior to exploratory procedures, surgery or radiography.

Marketing Authorisation Holder: E-Z-EM Limited, Bicester, Oxfordshire, OX26 2UB, UK.

Manufacturer responsible for batch release in the EU: E-Z-EM Limited, Bicester, Oxfordshire, OX26 2UB, UK.

WHEN SHOULD SOLO PREP NOT BE USED?

If you are suffering from kidney disease you may be at risk from high blood levels of magnesium and should tell your doctor before taking SoLo Prep. Before you take the product, you should tell your doctor if you are pregnant or think you could be pregnant, or breast-feeding.

SoLo Prep should not be taken if you are suffering from Crohn's disease, (inflammation of the intestinal tract), or if you have a known perforation (hole) or obstruction of the intestinal tract.

Care is advised if you are suffering from any disease which may result in high blood levels of potassium such as Addison's disease, hypoadosteronism (low levels of the hormone aldosterone) and treatment with diuretics such as amiloride, spironolactone or triamterene.

SoLo Prep contains on average 275mg of potassium per sachet. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Please tell your doctor if any of these circumstances apply to you.

HOW IS SOLO PREP ADMINISTERED?

SoLo Prep effervescent powder is mixed with water to form a solution.

An appointment has been made for you to have an examination of your bowel. To prepare for this your bowel must be empty as possible. It is important that you follow these instructions and this will provide the best results and avoid having to repeat the procedure at a later date. On the day before the examination:

Adults: First dose:

At 8:00am slowly add the contents of one sachet to 200ml (8fl. oz) of cold water into a large glass. Stir gently. After effervescence (fizzing) stops, stir until dissolved then drink.

Second dose:

Between 2:00 and 4:00pm on the day prior to the examination, take the second sachet as described above.

The dose may be reduced to half a sachet for very ill or very thin, elderly patients who may tolerate vigorous bowel cleansing poorly.

Children over 10 years: Half a sachet per dose, timing as for adults.

Children 5-9 years: A third of a sachet per dose, timing as for adults.

Individual responses to laxatives vary so remain close to toilet facilities once you have taken SoLo Prep. Remember SoLo Prep will cause diarrhoea.

The examination may be preceded by a low residue or fluid only diet according to the instructions of your doctor. Plenty of clear fluids, at least 8 glasses of water, should be taken between taking SoLo Prep and the examination. Take only medicines and foods as directed by your doctor.

If you are suffering from diabetes you should contact the hospital department where your appointment has been made for advice on diet.

On the day of the examination

DO NOT eat any solid food until after the examination, and keep drinking clear fluids.

After the examination

You may eat normally after the examination is over. A high residue diet such as wholemeal food will help to restore normal bowel function, which should return to normal with a day or two.

WHAT UNDESIRABLE EFFECTS MAY SOLO PREP CAUSE?

SoLo Prep will cause diarrhoea. You may also experience abdominal pain. If you experience any other unexpected effects contact your doctor.

HOW TO STORE SOLO PREP

Do not store above 30°C. Stored in the original packaging. This product should be taken immediately following mixing in water and should not be stored. Any unused product should be discarded immediately. Each sachet carries an expiry date after which the product must not be used.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Date of preparation of package insert: October 2004



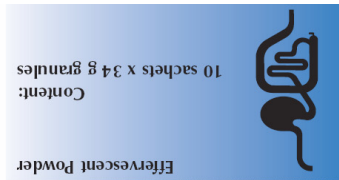
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Labels/Packaging

SOLO PREP

PL 11847/0013

Carton



Content:
10 sachets x 3.4 g granules

Effervescent Powder

SoLo Prep™

SoLo Prep™

Magnesium Carbonate 10.38g
Anhydrous Citric Acid 22.07g
Potassium Citrate 1.025g

Effervescent Powder

For the evacuation of the bowel
before exploratory procedures,
surgery or radiography

Contents: 10 sachets x 3.4g



Marketing Authorisation held by:
E-Z-EM Limited
Bicester
Oxfordshire
OX26 2UB
UK

SoLo Prep™

Effervescent Powder

Active ingredients: Each sachet contains the active ingredients: Magnesium Carbonate 10.38g/sachet, Anhydrous Citric Acid 22.07g/sachet, and Potassium Citrate 1.025g/sachet which on addition to water forms Magnesium Citrate solution.

Other constituents: Saccharin Sodium, Polyethylene Glycol 8000

Use: For the evacuation of the bowel before exploratory procedures, surgery or radiography.

Dosage and method of administration: SoLo Prep is for oral administration.

Adults:

First dose: The contents of one sachet reconstituted at 8:00am on the day prior to the examination.

Second dose: The contents of one sachet, reconstituted between 2:00 and 4:00pm on the day prior to the examination.

The dose may be reduced to half a sachet for very ill or very thin, elderly patients who may tolerate vigorous bowel cleansing poorly.

Children over 10 years: Half the adult a dose, timing as for adults.

Children 5-9 years: A third of the adult dose, timing as for adults.

The examination may be preceded by a low residue or fluid only diet according to the instructions of the treating physician. Plenty of clear fluids, at least 6 glasses of water, should be consumed between taking SoLo Prep and the examination.

SoLo Prep™

Magnesium Carbonate 10.38g
Anhydrous Citric Acid 22.07g
Potassium Citrate 1.025g

Effervescent Powder

For the evacuation of the bowel
before exploratory procedures,
surgery or radiography

Contents: 10 sachets x 3.4g



Marketing Authorisation held by:
E-Z-EM Limited
Bicester
Oxfordshire
OX26 2UB
UK

SoLo Prep™

Effervescent Powder

Contra-indications: SoLo Prep should not be used in patients with severely reduced renal function, acute gastrointestinal conditions such as intestinal perforation or obstruction, paralytic ileus or severe inflammatory conditions of the intestinal tract.

Warnings and precautions: SoLo Prep should not be used in patients suffering from nausea, vomiting, or abdominal pain unless directed by the treating physician. The risk of toxic hypermagnesaemia indicates the need for caution in the administration of magnesium citrate to patients with renal impairment. SoLo Prep should be used with caution in conditions in which hyperkalaemia can occur, such as Addison's disease, selective hypoadosteronism, and treatment with diuretics such as spironolactone, triamterene or amiloride.

SoLo Prep should only be used in pregnancy or nursing mothers at the discretion of the treating physician.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Do not store above 30°C. Store in original packaging. Discard any unused product immediately.

Please read the enclosed leaflet.

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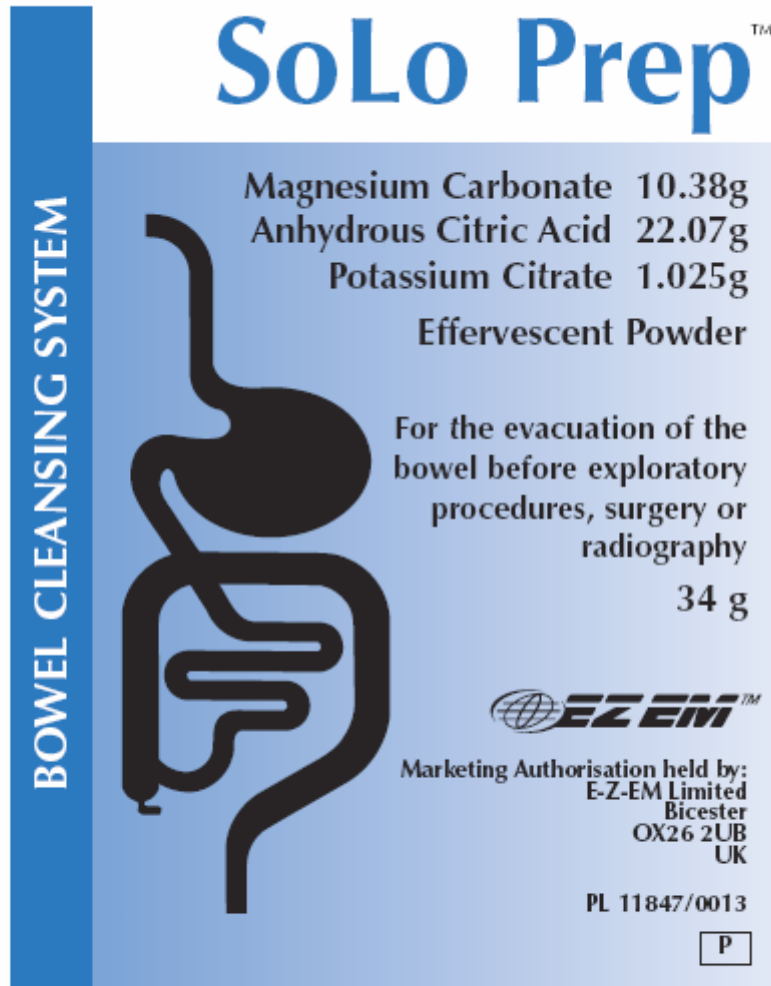
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SOLO PREP

PL 11847/0013

Sachet (front)



SoLo PrepTM


BOWEL CLEANSING SYSTEM


Magnesium Carbonate 10.38g
Anhydrous Citric Acid 22.07g
Potassium Citrate 1.025g

Effervescent Powder

For the evacuation of the
bowel before exploratory
procedures, surgery or
radiography

34 g



 **E-Z-EM**TM

Marketing Authorisation held by:
E-Z-EM Limited
Bicester
OX26 2UB
UK

PL 11847/0013

P

SOLO PREP

PL 11847/0013

Sachet (back)

SoLo Prep™

Magnesium Carbonate,
Anhydrous Citric Acid, Potassium Citrate
Effervescent Powder

Active ingredients: Each sachet contains the active ingredients: Magnesium Carbonate 10.38g/sachet, Anhydrous Citric Acid 22.07g/sachet, and Potassium Citrate 1.025g/sachet which on addition to water forms Magnesium Citrate solution.

Other constituents: Saccharin Sodium, Polyethylene Glycol 8000

Use: For the evacuation of the bowel before exploratory procedures, surgery or radiography.
Contra-indications: SoLo Prep should not be used in patients with severely reduced renal function, or acute gastro-intestinal conditions such as perforations, obstructions and severe inflammation conditions such as Crohn's disease. **Warnings and precautions:** SoLo Prep should not be used in patients suffering from nausea, vomiting, or abdominal pain unless directed by the treating physician. The risk of toxic hypermagnesaemia (high blood magnesium level) indicates the need for caution in the administration of magnesium citrate to patients with renal impairment. SoLo Prep should be used with caution in conditions in which hyperkalaemia (high blood potassium level) can occur, hypoaldosteronism (low levels of the hormone aldosterone), and treatment with diuretics such as spironolactone, triamterene or amiloride. SoLo Prep should only be used in pregnancy or nursing mothers at the discretion of the treating physician.

Dosage and administration: SoLo Prep is for oral administration following reconstitution in water. *Adults and Elderly: First dose:* The contents of one sachet reconstituted at 8:00am on the day prior to the examination. *Second dose:* The contents of one sachet, reconstituted between 2:00 and 4:00pm on the day prior to the examination. The dose may be reduced to half a sachet for very ill or very thin, elderly patients who may tolerate vigorous bowel cleansing poorly.

Children over 10 years: Half the adult a dose, timing as for adults.

Children 5 -9 years: A third of the adult dose, timing as for adults.

Individual responses to laxatives vary so remain close to toilet facilities once you have taken SoLo Prep. Remember SoLo Prep will cause diarrhoea. The examination may be preceded by a low residue or fluid only diet according to the instructions of the treating physician. Plenty of clear fluids, at least 8 glasses of water, should be consumed between taking SoLo Prep and the examination.

Mixing instructions: Slowly add the contents of the sachet to 200ml (8fl. oz) of cold water into a large glass. Stir gently. After effervescence stops, stir until dissolved.

Storage: Do not store above 30°C. Store in the original packaging. Discard any unused product immediately. **Important:** This product should be administered immediately following reconstitution in water and must not be stored.

Please read the enclosed leaflet.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

rev 10/04 xxxxxxx