Certificado Número: PP10159375

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MEDICINAS Y PRODUCTOS PARA EL CUIDADO DE LA SALUD AGENCIA REGULATORIA

En nombre del Departamento de Salud

CERTIFICADO DE UN PRODUCTO FARMACÉUTICO (1)

Este certificado está conforme al formato recomendado por la Organización Mundial de la Salud (se adjuntan notas aclaratorias)

País de exportación (certificador): **REINO UNIDO**

País de importación (solicitante): **CHILE**

1 Nombre y forma de dosis del producto:

A) En el Reino Unido – Bisoprolol 5mg Tabletas Recubiertas, TABLETA RECUBIERTA

B) En CHILE – Bisoprolol 5mg Tabletas Recubiertas, TABLETA RECUBIERTA

1.1 Ingrediente(s) activo(s) (2) y cantidad(es) (3) por unidad de dosis:

Ingrediente(s) Activo(s)	Cantidad por unidad de dosis
BISOPROLOL FUMARATO	5,000 MG

Para la composición cualitativa completa incluyendo excipientes, ver el adjunto. (4)

1.2 ¿Está este producto licenciado para ser colocado en el mercado para su uso en el país de exportación? (5) Si

1.3 ¿Está este producto actualmente en el mercado del país de exportación? Si

1.4 El producto no está en el mercado en el país de exportación debido a que

N/A

Millennial India International Chamber of Commerce Industry & Agriculture
08 APR 2019

NOTARY S. M. H. ZAIDI Mumbai & Thane Dist. Reg. No. 3640 GOVT. OF INDIA

2A.1 Licencia de Producto/Autorización de Comercialización
Número [7]: **PL 21880/0130**
Fecha de Emisión: 06 de agosto de 2012

2A.2 El nombre y dirección del titular de la Licencia de Producto/Autorización de Comercialización son:

Nombre: MEDREICH PLC

Dirección: WARWICK HOUSE, PLANE TREE CRESCENT, FELTHAM, TW13 7HF, REINO UNIDO

2A.3 Estado del titular de la Licencia de Producto/Autorización de Comercialización [8]:
c) no está involucrado en la manufactura, empaquetado o rotulado de la forma de dosis, pero es responsable por la calidad y liberación del producto.

2A.3.1 Para las categorías b, c y d los nombres y dirección de los sitios de fabricación donde la forma de dosis es producida son [9]:

Vea la página adjunta para Fabricantes/Empaquetadores

2A.4 ¿Se adjunta el Resumen de la Aprobación? [10] No

2A.5 ¿Es la información del producto aprobada oficialmente adjunta completa y consonante con la licencia? [11] Si

2A.6 Solicitante para el certificado, si es diferente del titular de la licencia (nombre y dirección) [12]:

Nombre:

Dirección:

Sección 2B no está incluida porque el producto nombrado en este certificado está licenciado en el Reino Unido [6]

3.	¿La autoridad certificadora organiza inspecciones periódicas de la planta de manufactura donde la forma de dosis es producida? (14)	Si

EN CASO DE NO O NO APLICAR PROCEDA A LA PREGUNTA 4

3.1	Periodicidad de las inspecciones de rutina (años)	3
3.2	¿El fabricante de este tipo de forma de dosis ha sido inspeccionado?	Si
3.3	¿Las instalaciones y operaciones están conforme a las BPM según lo recomienda la Organización Mundial de la Salud? (15)	Si
4	¿La información presentada por el solicitante satisface a la autoridad certificante en todos los aspectos de la manufactura del producto incluyendo las Buenas Prácticas de Manufactura (BPM)? (16)	Si
	Si No, explique	

Información adicional:

NINGUNA

Dirección de la autoridad certificante:

La Agencia Reguladora de Productos para el Cuidado de la Salud y Medicinas,
10 South Colonnade, Canary Wharf, Londres E14 4PU, Reino Unido

Número de Teléfono: +44 (0) 20 3080 6593

Nombre de la persona autorizada: Mahmoodullah Khan

Firma:

Timbre y Fecha: 05 de febrero de 2019

Nombres y Direcciones de los Fabricantes/Empaquetadores (9)

Fabricantes

Nombre: MEDREICH LIMITED
Dirección: UNIT 3, SURVEY NO. 4/3 AVALAHALLI, ANJANAPURA POST, OFF KANAKAPURA ROAD, BANGALORE, IN-560 062, INDIA

Sitio de Liberación de Lote:

Nombre: MEDREICH PLC
Dirección: WARWICK HOUSE, PLANE TREE CRESCENT, FELTHAM, TW13 7HF, REINO UNIDO

Excipiente	Modificador	Cantidad por unidad de dosis
OPADRY BLANCO		1,975 MG
CELULOSA MICRO CRISTALINA		68,750 MG
ESTEARATO DE MAGNESIO		0,750 MG
ALMIDÓN DE MAÍZ		7,000 MG
ÓXIDO FÉRRICO AMARILLO E172		0,024 MG
SÍLICE ANHIDRO COLOIDAL		0,750 MG
CROSPOVIDONA TIPO B		2,750 MG
AGUA PURIFICADA	CS	

Certificate Number: PP10159375

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Department of Health

CERTIFICATE OF A PHARMACEUTICAL PRODUCT (1)

This certificate conforms to the format recommended by the World Health Organisation (explanatory notes are attached)

Exporting (certifying) country: **UNITED KINGDOM**

Importing (requesting) country: **CHILE**

1 Name and dosage form of the product:

A) In the United Kingdom - Bisoprolol 5mg Film-Coated Tablets, FILM-COATED TABLET

B) In CHILE - Bisoprolol 5mg Film-Coated Tablets, FILM-COATED TABLET

1.1 Active ingredient(s) (2) and amount(s) (3) per unit dose:

Active Ingredient(s)	Amount per unit dose
BISOPROLOL FUMARATE	5.000 MG

For complete qualitative composition including excipients, see attached. (4)

1.2 Is this product licensed to be placed on the market for use in the exporting country? (5) Yes

1.3 Is this product actually on the market in the exporting country? Yes

1.4 The product is not on the market in the exporting country because

N/A

International Chamber of Commerce Industry & Agriculture Millennial India
08 APR 2019

NOTARY GOVT. OF INDIA S. M. H. ZAIDI Mumbai & Thane Dist. Reg. No. 3640

2A.1 Product Licence/Marketing Authorisation

Number [7]: **PL 21880/0130**

Date of Issue: 06 August 2012

2A.2 The name and address of the Product Licence/Marketing Authorisation holder are:

Name: MEDREICH PLC

Address: WARWICK HOUSE, PLANE TREE CRESCENT, FELTHAM, TW13 7HF, UNITED KINGDOM

2A.3 Status of the Product Licence/Marketing Authorisation holder [8]:

c) is not involved in manufacturing, packaging or labelling the dosage form but is responsible for the quality and release of the product

2A.3.1 For categories b,c and d the names and address of the manufacturing site where the dosage form is produced are [9]:

See attached page for Manufacturers/Packagers

2A.4 Is Summary Basis of Approval appended? [10] No

2A.5 Is the attached, officially approved product information complete and consonant with the licence? [11] Yes

2A.6 Applicant for certificate, if different from licence holder (name and address) [12] :

Name:

Address:

Section 2B is not included because the product named in this certificate is licensed in the UK[6]

3	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? (14)	Yes

IF NO OR NOT APPLICABLE PROCEED TO QUESTION 4

3.1	Periodicity of routine inspections (years)	3
3.2	Has the manufacturer of this type of dosage form been inspected?	Yes
3.3	Do the facilities and operations conform to GMP as recommended by the World Health Organisation ? (15)	Yes
4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product including Good Manufacturing Practice (GMP)? (16)	Yes
	If No, explain	

Additional Information:

NONE

Address of certifying authority:

The Medicines and Healthcare products Regulatory Agency,
10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom

Telephone Number: +44 (0) 20 3080 6593

Name of authorised person: Mahmoodullah Khan

Signature:

Stamp and Date: 05 February 2019

Names and Addresses of Manufacturers/Packagers (9)

Manufacturers

Name: MEDREICH LIMITED
Address: UNIT 3, SURVEY NO. 4/3 AVALAHALLI, ANJANAPURA POST, OFF KANAKAPURA ROAD, BANGALORE, IN-560 062, INDIA

Batch Release Site:

Name: MEDREICH PLC
Address: WARWICK HOUSE, PLANE TREE CRESCENT, FELTHAM, TW13 7HF, UNITED KINGDOM

Excipient	Modifier	Amount per unit dose
OPADRY WHITE		1.975 MG
MICROCRYSTALLINE CELLULOSE		68.750 MG
MAGNESIUM STEARATE		0.750 MG
MAIZE STARCH		7.000 MG
FERRIC OXIDE YELLOW E172		0.024 MG
COLLOIDAL ANHYDROUS SILICA		0.750 MG
CROSPOVIDONE TYPE B		2.750 MG
PURIFIED WATER	QS	

Explanatory Notes

1. This certificate, which is in the form recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the UK. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

2. Whenever possible International Non-proprietary Names (Inns) or national non-proprietary names have been used.

3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.

4. Details of the quantitative composition are preferred but their provision is subject to the agreement of the Marketing Authorisation holder.

5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the Marketing Authorisation.

6. Sections 2A and 2B are mutually exclusive.

7. Indicate when applicable if the licence is provisional or the product has not yet been approved.

8. Specify whether the person responsible for placing the product on the market:

   (a) manufactures the dosage form and is responsible for the quality assurance and release of the product.
   (b) packages and/or labels a dosage form manufactured by another company but is responsible for the quality assurance and release of the product.
   (c) is not involved in manufacturing, packaging or labelling the dosage form but is responsible for the quality and release of the product.
   (d) is involved in none of the above.

9. This information is optional and can be provided only with the permission of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

   It should be noted that:

   information concerning the site of manufacture is part of the Marketing Authorisation. If the manufacturing site is changed the licence must be updated or it will cease to be valid.

   in the UK manufacture of pharmaceutical products is only permitted on licensed manufacturing sites. When the product-licence holder or applicant conforms to status (b), (c) or (d) as described in note 8 above the Manufacturing Licence holder is responsible for the manufacture of the dosage form.

10. This refers to the document prepared by some national regulatory authorities that summarises the technical basis on which the product has been licensed. The UK Medicines and Healthcare products Regulatory Agency does not prepare such a document.

11. This refers to product information approved by the Medicines and Healthcare products Regulatory Agency such as a Summary of Product Characteristics (SPC).

12. In this circumstance permission for issuing the certificate is required from the Marketing Authorisation holder. This permission must be provided to the Medicines and Healthcare products Regulatory Agency by the applicant.

13. Please indicate the reason that the applicant has provided for not requesting registration:

    (a) the product has been developed exclusively for the treatment of conditions - particularly tropical diseases - not endemic in the UK.
    (b) the product has been reformulated with a view to improving its stability under tropical conditions.
    (c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the UK.
    (d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient.
    (e) this type of product does not require a Marketing Authorisation in the UK.
    (f) any other reason.

14. "Yes" means the Medicines and Healthcare products Regulatory Agency arranges periodic inspections of the manufacturing plant in which the dosage form is produced. "No" means that manufacture is taking place in a country other than the UK and inspections are not carried out by any Regulatory Authority. "Not applicable" means that manufacture is taking place in a country other than the UK and inspection is conducted under the aegis of the country of manufacture.

15. The requirements of good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty second report of the Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 823, 1992, Annex 1). Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardisation (WHO Technical Report Series No. 822, 1992, Annex 1).

16. This section is to be completed when the product-licence holder or applicant conforms to status (b), (c) or (d) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form and the extent and nature of any controls exercised over each of these parties.

Certificate Number: PP10159375

SUMMARY OF PRODUCT CHARACTERISTICS

Printed for Certificate of Pharmaceutical Product

1 NAME OF THE MEDICINAL PRODUCT

Bisoprolol 5mg film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Bisoprolol 5mg: Each Film coated tablet contains 5mg Bisoprolol Fumarate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Bisoprolol 5mg: White -yellow, heart-shaped with a break-line on both sides

The tablets can be divided into equal doses.

4.5 Interaction with other medicinal products and other forms of interaction

Combinations not recommended

Calcium antagonists of the verapamil type and to a lesser extent of the diltiazem type: Negative influence on contractility and atrio-ventricular conduction. Intravenous administration of verapamil in patients on β-blocker treatment may lead to profound hypotension and atrioventricular block.

Class I antiarrhythmic drugs (e.g. quinidine, disopyramide; lidocaine, phenytoin; flecainide, propafenone): Effect on atrio-ventricular conduction time may be potentiated and negative inotropic effect increased.

Centrally acting antihypertensive drugs such as clonidine and others (e.g. methyldopa, moxonodine, rilmenidine): Concomitant use of centrally acting antihypertensive drugs may worsen heart failure by a decrease in the central sympathetic tonus (reduction of heart rate and cardiac output, vasodilation). Abrupt withdrawal, particularly if prior to beta-blocker discontinuation, may increase risk of "rebound hypertension".

Combinations to be used with caution

Calcium antagonists of the dihydropyridine type such as felodipine and amlodipine: Concomitant use may increase the risk of hypotension, and an increase in the risk of a further deterioration of the ventricular pump function in patients with heart failure cannot be excluded.

Class-III antiarrhythmic drugs (e.g. amiodarone): Effect on atrio-ventricular conduction time may be potentiated.

Topical beta-blockers (e.g. eye drops for glaucoma treatment) may add to the systemic effects of bisoprolol.

Parasympathomimetic drugs: Concomitant use may increase atrio-ventricular conduction time and the risk of bradycardia.

Insulin and oral antidiabetic drugs: Intensification of blood sugar lowering effect. Blockade of beta-adrenoreceptors may mask symptoms of hypoglycaemia.

Anaesthetic agents: Attenuation of the reflex tachycardia and increase of the risk of hypotension (for further information on general anaesthesia see also section 4.4.).

Digitalis glycosides: Reduction of heart rate, increase of atrio-ventricular conduction time.

Non-steroidal anti-inflammatory drugs (NSAIDs): NSAIDs may reduce the hypotensive effect of bisoprolol.

β-Sympathomimetic agents (e.g. isoprenaline, dobutamine): Combination with bisoprolol may reduce the effect of both agents.

Sympathomimetics that activate both β- and α-adrenoceptors (e.g. noradrenaline, adrenaline): Combination with bisoprolol may unmask the α-adrenoceptor-mediated vasoconstrictor effects of these agents leading to blood pressure increase and exacerbated intermittent claudication. Such interactions are considered to be more likely with nonselective β-blockers.

Concomitant use with antihypertensive agents as well as with other drugs with blood pressure lowering potential (e.g. tricyclic antidepressants, barbiturates, phenothiazines) may increase the risk of hypotension.

Combinations to be considered

Mefloquine: increased risk of bradycardia

Monoamine oxidase inhibitors (except MAO-B inhibitors): Enhanced hypotensive effect of the beta-blockers but also risk for hypertensive crisis.

4.6 Fertility,pregnancy and lactation

Pregnancy:

Bisoprolol has pharmacological effects that may cause harmful effects on pregnancy and/or the fetus/newborn. In general, beta-adrenoceptor blockers reduce placental perfusion, which has been associated with growth retardation, intrauterine death, abortion or early labour. Adverse effects (e.g. hypoglycaemia and bradycardia) may occur in the fetus and newborn infant. If treatment with beta-adrenoceptor blockers is necessary, beta$_1$-selective adrenoceptor blockers are preferable.

Bisoprolol should not be used during pregnancy unless clearly necessary. If treatment with bisoprolol is considered necessary, the uteroplacental blood flow and the fetal growth should be monitored. In case of harmful effects on pregnancy or the fetus alternative treatment should be considered. The newborn infant must be closely monitored. Symptoms of hypoglycaemia and bradycardia are generally to be expected within the first 3 days.

Lactation:

It is not known whether this drug is excreted in human milk. Therefore, breastfeeding is not recommended during administration of bisoprolol.

Fertility:

In reproduction toxicology studies Bisoprolol had no influence on fertility or on general reproduction performance (see section 5.3).

4.7 Effects on ability to drive and use machines

In a study with coronary heart disease patients bisoprolol did not impair driving performance. However, due to individual variations in reactions to the drug, the ability to drive a vehicle or to operate machinery may be impaired. This should be considered particularly at start of treatment and upon change of medication as well as in conjunction with alcohol.

4.8. Undesirable effects

The following definitions apply to the frequency terminology used hereafter:

Very common (≥ 1/10)
Common (≥ 1/100, < 1/10)
Uncommon (≥ 1/1,000, < 1/100)
Rare (≥ 1/10,000, < 1/1,000)
Very rare (< 1/10,000)
Frequency not known (cannot be estimated from available data)

Cardiac disorders:
Very common: bradycardia.
Common: worsening of heart failure.
Uncommon: AV-conduction disturbances.

Investigations:
Rare: increased triglycerides, increased liver enzymes (ALAT, ASAT).

Nervous system disorders:
Common: dizziness, headache.
Rare: syncope

Eye disorders:
Rare: reduced tear flow (to be considered if the patient uses lenses).
Very rare: conjunctivitis.

Ear and labyrinth disorders:
Rare: hearing impairment.

Respiratory, thoracic and mediastinal disorders:
Uncommon: bronchospasm in patients with bronchial asthma or a history of obstructive airways disease.
Rare: allergic rhinitis.

Gastrointestinal disorders:
Common: gastrointestinal complaints such as nausea, vomiting, diarrhoea, constipation.

Skin and subcutaneous tissue disorders:

SUMMARY OF PRODUCT CHARACTERISTICS

Printed for Certificate of Pharmaceutical Product

Rare: hypersensitivity reactions (itching, flush, rash).
Very rare: beta-blockers may provoke or worsen psoriasis or induce psoriasis-like rash, alopecia.

Musculoskeletal and connective tissue disorders:
Uncommon: muscular weakness and cramps.

Vascular disorders:
Common: feeling of coldness or numbness in the extremities, hypotension.
Uncommon: orthostatic hypotension.

General disorders:
Common: asthenia, fatigue.

Hepatobiliary disorders:
Rare: hepatitis.

Reproductive system and breast disorders:
Rare: potency disorders.

Psychiatric disorders:
Uncommon: sleep disorders, depression.
Rare: nightmares, hallucinations.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.4 Special warnings and precautions for use

Bisoprolol must be used with caution in:

- bronchospasm (bronchial asthma, obstructive airways diseases)

- diabetes mellitus with large fluctuations in blood glucose values; symptoms of hypoglycaemia can be masked

- strict fasting

- ongoing desensitisation therapy

- first degree AV block

- Prinzmetal's angina

- peripheral arterial occlusive disease (intensification of complaints might happen especially during the start of therapy)

- general anaesthesia
In patients undergoing general anaesthesia beta-blockade reduces the incidence of arrhythmias and myocardial ischemia during induction and intubation, and the post-operative period. It is currently

recommended that maintenance beta-blockade be continued peri-operatively. The anaesthesist must be aware of beta-blockade because of the potential for interactions with other drugs, resulting in bradyarrhythmias, attenuation of the reflex tachycardia and the decreased reflex ability to compensate for blood loss. If it is thought necessary to withdraw beta-blocker therapy before surgery, this should be done gradually and completed about 48 hours before anaesthesia.

There is no therapeutic experience of bisoprolol treatment of heart failure in patients with the following diseases and conditions:

- insulin dependent diabetes mellitus (type I)
- severely impaired renal function
- severely impaired hepatic function
- restrictive cardiomyopathy
- congenital heart disease
- haemodynamically significant organic valvular disease
- myocardial infarction within 3 months

Combination of bisoprolol with calcium antagonists of the verapamil or diltiazem type, with Class I antiarrhytmic drugs and with centrally acting antihypertensive drugs is generally not recommended, for details please refer to section 4.5.

In bronchial asthma or other chronic obstructive lung diseases, which may cause symptoms, bronchodilating therapy should be given concomitantly. Occasionally an increase of the airway resistance may occur in patients with asthma, therefore the dose of $beta_2$-stimulants may have to be increased.

As with other beta-blockers, bisoprolol may increase both the sensitivity towards allergens and the severity of anaphylactic reactions. Adrenaline treatment does not always give the expected therapeutic effect.

Patients with psoriasis or with a history of psoriasis should only be given beta-blockers (e.g. bisoprolol) after carefully balancing the benefits against the risks.

In patients with phaeochromocytoma bisoprolol must not be administered until after alpha-receptor blockade.

Under treatment with bisoprolol the symptoms of a thyreotoxicosis may be masked.

SUMMARY OF PRODUCT CHARACTERISTICS

Printed for Certificate of Pharmaceutical Product

The initiation of treatment with bisoprolol necessitates regular monitoring. For the posology and method of administration please refer to section 4.2.

The cessation of therapy with bisoprolol should not be done abruptly unless clearly indicated. For further information please refer to section 4.2.

5.2 Pharmacokinetic properties

Absorption

Bisoprolol is absorbed and has a biological availability of about 90% after oral administration.

Distribution

The distribution volume is 3.5 l/kg. The plasma protein binding of bisoprolol is about 30%.

Biotransformation and Elimination

Bisoprolol is excreted from the body by two routes. 50% is metabolised by the liver to inactive metabolites which are then excreted by the kidneys. The remaining 50% is excreted by the kidneys in an unmetabolised form. Total clearance is approximately 15 l/h. The half-life in plasma of 10-12 hours gives a 24 hour effect after dosing once daily.

Linearity

The kinetics of bisoprolol are linear and independent of age.

Special population

Since the elimination takes place in the kidneys and the liver to the same extent a dosage adjustment is not required for patients with impaired liver function or renal insufficiency. The pharmacokinetics in patients with stable chronic heart failure and with impaired liver or renal function has not been studied. In patients with chronic heart failure (NYHA stage III) the plasma levels of bisoprolol are higher and the half-life is prolonged compared to healthy volunteers. Maximum plasma concentration at steady state is 64+21 ng/ml at a daily dose of 10 mg and the half-life is 17+5 hours.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or carcinogenicity. Like other beta-blockers, bisoprolol caused maternal (decreased food intake and decreased body weight) and embryo/fetal toxicity (increased incidence of resorptions, reduced birth weight of the offspring, retarded physical development) at high doses but was not teratogenic.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose (PH-112)

Maize Starch

Crospovidone (Type B)

Colloidal Anhydrous Silica

SUMMARY OF PRODUCT CHARACTERISTICS

Printed for Certificate of Pharmaceutical Product

Magnesium Stearate

Purified Water

Film coating (1.25mg tablets and 2.5mg tablets): Hypromellose, Macrogol 400 and Titanium dioxide (E171).

Film coating (3.75mg tablets, 5 mg tablets and 7.5mg tablets): Hypromellose, Macrogol 400, Titanium dioxide (E171) and Ferric oxide yellow (E172)

Film coating (10 mg tablets): Hypromellose, Macrogol 400, Titanium dioxide (E171), Ferric oxide yellow (E172), Ferric oxide red (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

No special requirements

6.5 Nature and contents of container

20, 28, 30, 50, 56, 60, 90, or 100 tablets

Not all pack sizes are marketed.

Tablets are packed in Aluminium (0.02mm thickness) and PVC (0.25mm)/ PVDC (120 gsm) blisters.

Blisters are packed in cartons.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Medreich Plc
Warwick House
Plane Tree Crescent
Feltham
TW13 7HF

Certificate Number: PP10159375

SUMMARY OF PRODUCT CHARACTERISTICS

Printed for Certificate of Pharmaceutical Product

8 **MARKETING AUTHORISATION NUMBER(S)**
PL 21880/0127-0132

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

6 August 2012

10 **DATE OF REVISION OF THE TEXT**

02/08/2016

NOTARY GOVT. OF INDIA S. M. H. ZAIDI Mumbai & Thane Dist. Regd. No. 3640

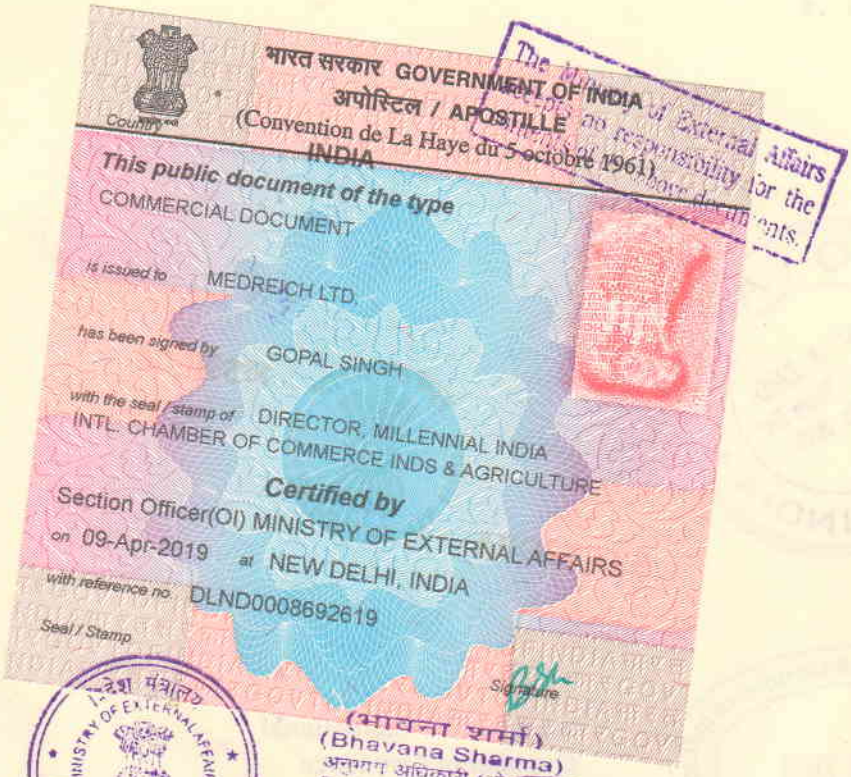
103167

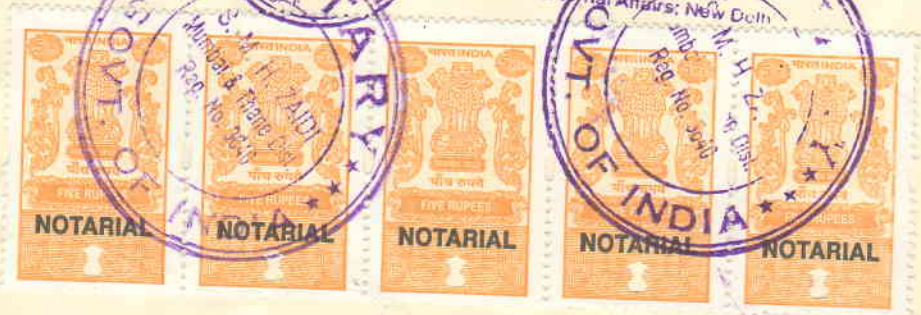
ATTESTED

Authorized Signatory
Millennial India International
Chamber of Commerce
Industry & Agriculture
New Delhi, (INDIA)

GOPAL SINGH
Director

Millennial India International Chamber of Commerce Industry & Agriculture
08 APR 2019





ATTESTED BY ME

S. M. H. ZAIDI
NOTARY
Government of India
Mumbai & Thane Dist

03 APR 2019