1. Name of medicinal product

MOGABALIN 150 (PREGABALIN CAPSULE 150 MG)

1.1 (Trade) name of product:

1.2 Strength

Each hard gelatin capsule contains
Pregabalin IP 150 mg
Excipients q.s.

1.3 Pharmaceutical Dosage Form

Capsule for oral administration

2. QUALITATIVE & QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

Each hard gelatin capsule contains

Pregabalin IP 150 mg

Excipients q.s.

2.2 Quantitative Declaration

Batch Size: 100,000 capsules

INGREDIENTS	SPEC.	QTY./CAPSULE (IN MG)	OVERAGES	STD. QTY. (IN KG)
Pregabalin	IP	150.00	-	30.000

Starch	BP	124.50	-	12.45
Talc	BP	25.00	-	2.500
Magnesium Stearate	BP	20.00	-	2.000
Colloidal Anhydrous Silica	BP	2.50	-	0.250
EHG Capsules Size-1 RED / WHITE CAPSULE	IH	1.00 Nos	-	102000

3 PHARMACEUTICAL DOSAGE FORM

Capsule for oral administration

Red Cap and white Body Hard gelatin capsule containing white powder.

4. Clinical Particulars

4.1 Indication

Neuropathic pain

It is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

It is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised anxiety disorder

It is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

4.2 Posology and Administration

Posology

The dose range is 150 to 600 mg per day given in either two or three divided doses.

Neuropathic pain

Pregabalin treatment can be started at a dose of 150 mg per day given as two or three divided doses. Based on individual patient response and tolerability, the dose may be increased to 150 mg per day after an interval of 3 to 7 days, and if needed, to a maximum dose of 600 mg per day after an additional 7-day interval.

Epilepsy

Pregabalin treatment can be started with a dose of 150 mg per day given as two or three divided doses. Based on individual patient response and tolerability, the dose may be increased to 150 mg per day after 1 week. The maximum dose of 600 mg per day may be achieved after an additional week.

Generalised Anxiety Disorder

The dose range is 150 to 600 mg per day given as two or three divided doses. treatment should be reassessed regularly.

Pregabalin treatment can be started with a dose of 150 mg per day. Based on individual patient response and tolerability, the dose may be increased to 300 mg per day after 1 week. Following an additional week the dose may be increased to 450 mg per day. The maximum dose of 600 mg per day may be achieved after an additional week.

Discontinuation of pregabalin

In accordance with current clinical practice, if pregabalin has to recommended this should be done gradually over a minimum of 1 week independent of the indication.

Renal impairment

Pregabalin is eliminated from systematic circulation primarily by renal excretion as unchanged drug. As pregabalin clearance is directly proportional to creatinine clearance. dose reduction in patients with compromised renal function must be individualised according to creatinine clearance (CLcr). as indicated in Table 1 determined using the following

formula:

$$CL_{cr}\,(ml/min) = \left(\frac{1.23 \times [140 - age\ (years)] \times weight\ (kg)}{Serum\ creatinine\ (\mu mol/l)} \right) (\times 0.85 \text{ for female patients})$$

Pregabalin is removed effectively from plasma by haemodialysis (50% of drug in 4 hours). For patients receiving haemodialysis, the pregabalin daily dose should be adjusted based on renal function. In addition to the daily dose, a supplementary dose immediately following every 4 hour haemodialysis treatment (see Table 1).

Table 1. Pregabalin dose adjustment based on renal function

Creatinine Clearance (CLcr) (mL/min)	Total pregabalin daily dose *		Dose regimen
	Starting dose (mg/day)	Maximum dose (mg/day)	
≥ 60	150	600	BID or TID
≥30 - <60	75	300	BID or TID
≥15 - <30	25 – 50	150	Once Daily or BID
< 15	25	75	Once Daily
Supplementary dosage following haemodialysis (mg)			
			Single dose[1]

TID = Three divided doses

BID = Two divided doses

Hepatic impairment

No dose adjustment is required for patients with hepatic impairment (see section 5.2).

Paediatric population

The safety and efficacy of pregabalin in children below the age of 12 years and in adolescents (12-17 years of age) have not been established. Currently available data are described in sections 4.8, 5.1 and 5.2 but no recommendation on a posology can be made.

Elderly

Elderly patients may require a dose reduction of pregabalin due to a decreased renal function (see section 5.2).

Method of administration

Pregabalin may be taken with or without food.

Pregabalin is for oral use only.

4.3 Contraindication

Hypersensitivity to the active substance or to any of the excipients

4.4 Special Warning & precautions for use

Diabetic patients

In accordance with current clinical practice, some diabetic patients who gain weight on pregabalin treatment may need to adjust hypoglycaemic medicinal products.

Hypersensitivity reactions

There have been reports in the postmarketing experience of hypersensitivity reactions, including cases of angioedema. Pregabalin should be discontinued immediately if symptoms of angioedema, such as facial, perioral, or upper airway swelling occur.

Dizziness, somnolence, loss of consciousness, confusion and mental impairment

Pregabalin treatment has been associated with dizziness and somnolence, which could increase the occurrence of accidental injury (fall) in the elderly population. confusion and mental impairment. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Since pregabalin is predominantly excreted unchanged in the urine, undergoes negligible metabolism in humans (< 2% of a dose recovered in urine as metabolites), does not inhibit drug metabolism in vitro, and is not bound to plasma proteins, it is unlikely to produce, or be subject to, pharmacokinetic interactions.

4.6 Fertility, Pregnancy and lactation

It should not be used during pregnancy unless clearly necessary.

4.7 Effects on ability to drive and use machines

It may have minor or moderate influence on the ability to drive and use machines. It may cause dizziness and somnolence and therefore may influence the ability to drive or use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities.

4.8 Undesirable effects

The most commonly reported adverse reactions during treatment are somnolence, dizziness, headache, palpitations, flushing, abdominal pain, nausea, ankle swelling, oedema and fatigue.

4.9 Overdose

The most commonly reported adverse reactions observed when pregabalin was taken in overdose included somnolence, confusional state, agitation, and restlessness. Seizures were also reported. In rare occasions, cases of coma have been reported.

Treatment of pregabalin overdose should include general supportive measures and may include haemodialysis if necessary.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-epileptics, other anti-epileptics ATC code: N03AX16

The active substance, pregabalin, is a gamma-aminobutyric acid analogue [(S)-3-(aminomethyl)-5-methylhexanoic acid].

Mechanism of action

Pregabalin binds to an auxiliary subunit (α2-δ protein) of voltage-gated calcium channels in the central nervous system.

5.2 Pharmacokinetic properties

Pregabalin steady-state pharmacokinetics are similar in healthy volunteers, patients with epilepsy receiving anti-epileptic drugs and patients with chronic pain.

Absorption

Pregabalin is rapidly absorbed when administered in the fasted state, with peak plasma concentrations occurring within 1 hour following both single and multiple dose administration. Pregabalin oral bioavailability is estimated to be ≥ 90% and is independent of dose. Following repeated administration, steady state is achieved within 24 to 48 hours. The rate of pregabalin absorption is decreased when given with food resulting in a decrease in Cmax by approximately 25-30% and a delay in tmax to approximately 2.5 hours. However, administration of pregabalin with food has no clinically significant effect on the extent of pregabalin absorption.

Distribution
In humans, the apparent volume of distribution of pregabalin following oral administration is approximately 0.56 l/kg. Pregabalin is not bound to plasma proteins.

Biotransformation
Pregabalin undergoes negligible metabolism in humans. Following a dose of radiolabelled pregabalin, approximately 98% of the radioactivity recovered in the urine was unchanged pregabalin. The N- methylated derivative of pregabalin, the major metabolite of pregabalin found in urine, accounted for 0.9% of the dose. In preclinical studies, there was no indication of racemisation of pregabalin S- enantiomer to the R-enantiomer.

Elimination
Pregabalin is eliminated from the systemic circulation primarily by renal excretion as unchanged drug. Pregabalin mean elimination half-life is 6.3 hours. Pregabalin plasma clearance and renal clearance are directly proportional to creatinine clearance

6. Pharmaceutical particulars

6.1 List of excipients

Starch

Talc

Magnesium Stearate

Colloidal Anhydrous Silica

EHG Capsules Size-1 RED/WHITE

6.2 Incompatibilities

Not Applicable

6.3 Shelf-Life

36 months from the date of manufacture.

6.3 Special Precautions for Storage

No special storage precautions

6.4 Nature and Contents of Container

10 X 15 capsules in Alu-PVC Blister pack in carton along with insert.

7.0 Marketing authorisation holder:

MOREHOPE PHARMA LIMITED.
No. 1, Omolabake Adeoti street, Ajao Estate,Ajao, Lagos,Nigeria.

Manufacturer:
FLOURISH PHARMA
24E, GOA-IDC, Daman Ind. Estate,
Somnath, Dabhel, Daman, (U.T.) – 396 215

8.0 Marketing authorisation number(s)

9.0 Date of first authorisation/renewal of the authorisation

10. Date of revision of the text