MOVICOL VANILLA 14G SACHET, POWDER FOR ORAL SOLUTION

PL 00322/0085

UKPAR

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MOVICOL VANILLA 14G SACHET, POWDER FOR ORAL SOLUTION

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LAY SUMMARY

The MHRA granted Norgine Limited a Marketing Authorisation (licence) on the 27th January 2006, for MOVICOL Vanilla 14g sachet, powder for oral solution. This Pharmacy-only medicine (P) is used to treat chronic constipation and faecal impaction.

MOVICOL Vanilla 14g sachet, powder for oral solution contains the active ingredients Macrogol 3350, which works as a laxative and Sodium Chloride, Sodium Bicarbonate and Potassium Chloride to maintain electrolyte and water balance in the body.

The clinical data presented to the MHRA, pre licensing, demonstrated that MOVICOL Vanilla 14g sachet, powder for oral solution is essentially similar or equivalent to the approved product, MOVICOL (PL 00322/0070) and, as such, can be used interchangeably.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of taking MOVICOL Vanilla 14g sachet, powder for oral solution outweigh the risks, hence a Marketing Authorisation have been granted.

MOVICOL VANILLA 14G SACHET, POWDER FOR ORAL SOLUTION

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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 MOVICOL Vanilla 14g sachet, powder for oral solution to Norgine Limited on 27th January 2006. The product is for sale in pharmacies only.

The application was submitted as abridged applications according to article 10.1(a) of Directive 2001/83/EC as amended, claiming essential similarity to the approved product, MOVICOL (PL 00322/0070).

The product contains the active ingredients Macrogol 3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride and is indicated in the treatment of chronic constipation and faecal compaction.

Macrogol is a long linear polymer which works as an osmotic agent as it retains water molecules by means of hydrogen bonds, leading to an increase in the volume of intestinal fluids, when administered orally. It is the volume of unabsorbed intestinal fluid, which accounts for the laxative properties of the solution. Sodium Chloride, Sodium Bicarbonate and Potassium Chloride act to maintain electrolyte and water balance

PHARMACEUTICAL ASSESSMENT

1. INTRODUCTION

This is a standard national abridged line extension Marketing Authorisation application for MOVICOL Vanilla submitted under article 10.1(a) (iii), paragraph 1 of the EEC directive 2001/83. MOVICOL Vanilla is a line extension of the product MOVICOL (PL 00322/0070) which was granted approval in December 1995. Reference is made to this product and MOVICOL Paediatric (PL 00322/0082) throughout the application.

1.1 Product Name and Legal Status

The legal status and name are acceptable.

MODULE 2

2.2 Introduction

2.3 Quality Overall Summary (QOS)

A quality overall summary along with an acceptable CV is provided. It is a non-critical summary of the data and is satisfactory.

MODULE 3 QUALITY

3.2.S. DRUG SUBSTANCE

3.2.S.1 GENERAL INFORMATION

An EDQM certificate of suitability for Macrogol has been provided and is acceptable.

3.2.S.1.1 Nomenclature

INN:
Macrogol
Sodium Chloride
Sodium Hydrogen Carbonate (Sodium Bicarbonate)
Potassium Chloride

3.2.S.1.2 Structure

Macrogol = $H-(OCH_2-CH_2)_n-OH$ where *n* represents the average number of oxyethylene groups (N=3350).

3.2.S.1.3 General Properties

Macrogol is an osmotic agent.
Sodium Chloride, Sodium Bicarbonate and Potassium Chloride act to maintain electrolyte and water balance

3.2.S.2 MANUFACTURE

The manufacture is cross referenced to PL 00322/0082 and the EDQM Certificate of Suitablity.

3.2.S.3 CHARACTERISATION

3.2.S.3.1 Elucidation of structure and other characteristics

3.2.S.3.2 Impurities

The above are cross referenced to PL 00322/0082 and the EDQM Certificate of Suitablity.

3.2.S.4 CONTROL OF DRUG SUBSTANCE

3.2.S.4.1 Specification

The routine tests performed by the manufacturer have been stated and are acceptable.

3.2.S.4.2 Analytical procedures

3.2.S.4.3 Validation of analytical procedures

3.2.S.4.4 Batch analyses

3.2.S.4.5 Justification of specification

All the above are cross referenced to PL 00322/0082 and the EDQM Certificate of Suitability.

3.2.S.5 REFERENCE STANDARDS OR MATERIALS

Cross reference to PL 00322/0082 and the EDQM Certificate of Suitability.

3.2.S.6 CONTAINER CLOSURE SYSTEM

Cross reference to PL 00322/0082 and the EDQM Certificate of Suitability.

3.2.S.7 STABILITY

3.2.S.7.1 Stability summary and conclusions

3.2.S.7.2 Post-approval stability protocol and stability commitment

3.2.S.7.3 Stability data

Cross reference to PL 00322/0082.

3.2.P. DRUG PRODUCT

3.2.P.1 DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

Below is a comparison of the contents of MOVICOL, one of the products referred to in the application and MOVICOL Vanilla.

Ingredient	Standard	MOVICOL	MOVICOL Vanilla
Actives			
Macrogol	Ph Eur/USNF	13.1250g	13.1250g
NaCl	Ph Eur	0.3507g	0.3507g
$NaHCO_3$	Ph Eur	0.1785g	0.1785g
KCl	Ph Eur	0.0466g	0.0502g
Excipients			
Acesulfame K		✓	×
Lime & Lemon Flavour		✓	×
Aspartame	Ph Eur	×	✓
Vanilla Flavour	IFF	×	✓
Electrolyte content		**mmol/L**	**mmol/L**
Na		65	65
Cl		53	53
K		5.4	5.8
HCO_3		17	17

The vanilla flavour is commercially available.
MOVICOL Vanilla will be supplied as 13.97g sachets for reconstitution in 125 ml water. It will be packaged in sachets identical to other MOVICOL preparations made of four layers; low density polyethylene, aluminium, low density polyethylene and paper. Sachets will then be boxed in packs of 6, 8, 10, 20, 30, 40, 50, 60 and/or 100, though not all pack sizes may be marketed.

3.2.P.2 PHARMACEUTICAL DEVELOPMENT

3.2.P.2.1 Components of the drug product

3.2.P.2.1.1 Drug substance

The active composition of MOVICOL Vanilla is based on that of MOVICOL (PL 00322/0070). MOVICOL Vanilla and MOVICOL contain Macrogol, an osmotic agent and the following actives which act to maintain electrolyte and water balance; Sodium Chloride, Sodium Bicarbonate and Potassium Chloride.
MOVICOL also contains the Acesulfame K which contributes to the overall Potassium Level.
The amount of Potassium Chloride in MOVICOL Vanilla has been increased to make up for the shortfall which results from the removal of Acesulfame K.

3.2.P.2.1.2 Excipients

There are only two excipients present in the formulation, a flavour and a sweetener.

3.2.P.2.2 Drug product

The drug product is based on MOVICOL (PL 00322/0070).

3.2.P.2.2.1 Formulation development

In this section the discussion is focused on two main areas; the acceptability (appearance, odour, immediate taste and after taste) of different flavours and the various electrolyte concentration changes imposed by changing the sweetener from acesulfame K to Aspartame. Overall an acceptable level of development is presented.

3.2.P.2.2.2 Overages
None.

3.2.P.2.2.3 Physicochemical and biological properties
Basic information on the drug substances is presented in this section.

3.2.P.2.3 Manufacturing process development
3.2.P.2.4 Container and closure system
3.2.P.2.5 Microbiological attributes
3.2.P.2.6 Compatibility
The above four topics are not discussed in this section, however the development is cross referenced to currently licensed MOVICOL products and is acceptable.

3.2.P.3 MANUFACTURE
3.2.P.3.1 Manufacturer(s)
An acceptable manufacturing license is provided in with the MAA form.
Additional sites for microbial testing of the drug substance and the finished drug product are stated.

3.2.P.3.2 Batch formula
The formula is correct for the given batch size.

3.2.P.3.3 Description of manufacturing process and process controls
Flow diagrams have been supplied for the manufacturing and packaging process. The product is manufactured using a simple powder blend technique.

3.2.P.3.4 Control of critical steps and intermediates
The product will be tested as per the previously granted licence PL 00322/0082. This is satisfactory.

3.2.P.3.5 Process validation and/or evaluation
The finished product manufacturer states they will fully validate the first three commercial batches and data will be provided on request. The protocol for this post licensing validation testing has been supplied and is acceptable.

3.2.P.4 CONTROL OF EXCIPIENTS
3.2.P.4.1 Specifications
3.2.P.4.2 Analytical procedures
3.2.P.4.3 Validation of analytical procedures
3.2.P.4.4 Justification of specifications
Both excipients are used in the food industry and neither is novel.

Aspartame (E951) Ph. Eur.;

A sweetener “generally regarded as safe”. The finished product manufacturer may retest on receipt or may accept the supplier’s Certificate of Analysis (though an identity test will be performed).
The applicant will use IR to confirm identity on receipt and a sample trace is supplied.

Vanilla Flavour (Cream);
Vanilla Flavour is commercially available with a specification set by the manufacturers. and the qualitative and quantative composition of the flavour has been supplied..

The flavour is supplied with a Suppliers certificate of analysis covering appearance, odour, identification, microbiology and moisture.
A sample certificate for the Vanilla (cream) flavour is supplied confirming that it meets the legal requirements for food flavourings (EEC directive 88/388/EEC).
The applicant will use IR to confirm identity on receipt and a sample trace is supplied.
Furthermore, microbiological tests will be conducted according to the Ph Eur. Other tests may also be performed by the applicant.

3.2.P.4.5 Excipients of human or animal origin
3.2.P.4.6 Novel excipients
None.

3.2.P.5 CONTROL OF DRUG PRODUCT
3.2.P.5.1 Specification(s)
The finished product specification has been cross referenced to MOVICOL and MOVICOL Paediatric and in general is similar. The specifications are also in line with current guidance.

3.2.P.5.2 Analytical procedures
The methods are used are based on those of MOVICOL (PL 00322/0070).
Macrogol is both identified and assayed via HPLC. Sodium, Potassium and chloride ions are identified and assayed by ion chromatography. Sodium and potassium are also identified and assayed by flame photometry tests. Chloride ions are identified by precipitation with silver nitrate and bicarbonate by reaction with phenolphthalein and both are assayed by titration.

3.2.P.5.3 Validation of analytical procedures
Acceptable validation has been provided.

3.2.P.5.4 Batch analyses
The supplied batch analysis is acceptable given that three MOVICOL products are currently marketed and an acceptable commitment for further batch analysis has been provided.

3.2.P.5.5 Characterisation of impurities
N/A

3.2.P.5.6 Justification of specifications
The specifications are justified by their similarity to the original MOVICOL (PL 00322/0070) specifications.

3.2.P.6 REFERENCE STANDARDS OR MATERIALS

All references are Ph Eur standard, with the exception of the Vanilla Flavour reference, which is a fully characterised, certified reference standard from the supplier.

3.2.P.7 CONTAINER-CLOSURE SYSTEM

The container-closure system is cross referenced to PL 00322/0082. Appropriate details were supplied and were acceptable.

3.2.P.8 STABILITY

3.2.P.8.1 Stability summary and conclusion

Stability studies were performed under ICH conditions and are acceptable The proposed shelf life is 3 years, as per other MOVICOL products and stability data supports this.

Reconstituted solution;

The proposed shelf life of the reconstituted solution is 6 hours when stored below 2-8°C. Satisfactory stability data has been submitted for the reconstituted product at 4°C.

3.2.P.8.2 Post-approval stability protocol and stability commitment

The first three batches will be placed on long term stability (25°C/60% RH) and accelerated stability. Annually a further batch will be placed on a long term stability study. This is acceptable.

3.2.P.8.3 Stability data

The data is in general acceptable, with all results being within specification and no trends being detected..

MODULE 1

MAA FORM

The MAA form is satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SPC is satisfactory.

LABELLING

Colour mock-ups of the final Packaging (including sachet) have been provided and are satisfactory.

The sachet and the carton labels contain the same information and are in line with the SPC. The label (sachet and carton) does not state storage requirements for reconstituted sachets; however the PIL does provide guidance in line with the SPC.

PATIENT INFORMATION LEAFLET

A mock-up of the final leaflet has been provided which is consistent with the SPC.

TSE

This product contains no materials at risk of TSE

PHARMACEUTICAL CONCLUSIONS

A product licence should be granted for this preparation.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

1. INTRODUCTION

This is a mainstream, national abridged standard licensing application for MOVICOL Vanilla for the treatment of chronic constipation and faecal impaction. The application is submitted under article 10.1(a) of the EEC directive 2001/83. MOVICOL Vanilla is a line extension of the product MOVICOL (PL 00322/0070) which was granted UK approval in December 1995. MOVICOL is currently licensed and actively marketed in over 40 countries worldwide including nine countries within the European Union in which marketing authorisation was granted via the mutual recognition procedure in July 1996, with the UK as the reference member state.

MOVICOL Vanilla is identical in terms of safety, efficacy and quality to MOVICOL. The only difference between MOVICOL Vanilla and the original product (MOVICOL) is the added flavour and sweetener to MOVICOL Vanilla. The sweetener and flavour effects are due to the addition of Aspartame and Vanilla flavour which are well established excipients. Therefore, the recommended dosage administered to the patient remains the same.

2. BACKGROUND

The main active ingredient of MOVICOL Vanilla is macrogol 3350. This high molecular weight polyethylene glycol has been shown to exert an osmotic effect that influences fluid transfer through the colon mucosa. Macrogol 3350 maintains an iso-osmotic liquid flow throughout the length of the gastrointestinal tract.

3. INDICATIONS

For the treatment of chronic constipation. MOVICOL is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon confirmed by physical examination of the abdomen and rectum.

This indication is appropriate.

4. DOSE & DOSE SCHEDULE

These are satisfactory.

5. TOXICOLOGY

No new toxicology data are submitted or required.

6. CLINICAL PHARMACOLOGY

6.1 Pharmacodynamics

The high molecular weight macrogols are long linear polymers which retain water molecules by means of hydrogen bonds. When administered by the oral route, they lead to an increase in the volume of intestinal fluids. It is the volume of unabsorbed intestinal fluid, which accounts for the laxative properties of the solution.

6.2 Pharmacokinetics

Following oral ingestion, Macrogol 3350 undergoes virtually no absorption from the gastrointestinal tact and passes unchanged through the gut. Any macrogol that may be absorbed is excreted via the urine.

6.3 **Bioequivalence**

Not applicable.

7. EFFICACY

No new efficacy data are submitted or required.

8. SAFETY

No new safety data are submitted or required.

9. EXPERT REPORT

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

10. SUMMARY OF PRODUCT CHARACTERISTICS

This is basically similar to the original product's SPC.

11. PATIENT INFORMATION LEAFLET

This is satisfactory.

12. LABELLING

This appears satisfactory.

13. DISCUSSION

Osmotic laxatives, including Macrogols (Polyethylene glycols), have been available in the European Union, including the UK for much more than ten years. Their use is well established with recognised efficacy and acceptable safety.

14. CONCLUSION

Marketing authorisation may be granted on medical grounds.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of MOVICOL Vanilla 14g sachet, powder for oral solution 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, including Macrogols (Polyethylene glycols), are well known and have been used for many years. The applicant has demonstrated essential similarity to the originator product, MOVICOL.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the innovator product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The data supplied supports the claim that the applicant’s products and the originator products are interchangeable. Extensive clinical experience with macrogol is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 16/07/2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 28/07/2004.
3	Following assessment of the application the MHRA requested further information relating to the quality dossier on 17/05/2005 and 01/11/2005.
4	The applicant responded to the MHRA's requests, providing further information on 04/07/2005 and 14/11/2005.
5	The application was determined on 27/01/2006.

MOVICOL VANILLA 14G SACHET, POWDER FOR ORAL SOLUTION

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

MOVICOL VANILLA 14G SACHET, POWDER FOR ORAL SOLUTION

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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MOVICOL Vanilla 14g sachet, powder for oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet of MOVICOL Vanilla contains the following active ingredients:

Macrogol (Polyethylene Glycol) 3350	13.1250 g
Sodium Chloride	0.3507 g
Sodium Hydrogen Carbonate	0.1785 g
Potassium Chloride	0.0502 g

The content of electrolyte ions per sachet when made up to 125 ml of solution is as follows:

Sodium	65 mmol/l
Chloride	53 mmol/l
Potassium	5.8 mmol/l
Hydrogen Carbonate	17 mmol/l

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Powder for oral solution.
Free flowing white powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the treatment of chronic constipation.MOVICOL Vanilla is also effective in resolving faecal impaction, defined as refractory constipation with faecal loading of the rectum and/or colon confirmed by physical examination of the abdomen and rectum.

4.2. Posology and method of administration

A course of treatment for constipation with MOVICOL Vanilla does not normally exceed two weeks, although this can be repeated if required.

As for all laxatives, prolonged use is not usually recommended. Extended use may be necessary in the care of patients with severe chronic or resistant constipation, secondary to multiple sclerosis or Parkinson's Disease, or induced by regular constipating medication, in particular opioids and antimuscarinics.

Adults, adolescents and elderly*:* 1-3 sachets daily in divided doses, according to individual response.
For extended use, the dose can be adjusted down to 1 or 2 sachets daily.

Children (below 12 years old): Not recommended.

Faecal impaction

A course of treatment for faecal impaction with MOVICOL Vanilla does not normally exceed 3 days.

Adults, adolescents and the elderly: 8 sachets daily, all of which should be consumed within a 6 hour period.

Children (below 12 years old): Not recommended.

Patients with impaired cardiovascular function: For the treatment of faecal impaction the dose should be divided so that no more than two sachets are taken in any one hour.

Patients with renal insufficiency: No dosage change is necessary for treatment of either constipation or faecal impaction.

Administration

Each sachet should be dissolved in 125ml water. For use in faecal impaction 8 sachets may be dissolved in 1 litre water.

4.3. Contraindications

Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon.

Known hypersensitivity to any of the active substances or to any of the excipients.

4.4. Special warnings and precautions for use

MOVICOL Vanilla contains Aspartame which is a source of phenylalanine. May be harmful for people with phenylketonuria.

Mild adverse drug reactions are possible as indicated in Section 4.8. If patients develop any symptoms indicating shifts of fluid/electrolytes (e.g. oedema, shortness of breath, increasing fatigue, dehydration, cardiac failure) MOVICOL Vanilla should be stopped immediately and electrolytes measured, and any abnormality should be treated appropriately.

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

No clinical interactions with other medicinal products have been reported. Macrogol raises the solubility of drugs that are soluble in alcohol and relatively insoluble in water. There is therefore a theoretical possibility that the absorption of such drugs could be transiently reduced.

4.6. Pregnancy and lactation

There is no experience of the use of MOVICOL Vanilla during pregnancy and lactation and it should only be used if considered essential by the physician

4.7. Effects on ability to drive and use machines

There is no effect on the ability to drive and use machines.

4.8. Undesirable effects

Abdominal distension and pain, borborygmi and nausea, attributable to the expansion of the contents of the intestinal tract can occur. Mild diarrhoea which usually responds to dose reduction. Allergic reactions are a possibility.

4.9. Overdose

Severe pain or distension can be treated by nasogastric aspiration. Extensive fluid loss by diarrhoea or vomiting may require correction of electrolyte disturbances.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

ATC code: A06A D65

Macrogol 3350 acts by virtue of its osmotic action in the gut, which induces a laxative effect. The electrolytes also present in the formulation ensure that there is virtually no net gain or loss of sodium, potassium or water. The laxative action of macrogol 3350 has a time course which will vary according to the severity of the constipation or faecal impaction being treated.

For the indication of faecal impaction controlled comparative studies have not been performed with other treatments (e.g. enemas). In a non-comparative study in 27 adult patients, MOVICOL cleared the faecal impaction in 12/27 (44%) after 1 day's treatment; 23/27 (85%) after 2 days' treatment and 24/27 (89%) at the end of 3 days.

Clinical studies in the use of MOVICOL in chronic constipation have shown that the dose needed to produce normal formed stools tends to reduce over time. Many patients respond to between 1 and 2 sachets a day, but this dose should be adjusted depending on individual response.

5.2. Pharmacokinetic properties

Macrogol 3350 is unchanged along the gut. It is virtually unabsorbed from the gastro-intestinal tract and has no known pharmacological activity. Any macrogol 3350 that is absorbed is excreted via the urine.

5.3. Preclinical safety data

Preclinical studies provide evidence that macrogol 3350 has no significant systemic toxicity potential, although no tests of its effects on reproduction or genotoxicity have been conducted.

There are no long-term animal toxicity or carcinogenicity studies involving macrogol 3350, although there are toxicity studies using high levels of orally administered high molecular macrogols that provide evidence of safety at the recommended therapeutic dose.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Aspartame (E951)
Vanilla Flavour

6.2. Incompatibilities

None are known.

6.3. Shelf life

The shelf life of the sachets is 3 years.

Discard any solution not used within 6 hours.

6.4. Special precautions for storage

Sachet: Do not store above 25°C.

Solution:-Store at 2-8ºC (in a refrigerator and covered)

6.5. Nature and contents of container

14g sachets contained in boxes of 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets.
Not all pack sizes may be marketed

6.6. Instruction for use and handling

None

7. MARKETING AUTHORISATION HOLDER

Norgine Limited
Chaplin House
Widewater Place
Moorhall Road
Harefield
UXBRIDGE
Middlesex UB9 6NS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00322/0085

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/01/2006

10 DATE OF REVISION OF THE TEXT

MOVICOL VANILLA 14G SACHET, POWDER FOR ORAL SOLUTION

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PRODUCT INFORMATION LEAFLET

Patient Information Leaflet

MOVICOL®
VANILLA

14 g sachet, powder for oral solution

Please read this leaflet carefully before taking your medicine.
If you have any questions or are not sure about anything, ask your doctor or pharmacist.

What is this medicine?

The name of this medicine is Movicol Vanilla 14g sachet, powder for oral solution.
Each sachet contains:

Macrogol (Polyethylene glycol) 3350	13.1250	g
Sodium chloride	350.7	mg
Sodium hydrogen carbonate	178.5	mg
Potassium chloride	50.2	mg

When it is made into a drink with 125 millilitres of water, each sachet gives the equivalent of:

Sodium	65	millimoles/litre
Chloride	53	millimoles/litre
Hydrogen carbonate	17	millimoles/litre
Potassium	5.8	millimoles/litre

Movicol Vanilla contains vanilla flavour and aspartame as a sweetener.

There are 6, 8, 10, 20, 30, 40, 50, 60 or 100 sachets in a box. Each sachet contains 14 grams of Movicol Vanilla powder. You mix the powder with water to make a drink.

NORGINE

The marketing authorisation holder of Movicol Vanilla is **Norgine Limited**, Moorhall Road, Harefield, Middlesex UB9 6NS, U.K.
It is made by **Norgine Limited**, New Road, Hengoed, Mid Glamorgan CF82 8SJ, U.K.

What is Movicol Vanilla used for?

Movicol Vanilla helps you to have a comfortable bowel movement even if you have been constipated for a long time. Movicol Vanilla also works in very bad constipation (called faecal impaction).

Before you take Movicol Vanilla

Do not take Movicol Vanilla if your doctor has told you that you have:

- an obstruction in the intestine (gut)
- a perforated gut wall
- severe inflammatory bowel disease like ulcerative colitis, Crohn's disease, or toxic megacolon
- paralysis of the bowel
- an allergy to any of the ingredients

If you are pregnant or breast feeding, talk to your doctor before you take Movicol Vanilla.

R11-0-UKvMr

Tell your doctor about any other medicines you are taking.

Movicol Vanilla contains a source of phenylalanine. If you suffer from phenylketonuria do not take this medicine.

The dose of Movicol Vanilla

Constipation

The dose of Movicol Vanilla is 1 sachet. Take this 1-3 times a day, according to the severity of your constipation. Treatment with Movicol Vanilla usually lasts about 2 weeks. Your doctor may recommend that you take Movicol Vanilla for longer than 2 weeks if you take drugs that cause constipation or if you have a disease which causes constipation for example Parkinson's disease or multiple sclerosis (MS). Usually for long term treatment the dose can be adjusted down to either one or two sachets a day.

Faecal impaction

The dose is 8 sachets a day taken within 6 hours. If you have a heart condition do not take more than 2 sachets in any one hour. You may need to take this dose for up to 3 days.

Children (below 12 years of age): not recommended.

How to take Movicol Vanilla

Open the sachet and put the powder into a glass which is half full of water (about 125 millilitres or ¼ pint). Stir well until the water is clear again then drink it. If you like, you can add a flavour such as orange squash to the drink.

If you are taking Movicol Vanilla for faecal impaction, it might be easier to dissolve 4 sachets in 500 ml (about 1 pint) of water.

If you take too much Movicol Vanilla and get bad diarrhoea, stop taking Movicol Vanilla until is clears, then start again at a lower dose. If you are worried, contact you doctor or pharmacist.

What about side effects?

Sometimes people have stomach ache or rumbles, or an allergic reaction, or feel bloated, or sick. You may have mild diarrhoea especially when starting to take Movicol Vanilla. If any of the above are troublesome or last more than a few days, or if you experience any other undesirable effect that is not listed, tell your pharmacist or doctor.

If you feel weak, breathless, very thirsty with a headache, or get puffy ankles stop taking Movicol Vanilla and tell your doctor immediately.

How to store Movicol Vanilla

Store your Movicol Vanilla at room temperature (do not store above 25°C). Do not use Movicol Vanilla after the expiry date on the label. Once you have made up Movicol Vanilla in water, if you cannot drink it straight away, put it in the fridge (2 - 8°C) and keep it covered. Throw away any solution not used within a six hour period.

Keep all medicines out of reach and sight of children

Date revised: June 2005

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LABELLING