SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Syngab 50mg Capsules

Syngab 100mg Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

- **Syngab 50mg Capsules**: Each capsule contains 50 mg of Pregabalin.
- **Syngab 100mg Capsules**: Each capsule contains 100 mg of Pregabalin.

Excipients with known effect:

- Contains Lactose monohydrate. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard Gelatin Capsule.

- **Syngab 50mg**: Size '3' capsules with light purple body and cap, filled with white to off-white granular powder.
- **Syngab 100mg**: Size '2' capsules with yellow body and cap, filled with white to off-white granular powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- **Neuropathic pain**: Treatment of peripheral and central neuropathic pain in adults.
- **Epilepsy**: Adjunctive therapy in adults with partial seizures with or without secondary generalisation.
- **Generalised Anxiety Disorder (GAD)**: Treatment of GAD in adults.

4.2 Posology and method of administration

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

- **Neuropathic pain**: Starting dose of 150 mg per day. May be increased to 300 mg per day after 3 to 7 days, and to a maximum of 600 mg per day after an additional 7 days.

- **Epilepsy**: Starting dose of 150 mg per day. May be increased to 300 mg per day after 1 week and to a maximum of 600 mg per day after an additional week.
- **Generalised Anxiety Disorder**: Starting dose of 150 mg per day. Dose may be increased in 150 mg increments every week to a maximum of 600 mg per day.

Special Populations

- **Renal Impairment**: Dose must be individualized according to creatinine clearance as per the table below:

Creatinine Clearance (CLcr) (mL/min)	**Starting Dose (mg/day)**	**Maximum Dose (mg/day)**	**Regimen**
≥ 60	150	600	Twice or thrice daily
$30 - < 60$	75	300	Twice or thrice daily
$15 - < 30$	25–50	150	Once or twice daily
< 15	25	75	Once daily

- **Hepatic Impairment**: No dose adjustment required.
- **Elderly**: May require dose reduction due to decreased renal function.

Paediatric Population The safety and efficacy of Pregabalin in children below 12 years and adolescents (12–17 years) have not been established. No recommendation on a posology can be made.

Method of administration For oral use. May be taken with or without food.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients (e.g., lactose).

4.4 Special warnings and precautions for use

- **Severe Cutaneous Adverse Reactions (SCARs)**: Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. Discontinue immediately if symptoms appear.
- **Dizziness and Somnolence**: May cause accidental injury (falls) in the elderly.
- **Suicidal ideation and behavior**: Patients should be monitored for signs of suicidal ideation.
- **Abuse and Dependence**: Caution in patients with a history of substance abuse; monitor for drug-seeking behavior.
- **Respiratory Depression**: Risk is higher in patients with compromised respiratory function or those using CNS depressants.

4.5 Interaction with other medicinal products and other forms of interaction

- **CNS Depressants**: May potentiate effects of ethanol and lorazepam.
- **Opioids**: Increased risk of respiratory failure, coma, and death.
- **Pharmacokinetics**: Unlikely to produce pharmacokinetic interactions as it is excreted predominantly unchanged in urine.

4.6 Fertility, pregnancy and lactation

- **Pregnancy**: Use in the first trimester may cause major birth defects. Effective contraception must be used by women of childbearing potential.
- **Breast-feeding**: Pregabalin is excreted into human milk. A decision must be made to discontinue nursing or the drug.
- **Fertility**: No effects on sperm motility at 600 mg/day.

4.7 Effects on ability to drive and use machines

Minor or moderate influence. May cause dizziness and somnolence.

4.8 Undesirable effects

- **Very Common**: Dizziness, somnolence, headache.
- **Common**: Nasopharyngitis, increased appetite, weight increased, blurred vision, constipation, erectile dysfunction.
- **Withdrawal Symptoms**: Insomnia, headache, nausea, and anxiety upon discontinuation.

Reporting of suspected adverse reaction:

Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

Symptoms include somnolence, confusion, agitation, and seizures. Treatment involves general supportive measures and potentially hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiepileptics, ATC code: N02BF02. **Mechanism of action**: Binds to the α_2 - δ subunit of voltage-gated calcium channels in the CNS.

5.2 Pharmacokinetic properties

- **Absorption**: Rapidly absorbed; peak plasma concentration within 1 hour (fasted). Bioavailability ≥90\%.
- **Distribution**: V_d is approximately 0.56 l/kg; not bound to plasma proteins.
- **Biotransformation**: Negligible metabolism <2\%.
- **Elimination**: Renal excretion as unchanged drug; half-life is 6.3 hours.

5.3 Preclinical safety data

Non-genotoxic. Increased incidence of hemangiosarcoma observed in mice at high exposures, but not in rats or humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- **Syngab 50mg Capsule:** Lactose monohydrate, Maize starch, Purified Talc, Empty Hard gelatin Capsule shell
- **Syngab 100mg Capsule:** Lactose monohydrate, Microcrystalline cellulose, Maize starch, Purified Talc, Empty Hard gelatin Capsule shell

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store or transport above 30°C. Protect from light, heat, and moisture.

6.5 Nature and contents of container

2 x 7's Tablets (Capsules) packed in Alu-Alu blister, packed in a printed carton.

6.6 Special precautions for disposal

Any unused medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

ATCO Laboratories Limited

B-18, S.I.T.E., Karachi - 75700, Pakistan.

8. MARKETING AUTHORIZATION NUMBER(S)

22230/R1

9. DATE OF FIRST AUTHORIZATION/RENEWAL

2026 September 02

10. DATE OF REVISION OF THE TEXT

2026 September 02