1. DESIGNATION OF A PRODUCT

Brand Name	:	XENOBREX
Generic Name	:	Celecoxib Capsules 200 mg
Dosage form	:	Hard Gelatin Capsules
Strength	:	Each hard gelatin Capsule contains: Celecoxib .....200 mg Excipients……...q.s.

2. NAME OF THE MANUFACTURER:

Manufacturing unit : **CELOGEN GENERICS PVT. LTD.**
Plot No. 646/1&2, Agrawal Industrial Estate,
Somnath Temple Road, Dabhel,
Daman - 396 210, U.T.

Manufactured under license with : **CELOGEN PHARMA PVT. LTD.**
B-106, Techno City, X4/1, TTC. Ind. Area,
M.I.D.C., Mahape, Navi Mumbai.400710.
Phone : 0091-22-41588700
Fax : 0091-22-41588750
E-mail: info@celogenpharma.com
URL: www.celogenpharma.com

3. NAME OF THE AGENT: **BOCHE PHARM NIG LTD**
41B, Iwaya Road, Yaba-Lagos, Nigeria.

4. POWER OF ATTORNEY: Enclosed

5. FORMULA TO BE DECLARED ON PACK
Each hard gelatin Capsule contains:
Celecoxib .....200 mg
Excipients……...q.s.

6. INDICATIONS AND DOSAGE

Indications

Symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.

Dosage

For oral administrations.

Celecoxib Capsules may be taken with or without food.

As the cardiovascular risks of Celecoxib may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis.

Osteoarthritis: The usual recommended daily dose is 200 mg taken once daily or in two divided doses. In some patients, with insufficient relief from symptoms, an increased dose of 200 mg twice daily may increase efficacy. In the absence of an increase in therapeutic benefit after two weeks, other therapeutic options should be considered.

Rheumatoid arthritis: The initial recommended daily dose is 200 mg taken in two divided doses. The dose may, if needed, later be increased to 200 mg twice daily. In the absence of an increase in therapeutic benefit after two weeks, other therapeutic options should be considered.

Ankylosing spondylitis: The recommended daily dose is 200 mg taken once daily or in two divided doses. In a few patients, with insufficient relief from symptoms, an increased dose of 400mg once daily or in two divided doses may increase efficacy. In the absence of an increase in therapeutic benefit after two weeks, other therapeutic options should be considered.

The maximum recommended daily dose is 400 mg for all indications.

Elderly: (>65 years) As in younger adults, 200 mg per day should be used initially. The dose may, if needed, later be increased to 200 mg twice daily. Particular caution should be exercised in elderly with a body weight less than 50 kg.

Hepatic impairment: Treatment should be initiated at half the recommended dose in patients with established moderate liver impairment with a serum albumin of 25-35 g/l. Experience in such patients is limited to cirrhotic patients.

Renal impairment: Experience with Celecoxib in patients with mild or moderate renal impairment is limited, therefore such patients should be treated with caution.

Children**:** Celecoxib is not indicated for use in children.

CYP2C9 Poor Metabolizers: Patients who are known, or suspected to be CYP2C9 poor metabolizers based on genotyping or previous history/experience with other CYP2C9 substrates should be administered Celecoxib with caution as the risk of dose-dependent adverse effects is increased. Consider reducing the dose to half the lowest recommended dose.

7. PACK, TYPE AND QUANTITY

1 x10’s capsules in Alu – Alu blister packs in a carton.

10 x10’s capsules in Alu – Alu blister packs in a carton.

8. PHARMACOLOGICAL CLASS

Cyclo-oxygenase (COX-2) inhibitor; analgesic; anti-inflammatory.

9. REGISTRATION IN OTHER COUNTRIES

10. TRADE MARKS

Applied for to patient & Trademark Section,
Federal Ministry of Trade, Application No. : Applied for

Registered by Patent & Trade Mark Section,
Federal Ministry of Trade, Registration No. : Applied for

Signature :

Name :

Status of Officer :

Date :

For Office Use Only