SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

1.1 Product Name

Carzepin Tablet 200mg

1.2 Strength

Carbamazepine 200 mg

1.3 Pharmaceutical Dosage Form

Tablet

2-Quality and Quantitative Composition:

ACTIVE INGREDIENTS	PER TABLET (MG)
Carbamazepine	200 mg

For excipients, see 6.1

3-Pharmaceutical Form:

Round, white uncoated tablet, bevel-edged, flat-faces, "HOVID" embossed on one face and scored on the other.

4-Clinical Particulars

4.1 Therapeutic indications

For treatment of:

- Partial seizures with complex symptomatology (psychomotor, temporal lobe).
- Generalized tonic-clonic seizures (grand mal).
- Mixed seizure patterns.
- Pain due to trigeminal neuralgia and glossopharyngeal neuralgia.

4.2 Posology and method of administration

For Oral use

Adults

Anticonvulsant

Initial : Oral, 200 mg two times a day on the first day, the dosage then being increased as needed.

Maintenance : Oral, 800 mg to 1.2 gram a day, in 3 or 4 divided doses.

Analgesic

Initial : Oral, 100 mg two times a day on the first day, the dosage then being increased as needed.

Maintenance : Oral, 200 mg to 1.2 grams a day, in 3 or 4 divided doses.

Children

Anticonvulsant

Below 6 years

Initial	:	Oral, 5 mg per kg body weight per day, the dosage being increased as needed.
Maintenance	:	Oral, 10 to 20 mg per kg body weight per day, in 3 or 4 divided doses.

6 to 12 years

Initial	:	Oral, 100 mg two times a day on the first day, the dosage being increased as needed.
Maintenance	:	Oral, 400-800 mg a day in 3 or 4 divided doses, not exceeding 1 gram daily.

The information given here is limited. For further information consult your doctor or pharmacist.

4.3 Contraindications

- Not recommended in patients with atrioventricular (AV) heart block, blood disorders, and history of bone marrow depression.
- Use in nursing mothers should generally be avoided

4.4 Special warning and precautions for use

- Caution in geriatic patients and in patients with coronary artery disease, diabetes mellitus, glaucoma, history of hematologic adverse reactions to other medications, urinary retention, cardiac, hepatic or renal disease.
- Abrupt discontinuation in a responsive epileptic patient may precipitate convulsions or status epilepticus; gradual withdrawal is recommended.
- Plasma carbamazepine concentration determinations is recommended periodically as a guide to efficacy and safety.
- Carbamazepine should be given with caution to patients who are hypersensitive to tricyclic antidepressants.
- This medication may cause drowsiness. Caution when driving or operating machinery. Avoid alcoholic beverages.
- Safety for use in pregnancy has not been established.
- Caution: Serious and sometimes fatal skin reactions, including toxic epidermal necrolysis (Lyell's Syndrome) and Stevens-Johnson Syndrome, have been known to occur during treatment with carbamazepine. They are significantly more common in patients with a particular human leucocyte antigen (HLA) allele, HLA-B*1502, which occurs almost exclusively in patients with ancestry across broad areas of Asia. Patients should be screened for HLA-B*1502 allele prior to initiating treatment with carbamazepine. If a patient tests positive, carbamazepine should not be started unless the expected benefit clearly outweighs the increased risk of serious skin reactions. Patients who have been taking carbamazepine for more than a few months without developing skin reactions are at low risk of these events ever developing from carbamazepine.

Patients treated with carbamazepine should closely be monitored for sign of hypersensitivity reactions, particularly during the first month of therapy. Immediate discontinuation of therapy should be made when cutaneous reactions occur.

- Potential for an increase in risk of suicidal thoughts or behaviours.

4.5 Interaction with other medicinal products and other forms of interactions

- Monoamine oxidase (MAO) inhibitors should be discontinued at least 14 days before carbamazepine therapy is initiated.
- Dosage adjustments may be necessary when used concurrently with anticoagulants, coumarin or indandione derivative, doxycycline, or tricyclic antidepressants.
- Effects of oral contraceptives, barbiturates, benzodiazepines, hydantoins, primidone, succinimides or valproic acid may be decreased during concurrent therapy with carbamazepine.
- Co-administration of erythromycin, propoxyphene or troleandomycin may increase carbamazepine plasma levels and toxicity.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy has not been established

4.7 Effects on ability to drive and use machine

This medication may cause drowsiness. Caution when driving or operating machinery. Avoid alcoholic beverages.

4.8 Undesirable effects

Dizziness, drowsiness, ataxia, nausea or vomiting.

4.9 Overdose

Clinical features: Dizziness, ataxia, nystagmus, abdominal discomfort, urinary retention, hyperreflexia.

Treat overdosage by emesis or gastric lavage, if appropriate; with the necessary supportive measures, if required.

5-Pharmacological Properties :

5.1 Pharmacodynamic properties

Exact mechanism of action of carbamazepine as an anticonvulsant is unknown but it is believed to stabilise rather than elevate the seizure threshold and to limit the spread of seizure activity.

5.2 Pharmacokinetic properties

Oral absorption is slow but fairly complete and plasma protein binding is extensive. It undergoes hepatic metabolism and renal excretion.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies on safety, pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and reproductive toxicity.

6-Pharmaceutical Particulars:

6.1 List of excipients

Lactose monohydrate
Cornstarch
Polyvinylpyrrolidone K-25
Sodium starch glycolate
Magnesium stearate
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Store below 30°C. Protect from moisture.

6.5 Nature and contents of container

Descriptions of each packaging material for Carzepin Tablet is as below:

Immediate Container/Packaging:
Polyvinylidene chloride (PVDC) coated Polyvinyl chloride (PVC) Film
Appearance: Clear transparent film

Aluminium blister foil
Appearance: Bright surface/Matt surface each side

Secondary packing components:
Outer Container/Packaging
Type: Unit Box
Material: Paper carton

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable

7- Applicant/ Holder of Certificate of Product Registration:

Marketing Authorization Holder:

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,

(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

8-Drug Product Manufacturer:

Manufacturer : Hovid Bhd.
Lot 56442, 7 ½ Miles Jalan Ipoh / Chemor,
31200 Chemor, Perak, Malaysia

9-NAFDAC Registration Number(s)

04-0685