Summary of product characteristics

1. Name of medicinal product

PREGATAS 75 (Pregabalin Capsules 75 mg)

2. Qualitative and quantitative compositions :

Each hard gelatin capsule contains:
Pregabalin USP . 75 mg
Approved colours used in
capsule shell See List of
Excipients in section 6.1.

3. Pharmaceutical form:

Capsules

4. Clinical particulars:

4.1. Therapeutics indications:

Pregabalin is indicated for the management of pain in painful diabetic peripheral neuropathy and post therapeutic neuralgia. It is also indicated as adjunctive therapy for adult epilepsy patients with partial onset seizures.

4.2. Posology and method of administration:

Pregabalin is given orally with or without food.

Adult patients

The recommended pregabalin dosage range for the treatment of neuropathic pain, which includes that associated with DPN and PHN, is 150-600 mg/day administered in two or three divided doses in patients with a creatinine clearance rate of at least 60 mL/min. An initial dosage of 150 mg/day may be increased to 300 mg/ after 3 - 7 days, based on individual patient response and tolerability; if necessary, the dosage can be increased to 600 mg/day (in 2 – 3 divided doses) after an additional 7 days. Pregabalin dosage adjustment should be considered in cases of renal impairment.

As an adjunct for the therapy of partial-onset seizures pregabalin should be started in a daily dose of 150 mg given in 2 or 3 equally divided portions in patients with a creatinine clearance rate of at least 60 mL/min. Based on individual patient response and tolerability, the dose may be increased to a maximum of 600 mg/day. Pregabalin dosage adjustment should be considered in cases of renal impairment.

When discontinuing pregabalin, taper gradually over a minimum of 1 week.

In case of renal impairment in adults, pregabalin dosage adjustment should be considered as per the table below:

Table: Pregabalin Dosage Adjustment Based on Renal Function

Creatinine Clearance (mL/min)	**Total Pregabalin Daily Dose (mg/day)**			**Dose Regimen**
≥ 60	150	300	600	BID or TID
30 – 60	75	150	300	BID or TID
15 – 30	25 – 50	75	150	OD or BID
< 15	25	25 – 50	75	OD
Supplementary dose following hemodialysis[b]				
Patients on the 25 mg OD regimen: Take one supplemental dose of 25 mg or 50 mg				
Patients on the 25 – 50 mg OD regimen: Take one supplemental dose of 50 mg or 75 mg				
Patients on the 75 mg OD regimen: Take one supplemental dose of 100 mg or 150 mg				

TID = three times daily; BID = two times daily; OD = once daily
[a] - Total daily dose should be divided as indicated by the dose regimen
[b] - Supplementary dose is a single additional dose

Elderly patients (>65 years of age):
Pregabalin oral clearance tends to decrease with increasing age. Reduction of pregabalin dose may be required in patients who have age-related compromised renal function. Dose adjustment should be done according to the above table in case of significant renal impairment.

Pediatric patients (<18 years of age):
Pregabalin is not recommended for use in this age group of patients because its safety and efficacy have not yet been evaluated in them.

4.3. Contra-indications:

Pregabalin is contraindicated in patients with known hypersensitivity to this drug or any of its components.

4.4. Special warning and

precautions for use: WARNINGS
Do not take this product if you are allergic to any ingredient in this product. If you
have any medical commodities, pregnancy, or breast-feeding than immediately inform your doctor and further queries regarding the medicine than contact your doctor.

PRECAUTIONS

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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

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

There are insufficient data for the withdrawal of concomitant antiepileptic medicinal products, once seizure control with pregabalin in the add-on situation has been reached, in order to reach monotherapy on pregabalin

In controlled studies, a higher proportion of patients treated with pregabalin reported blurred vision. Although the clinical significance of the ophthalmologic findings is unknown, patients should be informed that if changes in vision occur, they should notify their physician.

Peripheral Edema: As the thiazolidinedione class of antidiabetic drugs can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure, care should be taken when co-administering pregabalin and these agents.

Creatine Kinase Elevations: Prescribers should instruct patients to promptly report unexplained muscle pain, tenderness, or weakness, particularly if these muscle symptoms are accompanied by malaise or fever. Pregabalin treatment should be discontinued if myopathy is diagnosed or suspected or if markedly elevated creatine kinase levels occur.

4.5. Interaction with other drugs, other forms of interactions:

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.

Accordingly, in *in vivo* studies no clinically relevant pharmacokinetic interactions were observed between pregabalin and phenytoin,

carbamazepine, valproic acid, lamotrigine, gabapentin, lorazepam, oxycodone or ethanol. Population pharmacokinetic analysis indicated that oral antidiabetics, diuretics, insulin, phenobarbital, tiagabine and topiramate had no clinically significant effect on pregabalin clearance.

Co-administration of pregabalin with the oral contraceptives norethisterone and/or ethinyl estradiol does not influence the steady-state pharmacokinetics of either substance.

Multiple oral doses of pregabalin co-administered with oxycodone, lorazepam, or ethanol did not result in clinically important effects on respiration.
Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone. Pregabalin may potentiate the effects of ethanol and lorazepam.

No specific pharmacodynamic interaction studies were conducted in elderly volunteers.

4.6. Use in pregnancy and lactation:

Pregnancy: There are no adequate and well-controlled studies in pregnant women. Pregabalin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if pregabalin is excreted in human milk; it is, however, present in the milk of rats. Because many drugs are excreted in human milk, and because of the potential for tumorigenicity shown for pregabalin in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

4.7. Effects on ability to drive and operate machine:
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4.8 Undesirable effects:
Pregabalin is usually well tolerated. Adverse effects are nonserious in nature and

generally mild to moderate in intensity. The common adverse reactions are: dizziness, somnolence, dry mouth, asthenia, amblyopia, peripheral edema, abnormal thoughts, weight-gain, difficulty with concentration/attention, blurred vision, and constipation.

4.9. Overdoses:

In overdoses up to 15 g, no unexpected adverse reactions were reported. Treatment of pregabalin overdose should include general supportive measures and may include haemodialysis if necessary.

5. Pharmacological properties:

5.1. Pharmaco-dynamic properties:

Pregabalin has a similar pharmacological profile to that of gabapentin. It demonstrated antiallodynic and antihyperalgesic activities in various rodent models of neuropathic pain, including: vincristine-, streptozocin-, and nerve injury-induced mechanical allodynia; formalin-, carrageenan-, substance P-, NMDA and thermal injury-induced hyperalgesia; and surgically-induced mechanical allodynia. The exact mechanism of action of pregabalin is unclear. It is a structural analogue of GABA, like gabapentin, although neither compound interacts with GABA-A or -B receptors, or influences GABA uptake.

Pregabalin (and gabapentin) may, however, modulate the presynaptic release of excitatory neurotransmitters, such as glutamate and noradrenaline (norepinephrine), by selectively binding with high affinity to α_2-δ protein, an auxiliary subunit of voltage- gated calcium channels. Both pregabalin and gabapentin modulated the release of the sensory neuropeptides substance P and calcitonin gene-related peptide from rat spinal tissues, but only under conditions that correspond to significant inflammation-induced sensitization of the spinal cord.

5.2. Pharmaco-kinetic properties:

Pregabalin steady-state pharmacokinetics is 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 C_{max} by approximately 25-30% and a delay in t_{max} to approximately 2.5 hours. However, administration of pregabalin with food has no clinically significant effect on the extent of pregabalin absorption.

Distribution: In preclinical studies, pregabalin has been shown to

cross the blood brain barrier in mice, rats, and monkeys. Pregabalin has been shown to cross the placenta in rats and is present in the milk of lactating rats. 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. 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. Dosage adjustment in patients with reduced renal function or undergoing haemodialysis is necessary.

Pharmacokinetics in special patient groups
Gender: Clinical trials indicate that gender does not have a clinically significant influence on the plasma concentrations of pregabalin.

Renal impairment: Pregabalin clearance is directly proportional to creatinine clearance. In addition, pregabalin is effectively removed from plasma by haemodialysis (following a 4 hour haemodialysis treatment plasma pregabalin concentrations are reduced by approximately 50%). Because renal elimination is the major elimination pathway, dosage reduction in patients with renal impairment and dosage supplementation following haemodialysis is necessary.

Hepatic impairment: No specific pharmacokinetic studies were carried out in patients with impaired liver function. Since pregabalin does not undergo significant metabolism and is excreted predominantly as unchanged drug in the urine, impaired liver function would not be expected to significantly alter pregabalin plasma concentrations.

Elderly (over 65 years of age): Pregabalin clearance tends to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with decreases in creatinine clearance associated with increasing age. Reduction of pregabalin dose may be required in patients who have age related compromised renal function.
Pregnancy and lactation: There are no adequate data on the use of pregabalin in pregnant women.

Studies in animals have shown reproductive toxicity. The potential risk to humans is unknown. Therefore, pregabalin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the foetus.

It is not known if pregabalin is excreted in the breast milk of humans; however, it is present in the milk of rats. Therefore, breast-feeding is not recommended during treatment with pregabalin.

5.3. Pre-clinical safety data:

There are no preclinical data of relevance to the prescriber which are additional to that already included in the SPC.

6. Pharmaceutical particulars:

6.1. List of excipients:

Lactose
Starch
Purified
water Talc
EHG Capsule Size '4' Red/White

6.2. Incompatibilities:

Not applicable

6.3. Shelf-life:

24 Months from the date of Manufacturing

6.4. Special precaution for storage:

Store below 30°C.

6.5. Nature and contents of container:

Pregabalin Capsules 75 mg is available in blister of 10 capsules.

7. Marketing authorization holder:

Intas Pharmaceutical Limited
Corporate House,Near Sola
Bridge, S.G.Highway,Thaltej,
Ahmedabad.
Gujarat, INDIA

8. Marketing authorisation number(s)

H2017/CTD3843/176

9. Date of first authorisation/Renewal of the authorization

11 November 2025

10. Date and revision of text:

11 November 2025