

**TERBINAFINE TABLETS 250MG**

**PL 08553/0242**

**UKPAR**

**TERBINAFINE TABLETS 250MG**

**PL 08553/0242**

As this marketing authorisation is a duplicate of Terbinafine Tablets 250mg please refer to PL 08553/0241 for the complete report. See below for the Summary of Product Characteristics and product labelling for Terbinafine Tablets 250mg (PL 08553/0242).

**Product Summary for Terbinafine 250mg Tablets (PL 08553/0242):**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**1 NAME OF THE MEDICINAL PRODUCT**

Terbinafine 250mg Tablets

**2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablet contains 250mg terbinafine, as terbinafine hydrochloride

For excipients see section 6.1.

**3 PHARMACEUTICAL FORM**

Tablet

Round white flat bevelled edge tablet with a score line and R250 on reverse.

**4 CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

The treatment of terbinafine sensitive fungal infections such as Tinea corporis, Tinea cruris and Tinea pedis caused by Dermatophytes is considered appropriate due to the site, severity or extent of the infection.

The treatment of onychomycosis (terbinafine-sensitive fungal infection of the nails) caused by dermatophytes.

Terbinafine Tablets are not effective against Pityriasis versicolor. The official local guidelines should be borne in mind, for example, national recommendations relating to the correct use and prescription of antimicrobial drugs.

**4.2 Posology and method of administration**

Route of administration: oral use

The tablets should not be divided and duration of treatment varies according to the indication and severity.

Adults: 250mg once daily

Patients with impaired renal function (creatinine clearance less than 50ml/minute or serum creatinine of more than 300micromol/l) should receive half the normal dose.

Skin Infections

Likely duration of treatment:

Tinea pedis (interdigital, plantar/moccasin type)	2 – 6 weeks
Tinea corporis	2 - 4 weeks
Tinea cruris	2 – 4 weeks

The complete resolution of signs and symptoms of infection may not occur until several weeks after mycological cure.

#### Onychomycosis

For most patients the duration of treatment is between 6 and 12 weeks. In most cases 6 weeks' treatment is sufficient in fingernail onychomycosis. Treatment periods of less than 12 weeks can be anticipated in younger patients or those with fingernail infections or toenail infections other than the big toe. 12 weeks is usually sufficient in the treatment of toenail infections although some patients may require 6 months treatment or longer.

Poor nail outgrowth during the first weeks of treatment may indicate those patients where longer therapy is required. The complete resolution of signs and symptoms of infection may not occur until several weeks after mycological cure.

Children and adolescents: Not recommended due to lack of experience with oral terbinafine.

Use in the elderly: There is no evidence to suggest that elderly patients require different dosages.

### **4.3 Contraindications**

Known hypersensitivity to Terbinafine or any of the excipients.

Severe renal impairment.

Severe hepatic impairment.

### **4.4 Special warnings and precautions for use**

Rarely, cases of cholestasis and hepatitis have been reported, these usually occur within 2 months of starting treatment. If a patient presents with signs or symptoms suggestive of liver dysfunction (pruritus, persistent nausea, anorexia, tiredness, or jaundice, vomiting, fatigue, abdominal pain or dark urine or pale stools, see section 4.8), liver function should be verified and treatment stopped. Single dose pharmacokinetic studies in patients with chronic or active liver disease indicate terbinafine clearance may be reduced by 50% (see section 5.2). The therapeutic use of Terbinafine in patients with chronic or active liver disease has not been studied in prospective clinical trials, and thus cannot be recommended.

Terbinafine should be used with caution in patients with psoriasis, as very rarely cases of exacerbation have been reported.

Patients on terbinafine who develop a high fever or sore throat should be examined concerning possible haematological reactions.

Terbinafine is a potent inhibitor of the isoenzyme, CYP2D6, which should be considered if terbinafine is combined with medicinal products metabolised by this isoenzyme that are titrated individually (see section 4.5) and as such dose adjustments should be made as necessary.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The plasma clearance of terbinafine may be accelerated by medicinal products which induce metabolism (such as rifampicin) and may be inhibited by medicinal products which inhibit cytochrome P450 (such as cimetidine). Where the use of such medicinal products is necessary, the dosage may need to be adjusted accordingly.

Terbinafine inhibits the CYP2D6-mediated metabolism. This may be of relevance to patients receiving substances metabolised by this enzyme, such as tricyclic antidepressants, *B*-blockers, selective serotonin reuptake inhibitors, and monoamine oxidase inhibitors type B, whilst simultaneously taking terbinafine. These patients should be monitored.

Studies indicate terbinafine has negligible effect on the clearance of medicinal products that are metabolised via other cytochrome P450 enzymes (cyclosporin, tolbutamine, terfenadine, triazolam, oral contraceptives). However, some cases of menstrual disturbance (breakthrough bleeding and an irregular cycle) have been reported in patients taking terbinafine with oral contraceptives.

#### **4.6 Pregnancy and lactation**

Animal studies suggest that terbinafine has no undesirable effects.

Pregnancy:

There is no clinical experience of the use of terbinafine in pregnant women. Terbinafine should not be administered during pregnancy unless clearly necessary.

Lactation:

Terbinafine has been found to be excreted in breast milk and therefore nursing mothers should not receive terbinafine whilst breast feeding. Breast feeding should be discontinued before starting treatment with Terbinafine Tablets.

#### **4.7 Effects on ability to drive and use machines**

Terbinafine has no or negligible influence on the ability to drive or use machinery, however some of the undesirable effects which may be seen may impair the ability of the patient to react.

#### **4.8 Undesirable effects**

Adverse reactions are transient and generally mild to moderate in severity.

Common undesirable effects (>1/100, <1/10): dyspepsia, feeling full, loss of appetite, nausea, mild abdominal pain, diarrhoea, rash, urticaria, headache, malaise and fatigue. Musculoskeletal disorders including arthralgia and myalgia have been reported. These may occur as part of a hypersensitivity reaction in association with allergic skin reactions.

Uncommon undesirable effects (>1/1000, <1/100): ageusia and dysgeusia. Taste disturbances and loss have been reported in a small percentage of patients treated. However, this usually resolves slowly on discontinuation.

Rare undesirable effects (>1/10,000, <1/1,000): paraesthesia, hypoaesthesia, dizziness, anaphylactic reaction, serum sickness like reaction, angioneurotic oedema have been reported rarely. Rare cases of serious hepatic dysfunction, including jaundice, cholestasis, hepatitis and increased hepatic enzymes have been reported. If hepatic dysfunction develops, treatment should be discontinued.

Very rare undesirable effects (<1/10,000): vertigo, blood disorders such as neutropenia, thrombocytopenia and agranulocytosis, exacerbation of psoriasis and psychiatric disturbances such as depression and anxiety have been reported very rarely. In rare cases serious skin reactions (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis, photosensitivity and hair loss) and appearance or aggravation of cutaneous or systemic lupus erythematosus have been reported. If a progressive skin rash occurs treatment should be discontinued. Menstrual disturbance (breakthrough bleeding and an irregular cycle) have also been reported in patients taking terbinafine concomitantly with oral contraceptives.

#### **4.9 Overdose**

Reports of overdose are rare but a few cases have been reported where up to 5g has been taken giving rise to headache, nausea, epigastric pain and dizziness.

Treatment: Activated charcoal to adsorb and eliminate the terbinafine and symptomatic supportive therapy.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Dermatologicals; antifungal for systemic use

ATC code: D01B A02

Terbinafine is a broad spectrum antifungal drug. At low concentrations terbinafine has fungicidal activity against dermatophytes, moulds and certain dimorphic fungi. Depending upon species, terbinafine demonstrates fungicidal or fungistatic activity against yeasts.

Terbinafine acts by interfering with fungal sterol biosynthesis at an early stage leading to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in cell death. Terbinafine also acts by inhibition of squalene epoxidase in the fungal cell membrane.

Terbinafine is used for the treatment of fungal infections of the skin and nails, which is caused by Trichophyton (eg *T. rubrum*, *T. mentagrophytes*, *T. verrucosum*, *T. violaceum*), *Microsporum canis* and *Epidermophyton floccosum*.

### **5.2 Pharmacokinetic properties**

A single oral dose of 250mg terbinafine results in mean peak plasma concentrations of 0.97mcg/ml within 2 hours after administration. The absorption half-life is 0.8 hours and the distribution half-life is 4.6 hours. Terbinafine binds strongly to plasma proteins (99%).

Terbinafine rapidly diffuses through the skin and concentrates in the lipophilic stratum corneum. Terbinafine is also secreted in sebum, thus achieving high concentrations in hair follicles, hair and parts of the skin rich in sebaceous glands. There is also evidence that terbinafine is distributed into the nail plate within a few weeks after commencing therapy.

Terbinafine is rapidly metabolised by the CYP-isoenzymes, mainly by CYP2C9, CYP1A2, CYP3A4, CYP2C8 and CYP2C19. Biotransformation results in metabolites with no antifungal activity, which are excreted predominantly in the urine. The elimination half-life is 17 hours. There is no evidence of accumulation in the plasma.

No age-dependent changes in pharmacokinetics have been observed but the elimination rate may be reduced in patients with renal or hepatic impairment, resulting in higher blood levels of terbinafine.

In patients with pre-existing mild to severe hepatic impairment, single dose pharmacokinetic studies have shown that the clearance of terbinafine can be reduced by 50%.

The bioavailability of terbinafine is only slightly affected by food, and therefore a dose adjustment is not necessary.

### **5.3 Preclinical safety data**

The LD50 value of terbinafine is over 4 g/kg in both mice and rats.

In long-term studies (up to 1 year) in rats and dogs no marked toxic effects were seen in either species up to oral doses of about 100mg/kg a day. At high oral doses, the liver and possibly also the kidneys were identified as potential target organs.

In a two year oral carcinogenicity study in mice, no neoplastic or other abnormal findings attributable to treatment were made up to doses of 130 (males) and 156 (females) mg/kg a day. In a two year oral carcinogenicity study in rats, an increased incidence of liver tumours was observed in males at the highest dosage level of 69 mg/kg, at which systemic exposure was similar to clinical exposure. The mechanism of tumour development has not been established. The clinical relevance is unknown. The changes which may be associated with peroxisome proliferation have been shown to be species-specific since they were not seen in carcinogenicity studies in mice, dogs or monkeys.

During high-dose studies in monkeys, refractile irregularities were observed in the retina at the higher doses (non-toxic effect level 50mg/kg). These irregularities were associated with the presence of a terbinafine metabolite in ocular tissue and disappeared after discontinuation of the active substance. They were not associated with histological changes.

A standard battery of *in vitro* and *in vivo* genotoxicity tests revealed no evidence of mutagenic or clastogenic potential.

No undesirable effects on fertility or other reproduction parameters were observed in studies in rats or rabbits.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Microcrystalline Cellulose

Croscarmellose Sodium

Anhydrous Colloidal Silica

Hypromellose

Magnesium Stearate

### **6.2 Incompatibilities**

Not applicable

**6.3 Shelf life**

3 years

**6.4 Special precautions for storage**

HDPE bottle: Do not store above 25°C. Store in the original package.

Blister pack: Do not store above 25°C. Keep blister in the outer carton.

**6.5 Nature and contents of container**

Aluminium foil/PVC/PVdC blisters in cartons of 14, 28, 42, 56 or 98 tablets

White HDPE bottle with a polypropylene child resistant cap containing 60 or 500 tablets

**6.6 Special precautions for disposal**

No special requirements

**7 MARKETING AUTHORISATION HOLDER**

Dr Reddy's Laboratories (UK) Ltd

6 Riverview Road

Beverley

HU17 0LD

UK

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 08553/0242

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

13/02/2006

**10 DATE OF REVISION OF THE TEXT**

13/02/2006

# **PATIENT INFORMATION LEAFLET**

Paper size: 270 x 90mm  
Font: Frutegerlight 9  
Component code

## TERBINAFINE 250mg TABLETS

### PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start taking this medicine. If you have any questions or are unsure about anything relating to your treatment, ask your doctor or pharmacist.

#### What you need to know about Terbinafine Tablets

The name of your medicine is Terbinafine Tablets. Terbinafine belongs to a family of medicines called antifungals. It is used in the treatment of a variety of fungal infections of the skin and nails in adults. The tablets contain terbinafine hydrochloride equivalent to 250mg Terbinafine. The tablets also contain: magnesium stearate, colloidal anhydrous silica, hypromellose, microcrystalline cellulose and croscarmellose sodium. This strength is available in blister packs containing 14, 28, 42, 56 or 98 tablets, and bottles containing 60 or 500 tablets.

Manufactured by the Authorisation Holder:

Dr. Reddy's Laboratories (UK) Ltd  
6 Riverview Rd, Beverley, HU17 0LD, UK.

#### Before taking your medicine:

Tell your doctor before you start taking Terbinafine Tablets if any of the following apply to you:

- You suspect or know that you have had an allergic reaction to, any of the ingredients in Terbinafine
- You have any liver problems or have had any disease which may have affected your liver
- You have psoriasis
- You have any kidney problems
- Are you pregnant, or planning to become pregnant?
- You are breast-feeding

If you do become pregnant whilst taking terbinafine, tell your doctor.

If you are taking any other medicines (either bought or prescribed), you should be aware that some medicines can interfere with your treatment, so check with your doctor or pharmacist before taking any other medicines. In particular, tell your doctor if you are taking Rifampicin, Cimetidine, Oral contraceptives (as irregular periods and breakthrough bleeding may occur in some women), Antidepressants or any Beta-blocker drugs. If you suffer from a high fever or sore throat whilst taking Terbinafine Tablets consult your doctor.

#### Taking your medicine

Your doctor will decide the right dose for you and how long to take your tablets for. It is important that you complete the course of treatment, even if the infection heals.

#### Adults and the Elderly

The usual adult dose is 250mg a day but this may be reduced to 125mg a day. For skin infections take for between 2 to 6 weeks. For nail infections take for between 6 to 12 weeks, although some patients with toenail infections may need to take the tablets for 26 weeks or longer. Patients with kidney problems should be instructed to take half the usual adult dose.

#### Children and Adolescents

Not recommended.

Swallow your tablets whole with a glass of water. If you forget to take your tablet, take another as soon as you remember or wait until it is time to take your next dose. Then go on as before.

#### Overdose

If you accidentally take too much of your medicine, tell your doctor immediately, or go to your nearest casualty department, remember to take the tablets and packaging with you.

#### After taking your medicine

As with other medicines, Terbinafine Tablets may occasionally cause side effects in some patients. These are often mild to moderate and usually disappear after a while. The most common side effects include headache, loss of appetite, feeling sick, indigestion, diarrhoea, feeling full or mild abdominal pain, rash, itching, swelling, general feeling of being unwell or tiredness. Pains in the muscles and joints have been reported, usually with an allergic skin reaction such as swelling or rash.

A loss of taste and taste disturbances have been reported by a small number of patients. This usually only lasts whilst you are taking the tablets.

Rare side effects include feeling dizzy, diminished sense of touch, severe allergic reaction, unwell or tired and numbness or tingling. Rare side effects may include liver problems, including a yellowing of your skin, inflammation, increase liver enzymes or a severe skin rash (swelling, blistering or weals). If you notice any of these symptoms occurring stop taking your medication and tell your doctor immediately.

Very rarely people may experience a decrease in the number of some blood cells, depression and anxiety, vertigo or a worsening of psoriasis symptoms. Those taking oral contraceptives should be aware that terbinafine may result in irregular bleeding. Serious skin reactions have been reported rarely including photosensitivity, hair loss, significant skin damage, Stevens-Johnson syndrome or the appearance or aggravation of areas of skin and tissue deformity. Treatment should be discontinued if a progressive skin rash arises.

The severity of some of these effects may affect your ability to drive or use machinery. You should tell your doctor or pharmacist about any other side effects not listed here.

#### Storing your medicine

Do not store above 25°C and store in the original packaging. In particular blisters should be kept in the outer carton. The packaging has a printed expiry date do not take these tablets if this date has passed. Keep your medicine in a safe place out of reach and sight of children. Any unused tablets should be returned to your pharmacist for safe disposal.

Date of preparation: November 2005  
Terbinafine 250mg Tablets: 08553/0242  
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Component code

## **LABELLING**

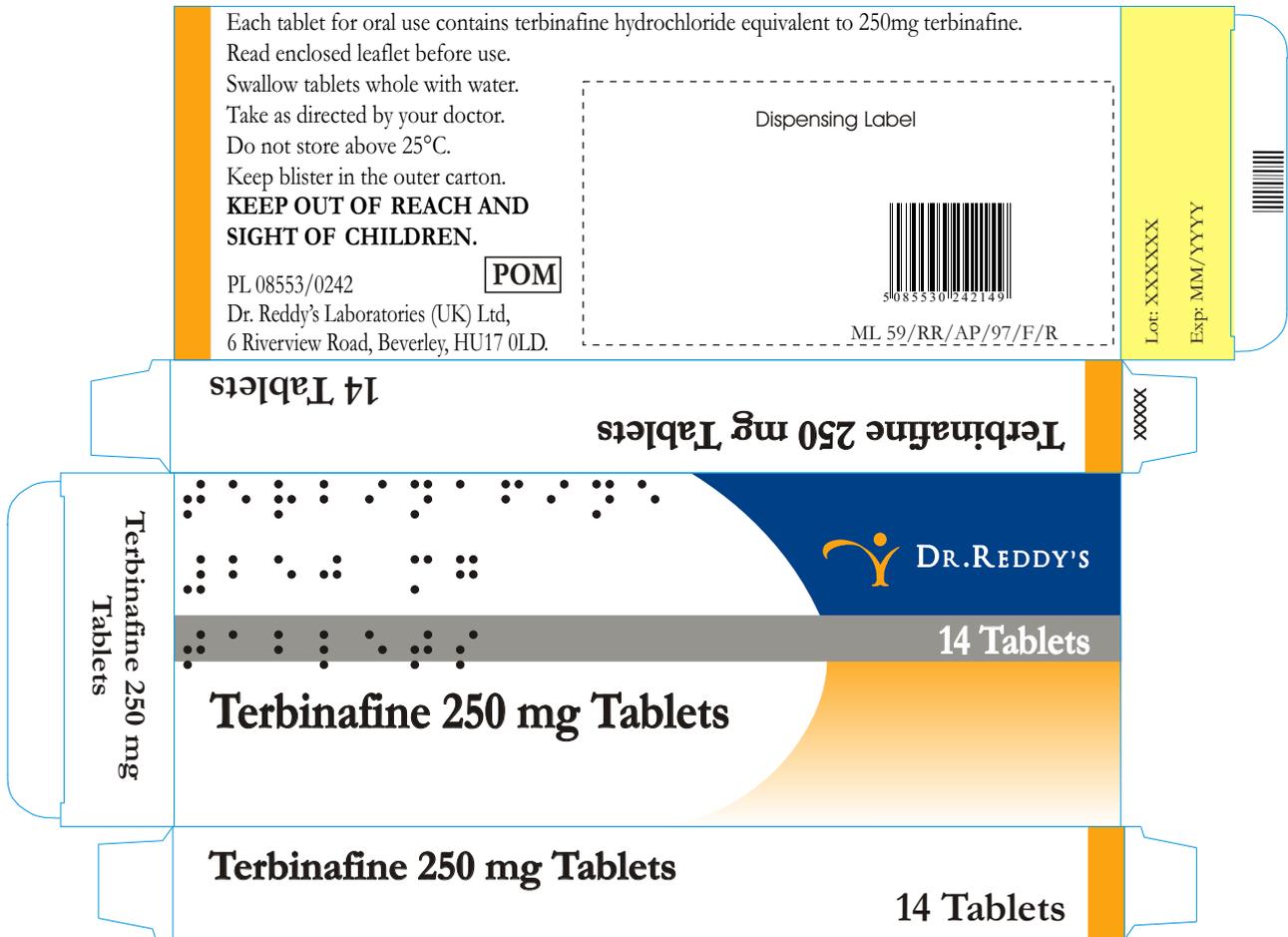
Terbinafine 250mg Tablets PL 08553/0242

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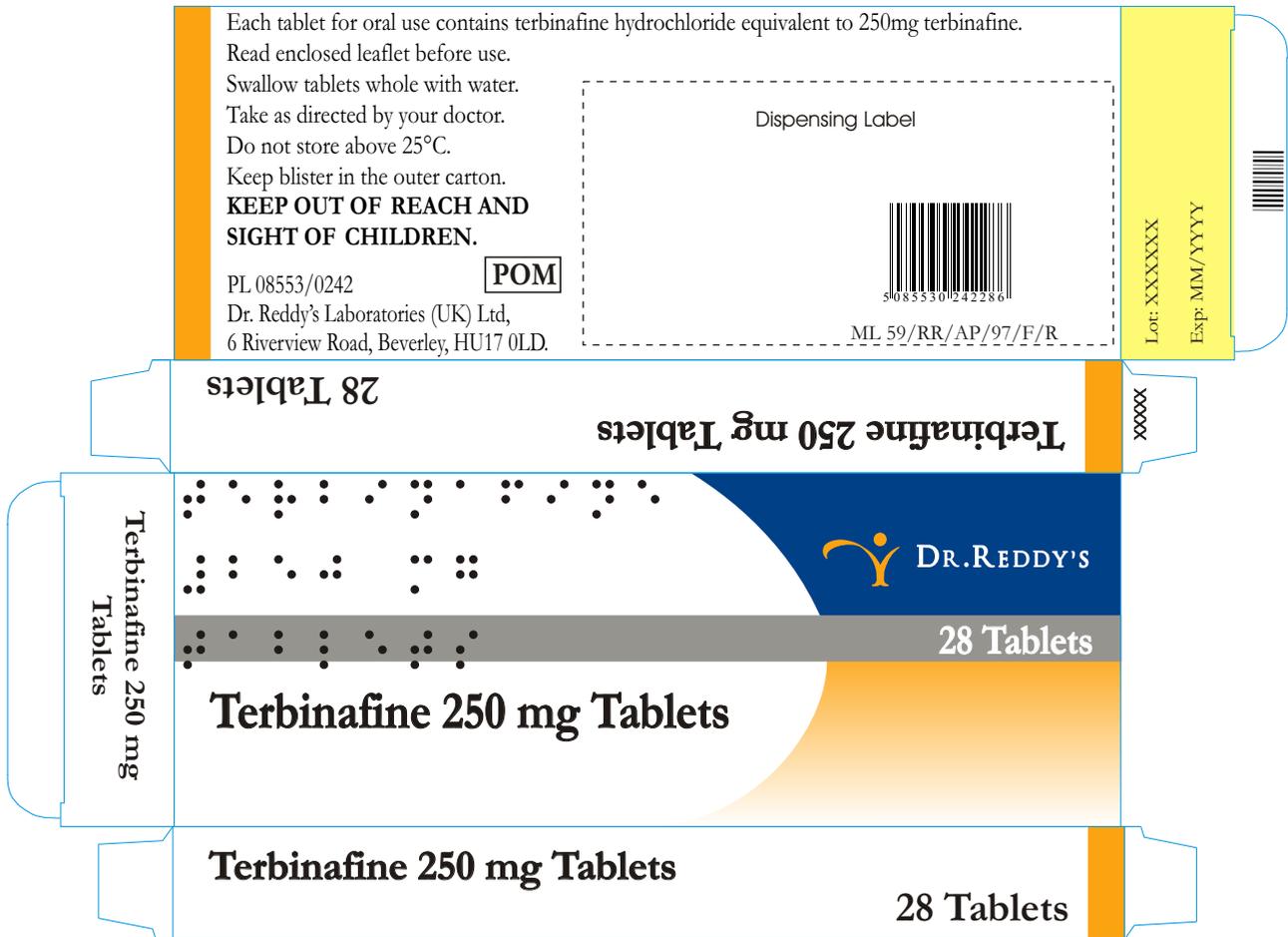
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Terbinafine 250mg Tablets PL 08553/0242



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Terbinafine 250mg Tablets PL 08553/0242



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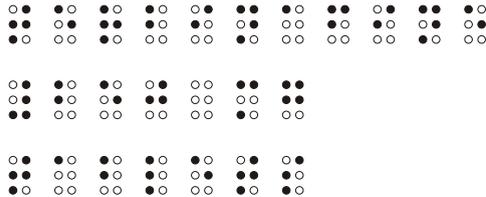
Terbinafine 250mg Tablets PL 08553/0242



Dr Reddy's Laboratories (UK) Ltd 6 Riverview Road Beverley HU17 0LD	Title:	Terbinafine 250mg (56's)	Colours: 294 CV 137 CV 423 CV Profile (do not print) No varnish
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Terbinafine 250mg Tablets PL 08553/0242

	 <p><b>60 Tablets</b></p> <p><b>Terbinafine 250 mg Tablets</b></p>	<p>Each tablet for oral use contains terbinafine hydrochloride equivalent to 250mg terbinafine. Read enclosed leaflet before use. Swallow tablets whole with water. Take as directed by your doctor. Do not store above 25°C. Store in the original package. <b>KEEP OUT OF REACH AND SIGHT OF CHILDREN.</b></p> <p>PL 08553/0242 Dr. Reddy's Laboratories (UK) Ltd, 6 Riverview Road, Beverley, HU17 0LD, UK</p>	<p>XXXXX</p>  <p>5 085330 241003</p> <p>Batch No. : Expiry Date :</p> <p><b>POM</b></p> <p>ML 59/RR/AP/97/F/R</p>
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Terbinafine 250mg Tablets PL 08553/0242

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 Read enclosed leaflet before use.  
 Swallow tablets whole with water.  
 Take as directed by your doctor.  
 Do not store above 25°C.

Keep blister in the outer carton.  
**KEEP OUT OF REACH AND SIGHT OF CHILDREN.**

PL 08553/0242 **POM**  
 Dr. Reddy's Laboratories (UK) Ltd,  
 6 Riverview Road, Beverley, HU17 0LD.

Dispensing Label



ML\_59/RR/AP/97/F/R

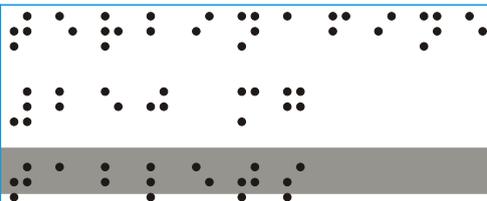
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 Exp: MM/YYYY

98 Tablets

Terbinafine 250 mg Tablets

XXXX

Terbinafine 250 mg Tablets



98 Tablets

Terbinafine 250 mg Tablets

Terbinafine 250 mg Tablets

98 Tablets

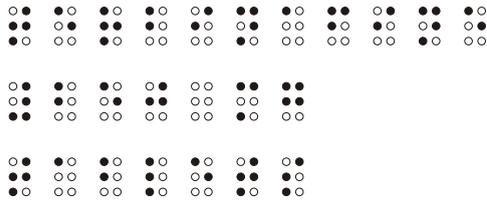
Dr Reddy's Laboratories (UK) Ltd  
 6 Riverview Road  
 Beverley  
 HU17 0LD

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		137 CV
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		No varnish
	Font:	Garamond

Marburg medium braille cell

Terbinafine 250mg Tablets PL 08553/0242



 <p align="center"><b>500 Tablets</b></p> <p><b>Terbinafine 250 mg Tablets</b></p>	<p>Each tablet for oral use contains terbinafine hydrochloride equivalent to 250mg terbinafine. <b>XXXXX</b></p> <p>Read enclosed leaflet before use. Swallow tablets whole with water. Take as directed by your doctor. Do not store above 25°C. Store in the original package.</p> <p><b>KEEP OUT OF REACH AND SIGHT OF CHILDREN.</b></p> <p>PL 08553/0242 Dr. Reddy's Laboratories (UK) Ltd, 6 Riverview Road, Beverley, HU17 0LD, UK</p>	 <p>Batch No. : Expiry Date :</p>
	<p><b>POM</b></p> <p>ML 59/RR/AP/97/F/R</p>	

Dr Reddy's Laboratories (UK) Ltd 6 Riverview Road Beverley HU17 0LD	<table border="1"> <tr> <td>Title:</td> <td>Terbinafine 250mg (500 bottle)</td> </tr> <tr> <td>Date of origination:</td> <td>13.05.2005</td> </tr> <tr> <td>Dimensions:</td> <td>125mm x 50mm</td> </tr> <tr> <td>Cutter ref:</td> <td></td> </tr> <tr> <td>Component code:</td> <td></td> </tr> <tr> <td>EAN number:</td> <td></td> </tr> <tr> <td>Software:</td> <td>CoreIDRAW 11.0</td> </tr> <tr> <td>Version number:</td> <td>02</td> </tr> <tr> <td>Revision date:</td> <td>14/11/05</td> </tr> <tr> <td>Reason for revision:</td> <td>Addition of Braille</td> </tr> </table>	Title:	Terbinafine 250mg (500 bottle)	Date of origination:	13.05.2005	Dimensions:	125mm x 50mm	Cutter ref:		Component code:		EAN number:		Software:	CoreIDRAW 11.0	Version number:	02	Revision date:	14/11/05	Reason for revision:	Addition of Braille	<table border="1"> <tr> <td rowspan="4">Colours:</td> <td> 294 CV</td> </tr> <tr> <td> 137 CV</td> </tr> <tr> <td> 423 CV</td> </tr> <tr> <td> No varnish</td> </tr> <tr> <td align="right">Font:</td> <td>Garamond</td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td></td> <td></td> </tr> </table>	Colours:	 294 CV	 137 CV	 423 CV	 No varnish	Font:	Garamond				
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