### **Glimepiride** Tablets

Each Uncoated tablet contains Glimepiride USP......4mg



#### COMPOSITION:

Glimepiride 1 Each tablet contains
Glimepiride1 mg
Excipientsq.s.
Glimepiride 2
Each tablet contains
Glimepiride2 mg
Excipientsq.s.
Glimepiride 4

Each tablet contains
Glimepiride4mg
Excipientsq.s.

#### INDICATIONS:

Glimepiride is indicated as an adjunct to diet and exercise to lower the blood glucose in patients with non insulin-dependent (Type 2) diabetes mellitus (NIDDM) whose hyperglycaemia cannot be controlled by diet and exercise alone. Glimepiride may be used concomitantly with metformin when diet, exercise, and glimepiride or metformin alone do not result in adequate glycaemic control.

Glimepiride is also indicated for use in combination with insulin to lower blood glucose in patients whose hyperglycaemia cannot be controlled by diet and exercise in conjunction with an oral hypoglycaemic agent. Combined use of glimepiride and insulin may increase the potential for hypoglycaemia.

#### DOSAGEANDADMINISTRATION:

#### General

Dosage should be individualized on the basis of both effectiveness and tolerance. There is no fixed dosage regimen for the management of diabetes mellitus with glimepiride or any other hypoglycaemic agent.

#### **Usual Starting Dose**

The usual starting dose of Glimepiride as initial therapy is 1-2 mg once daily, administered with breakfast or the first main meal. Those patients who may be more sensitive to hypoglycaemic drugs should be started at 1 mg once daily, and should be titrated carefully.

No exact dosage relationship exists between glimepiride and the other oral hypoglycaemic agents. The maximum starting dose of Glimepiride should be no more than 2 mg. Failure to follow an appropriate dosage regimen may precipitate hypoglycaemia. Patients who do not adhere to their prescribed dietary and drug regimen are more prone to exhibit unsatisfactory response to therapy.

#### **Usual Maintenance Dose**

The usual maintenance dose is 1 to 4 mg once daily. The maximum recommended dose is 8 mg once daily. After reaching a dose of 2 mg, dosage increases should be made in increments of no more than 2 mg at 1-2 week intervals based upon the patient's blood glucose response. Long-term efficacy should be monitored by measurement of HbA1clevels, for example, every 3 to 6 months.



Note: This site contains medical information that is intended for doctors or medical practitioner only and is not meant to substitute for the advice provided by a medical professional. Always consult a physician if you have health concerns. Use and access of this site is subject to the terms and conditions as set out in our Privacy Policy and Terms of Use. © Copyright 2012 Taj Pharma Group (India),. All rights reserved. Note:-We are committed to helping you find the right answers to your questions and concerns. However, this Report is not intended to give investment advice, promote the use of Taj Pharmaceuticals. Ltd products or provide information on which to base medical treatment. If you have questions regarding any Taj Pharmaceuticals Ltd product or are experiencing a medical emergency, please consult your health care provide. Active Pharmaceutical Ingredients manufacturer, exporter, drug ingredients, pharmaceuticals, India Additionally, contact information on this Report cannot be used to report adverse drug events. If you are a physician, please follow the procedures required by your country's regulations. Please choose one of the given options to contact us and we will respond to

## **Glimepiride Tablets**



#### Glimepiride-Metformin Combination Therapy

If patients do not respond adequately to the maximal dose of Glimepiride monotherapy, addition of metformin may be considered. Published clinical information exists for the use of other sulphonylureas including glyburide, glipizide, chlorpropamide, and tolbutamide in combination with metformin.

With concomitant glimepiride and metformin therapy, the desired control of blood glucose may be obtained by adjusting the dose of each drug. However, attempts should be made to identify the minimum effective dose of each drug to achieve this goal. With concomitant glimepiride and metformin therapy, the risk of hypoglycaemia associated with glimepiride therapy continues and may be increased. Appropriate precautions should be taken.

#### **Glimepiride-Insulin Combination Therapy**

Combination therapy with glimepiride and insulin may also be used in secondary failure patients. The fasting glucose level for instituting combination therapy is in the range of >150 mg/dL in plasma or serum depending on the patient. The recommended glimepirde dose is 8 mg once daily administered with the first main meal. After starting with low-dose insulin, upward adjustments of insulin can be done approximately weekly as guided by frequent measurements of fasting blood glucose. Once stable, combination-therapy patients should monitor their capillary blood glucose on an ongoing basis, preferably daily. Periodic adjustments of insulin may also be necessary during maintenance as guided by glucose and HbA1clevels.

#### **CONTRAINDICATIONS:**

Glimepiride is contraindicated in patients with

1. Known hypersensitivity to the drug.

2. Diabetic ketoacidosis, with or without coma. This condition should be treated with insulin

#### **PACKAGING INFORMATION:**

Glimepiride 1 .....Strip of 10 tablets

Glimepiride 2 .....Strip of 10 tablets

Glimepiride 3 .....Strip of 10 tablets

#### For Information about Generic Medicines : genericmedicines@tajpharma.com

<u>Note</u>: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world. The Price of the drugs indicated above may not match the actual price at which they are sold. Prices can change depending on many factors, including local taxes. These are only approximate indicative prices of the drug. The products discussed herein may have different product labelling in different countries. The product information provided in this site is intended only for the residents of India.

Information for Health Care Professionals

\*\*\* Please consult local Prescribing Information for any product before use. This website is an international information resource for healthcare professionals with an interest in disease management. This website is not intended to replace the advice of a qualified healthcare professional. Above brand is a trademark of the Taj group of companies (Taj Pharmaceuticals Limited).



Note: This site contains medical information that is intended for doctors or medical practitioner only and is not meant to substitute for the advice provided by a medical professional. Always consult a physician if you have health concerns. Use and access of this site is subject to the terms and conditions as set out in our Privacy Policy and Terms of Use.

© Copyright 2012 Taj Pharma Group (India),. All rights reserved.

Note:-We are committed to helping you find the right answers to your questions and concerns. However, this Report is not intended to give investment advice, promote the use of Taj Pharmaceuticals Ltd products or provide information on which to base medical treatment. If you have questions regarding any Taj Pharmaceuticals Ltd product or are experiencing a medical emergency, please consult your health care provider. Active Pharmaceutical Ingredients manufacturer, exporter, drug ingredients, pharmaceuticals, India Additionally, contact information on this Report cannot be used to report adverse drug events. If you are a physician, please follow the procedures required by your country's regulations. Please choose one of the given options to contact us and we will respond to





# THIS PRESENTATION IS NOT AN ADVERTISEMENT OF SECURITIES IN ANY JURISDICTION.

## NOT FOR RELEASE, DIRECTLY OR INDIRECTLY, IN THE UNITED STATES OF AMERICA, AUSTRALIA, CANADA OR JAPAN.

This document includes statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the fact that they do not only relate to historical or current events. Forward-looking statements often use words such as" anticipate", "target", "expect", "estimate", "intend", "expected", "plan", "goal" believe", or other words of similar meaning. By their nature, forward-looking statements involve risk and uncertainty because they relate to future events and circumstances, a number of which are beyond Company's control. As a result, actual future results may differ materially from the plans, goals and expectations set out in these forward-looking statements. Any forward-looking statements made by or on behalf of the Company speak only as at the date of this announcement. Save as required by any applicable laws or regulations, the Company undertakes no obligation publicly to release the results of any revisions to any forward-looking statements in this document that may occur due to any change in its expectations or to reflect events or circumstances after the date of this document. The securities referred to herein have not been and will not be registered under the US Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold in the United States or to US persons unless the securities are registered under the Securities Act, or an exemption from the registration requirements of the Securities Act is available. No public offering of the securities will be made in the United States. This communication is being distributed only to and is directed only at (a) persons outside the United Kingdom, (b) persons who have professional experience in matters relating to investments, i.e., investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order"), and (c) high net worth companies, unincorporated associations and other bodies to whom it may otherwise lawfully be communicated in accordance with Article 49 of the Order (all such persons together being referred to as "relevant persons"). The securities are available only to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be available only to or will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this communication or any of its contents.





Note: This site contains medical information that is intended for doctors or medical practitioner only and is not meant to substitute for the advice provided by a medical professional. Always consult a physician if you have health concerns. Use and access of this site is subject to the terms and conditions as set out in our Privacy Policy and Terms of Use. © Copyright 2011 Taj Pharma Group (India),. All rights reserved.



### About Taj Pharmaceutical Limited

Taj Pharmaceuticals Limited is a pharmaceutical company founded and based in India. The company manufacturers pharmaceutical formulations and API for India and other countries of world. The company was established in 1995 as an enterprise and in 2004 became a public limited company. As per Mumbai pharmaxil and Chemixil association the company manufacturers and exports to countries like Albania, Argentina, Austria, Chile and Iraq. In 1995 pharmaceuticals wing only has a schedule M certification for pharmaceuticals products manufacturing in India. Taj Pharmaceuticals established its manufacturing unit in Gujarat because of government policies in 1999 with WHO / GMP licence. The company in 2003 revived all the old manufacturing units and approached the FDA Gujarat for 4000 new pharmaceuticals drug permissions for the first time in India.

According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.

www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.



Taj Pharmaceuticals Limited

Note: This site contains medical information that is intended for doctors or medical practitioner only and is not meant to substitute for the advice provided by a medical professional. Always consult a physician if you have health concerns. Use and access of this site is subject to the terms and conditions as set out in our Privacy Policy and Terms of Use. © Copyright 2011 Taj Pharma Group (India),. All rights reserved.



Note: This site contains medical information that is intended for doctors or medical practitioner only and is not meant to substitute for the advice provided by a medical professional. Always consult a physician if you have health concerns. Use and access of this site is subject to the terms and conditions as set out in our Privacy Policy and Terms of Use. © Copyright 2011 Taj Pharma Group (India),. All rights reserved.

Taj Pharmaceuticals Limited (the "Company") believes that the information included in the Investor Relations section of this website was correct at the time it was added to the website. However, the Company expressly disclaims any duty to update the information on the website and makes no representation or warranty as to accuracy and completeness of the contents of this Investors Relations section of the website or any other section of the website. Access to and use of the information on this website is at the user's own risk. The Company assumes no responsibility for any errors or omissions in the content of this website and disclaims any liability for damages of any kind (whether direct, consequential or punitive) arising out of the use of this website or the information contained on the website or on links to or from this website.

The Investor Relations section of this website contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. All statements other than statements of historical facts, included on this website regarding the Company's strategy, expected future financial position, results of operations, cash flows, financing plans, discovery and development of products, strategic alliances, competitive position, plans and objectives of management are forward-looking statements. Words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "will" and other similar expressions help identify forwardlooking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding the Company's financial results and outlook, the continued implementation of the Company's strategic plan, the development of the Company's pipeline, the commencement of Phase 3 clinical trials for Puricase (pegloticase) are forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on current expectations, assumptions, estimates and projections about the Company's business and the biopharmaceutical and specialty pharmaceutical industries in which the Company operates. Such risks and uncertainties include, but are not limited to, the delay or failure in developing Puricase (pegloticase) and other product candidates; difficulties of expanding the Company's product portfolio through in-licensing or acquisition; not being able to manufacture commercial quantities of our products; not gaining market acceptance sufficient to justify development and commercialization costs if our products are approved for marketing; introduction of generic competition for API; fluctuations in buying patterns of wholesalers; potential future returns of API or other products; the Company continuing to incur substantial net losses for the foreseeable future; difficulties in obtaining financing; potential development of alternative technologies or more effective products by competitors; reliance on third-parties to manufacture, market and distribute many of the Company's products; risks of maintaining protection for the Company's intellectual property; risks of an adverse determination in any future intellectual property litigation; and risks associated with stringent government regulation of the biopharmaceutical and specialty pharmaceutical industries and other factors set forth more fully in certain reports filed with the Securities and Exchange Commission, to which investors are referred for further information. The Company may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on the Company's forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that the Company makes. The Company's forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that the Company may make. The Company does not have a policy of updating or revising forward-looking statements and assumes no obligation to update any forward-looking statements.



Further Details Please Visit: www.tajpharma.com

The contents and design of this website, including Authority logos, are the property of the Taj Pharmaceuticals Limited India, and are protected under copyright law and international treaty.

All rights reserved. Except under the conditions described in the Copyright Act 1968 and subsequent amendments, no part of this website may be reproduced or communicated by any process without prior permission in writing from



Copyright © 2004-2011 Taj Pharmaceuticals Limited. All rights reserved. Legal Notice The products discussed herein may have different product labeling in different countries. The product information provided in this site is intended only for the residents of India.