Fulsovin 125 mg/5 ml Oral Suspension

UK Public Assessment Report

The marketing authorisation for Fulsovin 125 mg/5 ml Oral Suspension was revoked on 23 January 2013.

This Public Assessment Report has been updated accordingly to explain the reasons for revocation.

The original Public Assessment report (25 March 2010) is appended to this report.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Assessment Report: Revocation of a Marketing Authorisation</td>
<td>3</td>
</tr>
<tr>
<td>Background to Licence Revocation</td>
<td>4</td>
</tr>
<tr>
<td>Revision history</td>
<td>4</td>
</tr>
<tr>
<td>Annex 1 – superseded PAR</td>
<td>5</td>
</tr>
</tbody>
</table>
FULSOVIN 125MG/5ML ORAL SUSPENSION
PL 20249/0009

Public Assessment Report: Revocation of a Marketing Authorisation

On 23 January 2013, the MHRA revoked a marketing authorisation (“product licence”) for the medicinal product, Fulsovin 125mg/5ml Oral Suspension (PL 20249/0009) meaning that this product could no longer be supplied to the market. This licence had been granted to Kappin Limited on 25th March 2010.

Information presented in the licence application supported the shelf-life and storage conditions that were approved. However, a Good Manufacturing Practice inspection performed by the MHRA in November 2011 cast doubt upon the reliability of this information. Subsequent monitoring identified significant quality concerns with product stability and manufacture.

Kappin Limited ceased to market the product on 08 May 2012 at the request of the MHRA; product remaining in pharmacies and wholesalers was recalled.

The MHRA asked advice from the Commission on Human Medicines (an independent panel of experts with whom the licensing authority consults regarding the safety, quality and efficacy of medicines). Having examined the evidence, the advice of the Commission in January 2012 was that the marketing authorisation for Fulsovin 125mg/5ml Oral Suspension should be revoked.
Background to Licence Revocation

Fusolvin 125mg/5ml Oral Suspension was granted a Marketing Authorisation on 25 March 2010 with a 24 month shelf-life when stored below 25°C. This product represented the sole, licensed, oral liquid presentation of griseofulvin.

Stability data reviewed on 12 April 2012 identified a number of results for assay (content of drug substance) that did not comply with their specified control limits. These showed a decreasing trend with time and temperature and did not support the approved shelf-life.

Recent process validation data also raised concerns that the manufacturing process was not assured and may not be sufficiently robust.

In light of a lack of assurance of stability performance and process validation, Kappin Ltd. complied with the MHRA’s request to cease to market this product on 08 May 2012. This was accompanied by a pharmacy-level recall.

The licence was revoked by the MHRA on 23 January 2013.

REVISION HISTORY

<table>
<thead>
<tr>
<th>Issue of UKPAR: Update 01</th>
<th>08 Feb 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial issue</td>
<td>25 March 2010</td>
</tr>
</tbody>
</table>
Annex 1 - UKPAR for initial grant of Marketing Authorisation:

Fulsovin 125 mg/5 ml Oral Suspension (25 March 2010)

TABLE OF CONTENTS

Lay Summary .......................... Page 2
Scientific discussion ................. Page 3
Steps taken for assessment .......... Page 12
Steps taken after authorisation – summary Page 13
Summary of Product Characteristics
Product Information Leaflet
Labelling
FULSOVEN 125MG/5ML ORAL SUSPENSION
PL 20249/0009

LAY SUMMARY

On 25th March 2010, the MHRA granted Kappin Limited a licence for the medicinal product Fulsoven 125mg/5ml Oral Suspension (PL 20249/0009). This is a prescription-only medicine (POM) to treat infections of the skin, scalp, hair or nails.

Fulsovin Oral Suspension contains a medicine called griseofulvin. This belongs to a group of medicines called antifungals. Antifungals are use to kill fungi that cause infections.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Fulsoven 125mg/5ml Oral Suspension outweigh the risks, hence a Marketing Authorisation has been granted.
FULSOVEN 125MG/5ML ORAL SUSPENSION
PL 20249/0009

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Pharmaceutical assessment</td>
<td>5</td>
</tr>
<tr>
<td>Preclinical assessment</td>
<td>7</td>
</tr>
<tr>
<td>Clinical assessment (including statistical assessment)</td>
<td>8</td>
</tr>
<tr>
<td>Overall conclusions and risk benefit assessment</td>
<td>11</td>
</tr>
</tbody>
</table>
INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Kappin Limited a Marketing Authorisation for the medicinal product Fulsoven 125mg/5ml Oral Suspension (PL 20249/0009) on 25th March 2010. Fulsoven 125mg/5ml Oral Suspension is indicated for the treatment fungal infections of the skin, scalp, hair or nails where topical therapy is considered inappropriate or has failed.

The application was submitted under Article 10.3 of Directive 2001/83/EC, as amended, as a hybrid application claiming to be a generic medicinal product of Grisovin 125mg Tablets (GlaxoWellcome UK), which was originally granted a licence in 1988.

Griseofulvin is a fungistatic antibiotic, which inhibits fungal cell division by disruption of the mitotic spindle structure and may also interfere with DNA production. It is active against the common dermatophytes, including some species of *Epidermophyton*, *Microsporum*, or *Trichophyton*. 
PHARMACEUTICAL ASSESSMENT

ACTIVE SUBSTANCE

INN: Griseofulvin
Chemical Name: (2S,4'R)-7-Chloro-2',4,6-trimethoxy-4'-methylspiro [benzofuran-2(3H),3'-cyclohexene]-3,6'-dione
Molecular Formula: CH_{17}ClO_{6}

Structure:

Molecular Weight: 352.8
Appearance: White or yellowish-white powder, practically insoluble in water; slightly soluble in dehydrated alcohol and in methyl alcohol; freely soluble in dimethylformamide and in tetrachloroethane.

The active substance, griseofulvin, is the subject of a European Pharmacopeia (Ph Eur) monograph.

All aspects of the manufacture and control of the active substance are covered by a European Directorate for the Quality of Medicines (EDQM) Certificate of Suitability.

A suitable retest period has been set, based on stability data collected in-line with current requirements.

DRUG PRODUCT

Other ingredients
Other ingredients consist of glycerol, xanthan gum (E415), maltitol liquid (E965), citric acid monohydrate, saccharin sodium (E954), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), peppermint flavour (containing ethanol) and purified water.

All excipients comply with their respective European Pharmacopoeia monographs, with the exception of peppermint flavour (which is controlled to a suitable in-house specification). Suitable Certificates of Analysis have been provided for all excipients, showing compliance with the proposed specifications.

None of the excipients is derived from materials of animal or human origin. No genetically modified materials are used in the manufacture of any of the excipients.

Container-closure system
The product is packaged in amber Type III glass bottles, with child-resistant tamper-evident caps (made from high density polypropylene with a polyethylene lining). The pack size is 100ml. All packs come with a 5ml/2.5ml polypropylene double-ended spoon.
Suitable specifications and Certificates of Analysis have been provided for the finished packaging. All packaging components comply with relevant guidelines concerning contact with foodstuff.

**Product development**
A suitable product development section has been provided.

**Manufacture**
A satisfactory batch formula has been provided for the manufacture of the product along with an appropriate account of the manufacturing process.

In-process controls are appropriate considering the nature of the product and the method of manufacture.

The manufacturing process has been validated and has shown satisfactory results.

**Finished product specification**
The finished product specifications proposed for both release and shelf life are acceptable, and provide an assurance of the quality and consistency of the finished products. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety.

Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification. Certificates of Analysis have been provided for any reference standards used.

**Stability of the product**
Stability data has been provided for batches of the finished product stored in-line with ICH guidelines. All batches were manufactured by the finished product manufacturer, according to the proposed manufacturing method and stored in the packaging proposed for marketing.

Based on these stability studies, a shelf-life of 24 months has been proposed with storage conditions of “Do not store above 25°C. Store in the original container. Discard after 3 months of first opening.” These are acceptable.

**Summary of Product Characteristics (SPC), Patient Information Leaflet (PIL) and Labelling**
The SPC, PIL and labels are pharmaceutically acceptable.

The applicant has submitted results of PIL user testing. The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

**MAA Form**
The MAA form is pharmaceutically satisfactory.
Pharmaceutical expert report
The pharmaceutical expert report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

CONCLUSION
It is recommended that a Marketing Authorisation is granted for this application.
PRECLINICAL ASSESSMENT

This application is for a generic medicinal product of Grisovin 125mg Tablets (GlaxoWellcome UK), which has been licensed within the EEA for over 10 years. No new preclinical data have been supplied with this application and none are required for an application of this type.

A satisfactory environmental risk assessment has been submitted. As part of the screening for persistence, bioaccumulation and toxicity, the applicant has measured the log\(K_{OW}\) of griseofulvin to be 2.07, which is below the threshold of < 4.5 stated in the Guideline on the Environmental Risk Assessment of Medicinal products for Human Use. As such, there are no environmental persistence, bioaccumulation or toxicity concerns associated with griseofulvin.

A suitable preclinical expert report has been submitted, written by an appropriately qualified person.
CLINICAL ASSESSMENT

CLINICAL PHARMACOLOGY
To support the application, a bioequivalence study has been submitted.

Bioequivalence Study: a single-centre, randomized, single-dose, two-treatment, two-period, open-label, crossover study, comparing the pharmacokinetic profiles of test Griseofulvin 125mg/5ml oral suspension (Kappin Limited) versus reference Grisovin 125mg tablets in healthy male subjects under fed conditions.

Blood samples for pharmacokinetic analysis were taken pre- and up to 72 hours post dose. The two treatment periods were separated by a washout period of 7 days. The log-transformed results for both enantiomers of active substance are presented below:

<table>
<thead>
<tr>
<th>Geometric means</th>
<th>Ratio T/R</th>
<th>90% CI</th>
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<tbody>
<tr>
<td></td>
<td>Test</td>
<td>Reference</td>
</tr>
<tr>
<td>C&lt;sub&gt;max&lt;/sub&gt;</td>
<td>ng/ml</td>
<td>968.088</td>
</tr>
<tr>
<td>AUC&lt;sub&gt;(0-t)&lt;/sub&gt;</td>
<td>ng.h/ml</td>
<td>22980.23</td>
</tr>
<tr>
<td>AUC&lt;sub&gt;(0-a)&lt;/sub&gt;</td>
<td>ng.h/ml</td>
<td>25194.24</td>
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</table>

The 90% confidence intervals lie between the acceptance criteria stated in the Notes for Guidance on Investigation of Bioavailability and Bioequivalence. Thus, bioequivalence has been shown between the test and reference products.

Efficacy
No new data have been provided.

Safety
No new data have been provided.

EXPERT REPORTS
A clinical expert report has been written by a suitably qualified person and is satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)
This is consistent with that for the reference product and is satisfactory.

PATIENT INFORMATION LEAFLETS (PIL)
This is consistent with the SPC and is satisfactory.

Labeling
These are satisfactory.

APPLICATION FORM (MAA)
This is satisfactory.
DISCUSSION
Bioequivalence has been satisfactorily demonstrated between the oral suspension and the reference product (Grisovin 125mg Tablets), in accordance with CHMP criteria.

MEDICAL CONCLUSION
The grant of a Marketing Authorisation is recommended for this application.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Fulsoven 125mg/5ml Oral Suspension 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 an application of this type.

EFFICACY
Bioequivalence has been demonstrated between the applicant’s and reference products.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with those for the reference product, where necessary.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with griseofulvin is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.
## STEPS TAKEN FOR ASSESSMENT

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 8th March 2007.</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 17th October 2007.</td>
</tr>
<tr>
<td>3</td>
<td>Following assessment of the application, the MHRA requested further information relating to the quality dossiers on 20th September 2008 and 25th August 2009. No requests for further information were made for the clinical dossiers.</td>
</tr>
<tr>
<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information for the quality dossier on 4th December 2008 and 25th August 2009.</td>
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<tr>
<td>5</td>
<td>The application was determined on 25th March 2010.</td>
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FULSOVEN 125MG/5ML ORAL SUSPENSION  
PL 20249/0009

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Fulsovin 125mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5ml contains Griseofulvin 125 mg
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM
Oral Suspension.
White suspension with an aroma of peppermint.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
Fulsovin Oral Suspension is indicated for the treatment of fungal infections of the skin, scalp, hair or nails where topical therapy is considered inappropriate or has failed.

When griseofulvin is given orally for systemic treatment of fungal infections, it enables newly-formed keratin of the skin, hair and nails to resist attack by the fungi. As the new keratin extends, the old infected keratin is shed. Fulsovin is effective against the dermatophytes causing ringworm (tinea), including: Microsporum canis and T. Verrucosum.

Fulsovin is not effective in infections caused by Candida albicans (monilia), Aspergilli, Malassezia furfur (Pityriasis versicolor) and Nocardia species.

4.2 Posology and method of administration
Dosage and Administration
Doses should be taken after meals; otherwise absorption is likely to be inadequate.

Adults
Normally 500 to 1000 mg daily, but not less than 10 mg/kg bodyweight daily. A single dose daily is often satisfactory, but divided doses may be more effective in patients who respond poorly.

Children
Usually 10 mg/kg (5 mg/lb) body weight daily in divided doses.

Duration of Treatment
This depends upon the thickness of keratin at the site of infection. For hair or skin at least four weeks treatment is required, whereas toe or finger nails may need six to twelve months treatment. Therapy should be continued for at least two weeks after all signs of infection have disappeared.

4.3 Contraindications
Porphyria or severe liver disease. Griseofulvin may cause liver disease to deteriorate, and liver function should be monitored in such conditions.

Griseofulvin should not be used in pregnancy, or in women intending to become pregnant within one month following cessation of treatment (see section 4.6).
Males should not father children within six months of treatment with griseofulvin (see section 4.6 and 5.3).

Systemic Lupus Erythematosus: griseofulvin has been reported to exacerbate the condition.

Hypersensitivity to any ingredient of the preparation.

Fulsovin Oral Suspension should not be used prophylactically (See section 5.3).
4.4 Special warnings and precautions for use

Reports of fatalities associated with griseofulvin use are very rare. The fatalities reported are in various organ systems as follows; cardiac arrest, Spina bifida, multiple congenital abnormalities, adrenal insufficiency, primary biliary cirrhosis, systemic lupus erythematosus and peripheral neuropathy.

4.5 Interaction with other medicinal products and other forms of interaction

Griseofulvin may decrease the blood level and hence efficacy of certain drugs, which are metabolised by cytochrome P450 3A4. These include oral contraceptives, coumarin anticoagulants and cyclosporin. Appropriate monitoring should be undertaken and dosage should be adjusted as necessary. Additional contraceptive precautions should be taken during griseofulvin treatment and for a month after stopping griseofulvin.

Absorption of griseofulvin is inhibited when phenobarbitone is taken concurrently. The blood level, and hence efficacy, of griseofulvin may also be impaired as the result of concurrent administration of substances such as phenylbutazone and sedative and hypnotic drugs which induce metabolising enzymes.

Patients should be warned that an enhancement of the effects of alcohol by griseofulvin has been reported.

4.6 Pregnancy and lactation

Data on a limited number of exposed pregnancies indicate that griseofulvin has harmful effects on the fetus. Griseofulvin is contraindicated in pregnancy (see section 4.3). Women of childbearing potential have to use effective contraception during (and up to 1 month after) treatment.

Males should not father children within six months of treatment (see section 5.3).

It is not known whether griseofulvin is excreted in human milk and a risk to the suckling child can not be excluded.

4.7 Effects on ability to drive and use machines

In those rare cases where individuals are affected by drowsiness while taking griseofulvin, they should not drive vehicles or operate machinery.

4.8 Undesirable effects

Skin disorders: Urticaria, rashes, photosensitive reactions, erythematous rash, erythema nodosum, angioedema, steven Johnson syndrome, alopecia, purpura, acne, eczema, toxic epidermal necrolysis.

Nervous system disorders: headache, dizziness, paraesthesia, peripheral neuropathy, somnolence, dysgeusia, syncope, migraine, abnormal coordination.

Gastrointestinal disorders: Diarrhea, nausea, vomiting, abdominal pain, dyspepsia, glossitis.

General disorders: fatigue, malaise, pyrexia, facial oedema, chest pain.

Reproductive & breast disorders: metrorrhagia, irregular menstruation, erectile dysfunction.

Psychiatric disorders: depression, confusional state, nightmare, anxiety, agitation.

Muscle and tissue disorders: Myalgia, arthalgia, arthropathy, systemic lupus erythematosus.

Cardiac disorders: Palpitations, tachycardia, arrhythmia, extrasystoles, cardiomyopathy.

Hepatic disorders: jaundice, abnormal hepatic function, hepatitis.

Blood disorders: Thrombocytopenia, leucopenia, granulocytopenia, neutropenia.
Ear disorders: Tinnitus, vertigo

Eye disorders: Conjunctival haemorrhage, conjunctivitis, eye pain

Immune System disorders: hypersensitivity, anaphylactic reaction

Metabolic disorders: anorexia, gout, alcohol intolerance

Pregnancy conditions: abortion, unintended pregnancy

Renal and urinary disorders: acute renal failure, dysuria

Respiratory disorders: dyspnoea, asthma, pulmonary fibrosis

Vascular disorders: flushing, vasculitis

4.9 Overdose
Treatment is unlikely to be required in cases of acute overdosage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Antifungals

ATC Code: D01AA08; D01BA01

Mode of action: griseofulvin is an antifungal antibiotic which is active in vitro against common dermatophytes. It exerts its antifungal effect by disrupting the cell division spindle apparatus of fungal cells, thereby arresting cell division.

A prominent morphological manifestation of the action of griseofulvin is the production of multinucleate cells as the drug inhibits fungal mitosis.

Griseofulvin causes disruption of the mitotic spindle by interacting with polymerised microtubules while the effects of the drug are thus similar to those of colchicine and vinca alkaloids, its binding sites on the microtubular protein are distinct.

5.2 Pharmacokinetic properties

The absorption of griseofulvin from the gastrointestinal tract is variable and incomplete. On average, less than 50% of the oral dose is absorbed, but fatty foods and a reduction in particle size will increase the rate and extent of the absorption.

After oral dosing there is a phase of rapid absorption followed by slower prolonged absorption. Peak plasma levels (0.5 - 1.5 micrograms after a 500mg oral dose) are achieved by 4 hours and are maintained for 10 - 20 hours. The terminal plasma half-life ranges from 9.5 - 21 hours, there being considerable intersubject variability. In plasma griseofulvin is approximately 84% bound to plasma proteins, predominantly albumin.

The absorbed griseofulvin is excreted in the urine mainly as 6-desmethylgriseofulvin or its glucuronide conjugate.

There is selective deposition of griseofulvin in newly formed keratin of hair, nails and skin, which gradually moves to the surface of these appendages.

5.3 Preclinical safety data

Griseofulvin can induce aneuploidy and meiotic delay in mouse oocytes following oral administration of high doses, i.e. 250mg/kg or greater. In addition, griseofulvin caused increases in numerical and structural chromosome aberrations in mouse spermatocytes at doses of 500mg/kg and above. Aneuploidy was observed at doses of 1500mg/kg.
Griseofulvin administered to rats and mice during pregnancy has been associated with fetotoxicity and fetal malformations.

Long-term administration of high doses of griseofulvin with food has been reported to induce hepatomas in mice and thyroid tumors in rats but not hamsters. The effects in mice may be due to a species specific effect on porphyrin metabolism. The clinical significance of these findings is not known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Glycerol
xanthan gum (E415)
maltitol liquid (E965)
citric acid monohydrate
saccharin sodium (E954)
sodium methyl parahydroxybenzoate (E219)
sodium propyl parahydroxybenzoate (E217)
peppermint flavour (containing ethanol)
purified water

6.2 Incompatibilities
Not applicable

6.3 Shelf life
24 months

6.4 Special precautions for storage
Do not store above 25°C. Store in the original container. Discard after 3 months of first opening.

6.5 Nature and contents of container
Amber Type III Glass

Child Resistant Tamper Evident Cap- High density polypropylene cap with a polyethylene lining

5 ml/2.5ml polypropylene double ended spoon

Pack sizes available: 100 ml

6.6 Special precautions for disposal
Not applicable

7 MARKETING AUTHORISATION HOLDER
Kappin Limited
Cunard Road
Park Royal
London
NW10 6PN

8 MARKETING AUTHORISATION NUMBER(S)
PL 20249/0009

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
25/03/2010

10 DATE OF REVISION OF THE TEXT
25/03/2010
UKPAR Fulsoven 125mg/5ml Oral Suspension

Patient Information Leaflet
Fulsoven 125mg/5ml Oral Suspension

In this leaflet
1. What Fulsoven Oral Suspension is and what is it used for
2. Before you take Fulsoven Oral Suspension
3. How to take Fulsoven Oral Suspension
4. Possible side effects
5. How to store Fulsoven Oral Suspension
6. Further information

What Fulsoven Oral Suspension is and what is it used for
Fulsoven Oral Suspension contains a medicine called Griseofulvin. This belongs to a group of medicines called anthracyclines. Anthracyclines are used to kill fungi that cause infections.
Fulsoven Oral Suspension can be used to treat infections of the skin, scalp, hair or nails.

Before you take Fulsoven Oral Suspension
Do not take this medicine if you.......:
- are allergic (hypersensitive) to griseofulvin or any of the other ingredients of Fulsoven Oral Suspension (see section 6. Further Information).
- have liver problems. Your condition may worsen with this medicine.
- suffer from systemic lupus erythematosus, commonly called SLE (allergic condition which causes joint pain, skin rashes and fever). Your condition may worsen with this medicine.
- have a rare inherited porphyria which affects your metabolism
- are pregnant or planning to become pregnant. (see section on Pregnancy and breast feeding below). If you are on the "pill" (oral contraceptive) Griseofulvin may stop it working properly.
- are a man taking this medicine, you must be careful not to father any children for six months after stopping to take this medicine.
- are on the pill (oral contraceptive) you should use extra contraceptive precautions such as condoms.
- are on the pill. You should use additional forms of contraception such as condoms while taking griseofulvin and up to one month after stopping griseofulvin.
- have liver problems.

Taking Fulsoven Oral Suspension with other medicines
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Fulsoven Oral Suspension can affect the way some other medicines work. Also some medicines can affect the way Fulsoven Oral Suspension works.

Driving and using machines
Your medicine is unlikely to affect your ability to drive or operate any machinery. However, some people may feel sleepy whilst taking this medicine. If you are affected by this do not drive or operate machinery.

Important information about some of the ingredients of Fulsoven Oral Suspension
- Sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) may cause allergic reactions (possibly delayed).
- Methyl alcohol: if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.
- The peppermint flavour used in this medicinal product contains small amounts of ethanol (alcohol). The total ethanol (alcohol) content is less than 100 mg per 20ml of Fulsoven Oral Suspension.

3. How to take Fulsoven Oral Suspension
Always take Fulsoven Oral Suspension exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine
- Fulsoven Oral Suspension should be swallowed.
- It should be taken after food.
- Shake the bottle before measuring the dose.
- A spoon has been provided to help measure the dose.

Adults
The usual daily dose is 500mg to 1000mg daily.

Children
Your doctor will decide what dose should be taken by your child depending on their weight.

After starting to take your Fulsoven Oral Suspension
It is not unusual to be told to take Fulsoven Oral Suspension every day for many weeks or months while new skin, hair or nails grow. Be sure to take the suspension as your doctor has told you and continue to take it until your doctor tells you to stop. Do not stop just because the infection looks better; the medicine may not have killed all the fungus and it could come back.

Continued, please turn over
UKPAR Fulsoven 125mg/5ml Oral Suspension

If you take more Fulsoven Oral Suspension than you should
If you accidentally take an overdose of your medicine, either call your doctor straight away, or go to your nearest hospital casualty department. Always take any remaining medicine, the container and the label with you, so that the medicine can be identified.

If you forget to take a dose of Fulsoven Oral Suspension
If you forget to take your medicine, take your dose when you remember and then take your next dose at the usual time. Don’t take two doses at the same time, if you are worried, ask your doctor or pharmacist for advice.

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

4. Possible side effects

Like all medicines, Fulsoven Oral Suspension can have side effects although not everybody gets them.

A few people can be allergic to some medicines, if any of the following side effects come on soon after taking the oral suspension stop the medicine and tell your doctor immediately:

- Sudden wheeziness or tightness in the chest
- Swelling of the eyelids, face or lips, with or without a lumpy skin rash (hives) anywhere on the body
- Unexplained fever
- Feeling faint, especially on standing up.

Other side effects that may occur are:

- Effects on your stomach and intestines: diarrhoea, feeling/belching sick, stomach/abdominal pains, and heartburn
- Effects on your nervous system: headache, dizziness, drowsiness, reduced or altered sensitivity of the hands and feet, and reduced or altered sense of taste
- Effects on your skin: increased sensitivity of the skin to the damaging effects of ultraviolet (UV) light can occur. If affected, protect your skin from bright light, skin rash including hives, itching, red or purple patches on the skin, bleeding under the skin. Hair loss and blistering of the skin.

5. How to store Fulsoven Oral Suspension

- Keep out of the reach and sight of children
- Do not store above 25°C. Store in the original bottle.
- Do not use Fulsoven Oral Suspension after 12 weeks of first opening the bottle.
- Do not use Fulsoven Oral Suspension after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.
- Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

Fulsoven Oral Suspension is a white suspension with a smell of peppermint. Each 5ml of Fulsoven Oral Suspension contains Griseofulvin 125mg as active ingredient.

It also contains the following inactive ingredients: Glycerol, xanthan gum (E415), maltitol liquid (E966), citric acid monohydrate saccharin sodium (E954), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), peppermint flavour and purified water.

Each bottle contains 100 ml of oral suspension. A double ended 5ml and 2.5ml polypropylene spoon is also included to help measure the dose.

Fulsoven Oral Suspension is manufactured by Orbis Consumer Products Ltd, Cunard Road, Park Royal, London, NW10 6PN.

The Marketing Authorisation for Fulsoven Oral Suspension (PL 20249/0009) is held by Kappin Ltd., Cunard Road, Park Royal, London, NW10 6PN.

Contact us at the above address for information in large print, audio or braille

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