UROGON CYSTITIS RELIEF 4G GRANULES FOR ORAL SOLUTION
PL 22959/0005

UKPAR

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LAY SUMMARY

The MHRA granted Natural Options Health Products Limited Marketing Authorisations (licences) for the medicinal products Urogon Cystitis Relief 4g Granules for Oral Solution on 24th February 2006. This general sales licence product (GSL) contains sodium citrate and used to relieve the symptoms of cystitis in women. The product has since undergone a Change of Ownership application and the licence is currently owned by Line Range Limited (granted on 31st May 2006; PL 22959/0005).

The active ingredient sodium citrate acts by raising the pH of the urine which relieves the symptoms of cystitis.

This application is a duplicate of a previously granted application for Cystitis Relief (PL 05544/0089) which had, in turn, been a duplicate application cross-referring to Cystitis Relief (PL 10887/0017) and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Urogon Cystitis Relief 4g Granules for Oral Solution outweigh the risks, hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted marketing authorisations for the medicinal products Urogon Cystitis Relief 4g Granules for Oral Solution (PL 18284/0007) to Natural Options Health Products Limited on 24th February 2006. The products are general sales licence medicines. The product has since undergone a Change of Ownership application and the licence is currently owned by Line Range Limited (granted on 31st May 2006; PL 22959/0005).

The application was submitted as a simple abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Cystitis Relief (PL 05544/0089), approved on 29th November 1996. This application had, in turn, been a simple abridged application cross-referred to Cystitis Relief (PL 10887/0017), approved on 23rd November 1995.

No new data was submitted nor was it necessary for these simple applications, as the data is identical to that of the previously granted cross-reference product. As the cross-reference products were granted prior to the introduction of current legislation, no PARs were generated for them.

The product contains the active ingredient sodium citrate which acts by raising the pH of the urine. Urogon Granules are indicated to relieve the symptoms of cystitis in women

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 22959/0005
PROPRIETARY NAME: Urogon Cystitis Relief 4g Granules For Oral Solution
ACTIVE(S): Sodium Citrate
COMPANY NAME: Line Range Limited
E.C. ARTICLE: Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC
LEGAL STATUS: GSL

1. INTRODUCTION

This is a simple, piggy back application for Urogon Cystitis Relief 4g Granules For Oral Solution submitted under Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC. The proposed MA holder was originally Natural Options Health Products Limited, Charlwoods Road, East Grinstead, West Sussex, RH19 2HL. They were granted a licence on 24th February 2006. The product has since undergone a Change of Ownership application and the licence is currently owned by Line Range Limited (granted on 31st May 2006; PL 22959/0005).

The application cross-refers to Cystitis Relief (PL 05544/0089), approved on 29th November 1996. This application had, in turn, been a simple abridged application cross-referring to Cystitis Relief (PL 10887/0017), approved on 23rd November 1995. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Urogon Cystitis Relief 4g Granules For Oral Solution. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains sodium citrate, equivalent to 4g per sachet. It is to be stored in sachets composed of paper, polyethylene and aluminium. The proposed shelf-life (2 years) and storage conditions (Do not store above 25°C; Keep in the original package) are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the products will be subject to a medical prescription.

2.4 Marketing authorisation holder/Contact Persons/Company

The current MA holder is Line Range Limited, 16 Rancliffe Avenue, Keyworth, Nottingham, NG12 5HY, UK.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
No materials of animal or human origin are included in the product. This is consistent with the cross reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed summary is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. A Marketing Authorisation should be granted.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

As these are duplicate applications for PL 10887/0017, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application are consistent with that previously assessed for the cross-reference product and as such have been judged to be satisfactory.

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

EFFICACY
This application is identical to a previously granted application for Cystitis Relief (PL 05544/0089), which in turn, had been a simple abridged application cross-referring to Cystitis Relief (PL 10887/0017).

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products which, in turn, have been shown to be interchangeable with the innovator products. Extensive clinical experience with sodium chloride 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 ASSESMENT

1	The MHRA received the marketing authorisation application on 04/02/2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 18/02/2004.
3	Following assessment of the application the MHRA requested further information on 09/07/2004, 05/11/2004 and 20/01/2006.
4	The applicant responded to the MHRA's requests, providing further information on 13/09/2004, 20/01/2006 and 30/01/2006
5	The application was determined on 24/02/2006

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome
27-03-06	CoA	To change the MAH to Line Range Limited	Granted

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SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Urogon Cystitis Relief 4g granules for oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 4g sodium citrate
Also contains sucrose as an excipient.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Granules for oral solution.

White granules

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of the symptoms of cystitis in women.

4.2. Posology and method of administration

For oral administration only.

Adult women: The contents of one sachet dissolved in a glass of water, to be taken three times a day for two days.

Men and children: Not recommended.

4.3. Contraindications

Patients with diabetes, heart disease, hypertension, history of renal disease or those on a low salt diet.

During pregnancy and lactation.

4.4. Special warnings and precautions for use

If symptoms persist after the two day course of treatment is completed, medical attention should be sought.

Sodium content: 939mg per sachet. To be taken into consideration by patients on a controlled sodium diet.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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

None stated

4.6. Pregnancy and lactation
Contraindicated during pregnancy and lactation

4.7. Effects on ability to drive and use machines
None stated

4.8. Undesirable effects
None stated

4.9. Overdose
In the unlikely event of overdosage occurring with this product, treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
ATC Code: B05C B02

The effect of sodium citrate is to render the urine less acidic.

5.2. Pharmacokinetic properties
None relevant.

5.3. Preclinical safety data
None stated

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Sucrose (1.5g)
Colloidal Silica
Saccharin Sodium
Cranberry Flavouring

6.2. Incompatibilities
None stated

6.3. Shelf life
The granules have a two year shelf life.

The reconstituted solution should be used immediately.

6.4. Special precautions for storage
Do not store above 25°C. Store in the original package.

6.5. Nature and contents of container
Foil laminate sachets containing 5.575g of granule enclosed in a cardboard outer.
The composition of the sachets is paper/PE/Aluminium foil/PE
Each pack contains 6 sachets.

6.6. Instruction for use and handling
None stated.

7. MARKETING AUTHORISATION HOLDER

Line Range Ltd,
16 Rancliffe Avenue
Keyworth,
Nottingham NG12 5HY
UK

8. MARKETING AUTHORISATION NUMBER

PL 22959/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

UROGON CYSTITIS RELIEF 4G GRANULES FOR ORAL SOLUTION
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PRODUCT INFORMATION LEAFLET

Urogon Cystitis Relief 4g granules for oral solution
(Sodium citrate 4g)

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without a prescription, for you to treat a mild illness without a doctor's help. Nevertheless you still need to use Cystitis Relief 4g granules for oral solution carefully to get the best results from it.
●Keep this leaflet. You may need to read it again
●Ask your pharmacist if you need more information or advice
●You must see a doctor if your symptoms worsen or do not improve.

In this leaflet

The name of your medicine is Urogon Cystitis Relief 4g granules for oral solution, referred to as Cystitis Relief in this leaflet.

1. What Cystitis Relief is and what it is used for

Cystitis Relief contains sodium citrate which is used for the relief of the symptoms of cystitis in women.
Cystitis is an inflammation of the bladder, which causes painful irritation and an unpleasant burning sensation when passing water.
Sodium citrate relieves the painful irritation caused by cystitis by making the urine less acidic.

2. Before you take Cystitis Relief

You should not take these sachets if:
- You are allergic sodium citrate or to any of the ingredients listed in section 6.
- You suffer from heart disease, high blood pressure, diabetes or have a history of kidney disease.
- You are on a low salt diet.
- You are pregnant or breast feeding.
- You have an intolerance to some sugars.

Pregnancy and breast-feeding

Do not take Cystitis Relief if you are pregnant or breast-feeding.

Important information about some of the ingredients of Cystitis Relief
Cystitis Relief sachets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars you should not take this medicine. They also contain 939mg sodium. To be taken into consideration if you are on a controlled sodium diet

Taking other medicines

Although Cystitis Relief is not known to interact with other medicines, tell your doctor or pharmacist if you are taking any other medicines, including those you have bought yourself.

3. How to take Cystitis Relief

Each sachet contains granules, which should be dissolved in a glass of water to make a pleasant cranberry flavoured drink.
You should start to feel relief within a few hours.
Adult women: **Take the contents of one sachet dissolved in a glass of water, three times a day for two days. The reconstituted solution should be used immediately**
Not recommended for use in men and children

If symptoms persist after the two-day course is completed, consult your doctor.
Do not repeat the treatment without medical advice.

If you miss a dose**, take one as soon as you remember, but** do not **double up the next dose to compensate the missed dose.**

Do not take more than stated. If you have taken more than you should, seek medical advice immediately.

4. Possible side effects

Side effects do not usually occur with this product. However, tell your doctor or pharmacist if you notice any unwanted effects whilst taking this medicine.

5. How to store Cystitis Relief

Do not store above 25 °C. Store in the original package to protect from moisture.

Keep out of reach and sight of children.

Do not take this medicine after the expiry date shown on the sachet and carton.

6. Further Information

What does each sachet contain?
Each sachet contains white granules for oral solution.

The granules contain sodium citrate 4g as the active ingredient.

The other ingredients are sucrose, colloidal anhydrous silica, saccharin sodium and cranberry flavour.

What does each pack contain?

Each pack contains 6 sachets of Cystitis Relief, sufficient for a 2 day course of treatment.

Who manufactures this medicine?

The manufacturer is: Sussex Pharmaceutical Ltd, East Grinstead, West Sussex, UK and Marketing Authorisation holder is Natural Options Health Products Ltd, East Grinstead RH19 2HL.

Leaflet revised: January 2006

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LABELLING

Carton Text: Urogon Cystitis Relief 4g granules for oral solution

Urogon Cystitis Relief 4g granules for oral solution

(Sodium Citrate 4g)
For the relief of the symptoms of cystitis in women
Cranberry flavour
6 sachets

Each sachet contains 4g Sodium Citrate. Also contains sucrose. Each dose contains 939mg sodium, to be taken into consideration by patients on a controlled sodium diet
Granules for Oral Solution.

For oral use only.
Please read the enclosed leaflet carefully before taking this medicine.

Cystitis Relief is used for the relief of the symptoms of cystitis in women. The granules from one sachet should be dissolved in a glass of water to make a pleasant cranberry flavoured drink. You should start to feel relief within a few hours.

Adult women:
Take the contents of one sachet dissolved in a glass of water, three times a day for two days.

Not recommended for use in men and children.

If symptoms persist after the two-day course is completed, consult your doctor. Do not repeat the treatment without medical advice.

Do not store above 25°C. Keep in the original package to protect from moisture.

Keep out of the reach and sight of children.

MA Holder: Line Range Ltd, 16 Rancliffe Avenue, Keyworth, Nottingham NG12 5HY.
PL 22959/0005

Company Logo

Exp.

Batch No.

Sachet label text: Urogon Cystitis Relief 4g granules for oral solution

Urogon Cystitis Relief 4g granules for oral solution

(Sodium Citrate 4g)

Oral use

Before you take this medicine please read and

retain the patient information leaflet enclosed.

Adult women:

Take the contents of one sachet dissolved in a glass of water, three times a day for two days.

Not recommended for use in men and children.

If symptoms persist after the two-day course is completed, consult your doctor. Do not repeat the treatment without medical advice.

Ingredients: Each 5.575g sachet contains:	
Sodium citrate	4g
Sucrose	1.5g
Colloidal silica	10mg
Saccharin sodium	5mg
Cranberry favouring	60mg

Each dose contains 939mg sodium, to be taken into consideration by patients on a controlled sodium diet

Do not store above 25°C. Keep in the original package to protect from moisture.

Keep out of the reach and sight of children.