Summary of Product Characteristics

1. Name of the medicinal Product

Mejerol Tablets

2. Qualitative and Quantitative Composition

2.1 Qualitative declaration

Carbamazepine 200 mg BP

2. Quantitative declaration

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Oral tablet

White to off-white coloured, round shaped, flat, uncoated tablets, breakline on one side and plain on other side.

The breakline is only facilitate breaking for ease of swallowing and not to divide into equal dose.

4. Clinical Particulars

4.1 Therapeutic Indications

Carbamazepine Tablets BP is indicated in the treatment of partial seizures with complex symptomatology (psychomotor, temporal lobe), generalized tonic-clonic seizures (grand mal), mixed seizure patterns as well as trigeminal neuralgia.

4.2 Posology and Method of Administration

Epilepsy:

Adults and Children over 12 Years of Age: Initial: 400 mg/day in 2 divided doses; increase at weekly intervals by adding up to 200 mg per day using a twice a day regimen or three times a day or four times a day regimen until the optimal response is obtained. Dosage generally should not exceed 1000 mg daily in children 12 to 15 years of age, and 1200 mg daily in patients above 15 years of age. Doses up to 1600 mg daily have been used in adults in rare instances. Maintenance: Adjust dosage to the minimum effective level, usually 800-1200mg daily.

Children 6 -12 Years of Age: Initial: 100 mg twice a day, Increase at weekly intervals by adding up to 100 mg per day using a three times a day or four times a day regimen until the optimal response is obtained. Dosage generally should not exceed 1000 mg daily.

Maintenance: Adjust dosage to the minimum effective level, usually 400-800 mg daily.

Trigeminal neuralgia:

Adults: Initial: On the first day, 100 mg twice a day. This daily dose may be increased by up to 200 mg a day using increments of 100 mg every 12 hours, only as needed to achieve freedom from pain. Do not exceed 1200 mg/daily.

Maintenance: Control of pain can be maintained in most patients with 400 mg to 800 mg daily. At least once every 3 months throughout the treatment period, attempts should be made to reduce the dose to the minimum effective level or even to discontinue the drug.

3. Contraindications

Carbamazepine Tablets BP is contraindicated in the patients with a history of previous bone marrow depression, history of hypersensitivity to Carbamazepine or to any of the excipients of this product.

4. Special Warnings and Special Precautions for Use

Patients with a history of adverse hematological reaction to any drug may be particularly at risk.

Before administration of Carbamazepine, MAO inhibitors should be discontinued for a minimum of 14 days, or longer if the clinical situation permits.

Carbamazepine has shown mild anticholinergic activity, therefore, patients with increased intraocular pressure should be closely observed during therapy.

Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS), have been reported with Carbamazepine treatment.

Because of the relationship of the drug to other tricyclic compounds, the possibility of activation of a latent psychosis and, in elderly patients, of confusion or agitation should be borne in mind.

The use of Carbamazepine should be avoided in patients with a history of hepatic porphyria (e.g., acute intermittent porphyria, variegate porphyria, porphyria cutanea tarda).

Acute attacks have been reported in such patients receiving Carbamazepine therapy.

Pregnancy: Carbamazepine Tablets BP is not recommended during pregnancy.

Lactation: Carbamazepine Tablets BP is not recommended in breast-feeding women.

5. Interaction with other medicinal products and other forms of interaction

Carbamazepine may increase the metabolism of Paracetamol.

Carbamazepine may enhance the adverse/toxic effect of Adenosine.

CYP 3A4 inhibitors (cimetidine, danazol, diltiazem, macrolides, erythromycin, troleandomycin, clarithromycin, etc.) inhibit Carbamazepine metabolism and can thus increase plasma Carbamazepine levels.

CYP 3A4 inducers (cisplatin, doxorubicin HCl, fosphenytoin, rifampin, phenobarbital, phenytoin, primidone, methsuximide, aminophylline) can increase the rate of Carbamazepine metabolism.

Antifungal Agents (Azole Derivatives, Systemic): May decrease the metabolism of Carbamazepine.

Concomitant administration of Carbamazepine and lithium may increase the risk of neurotoxic side effects.

6. Fertility, Pregnancy and Lactation

Pregnancy: Carbamazepine Tablets BP is not recommended during pregnancy.

Lactation: Carbamazepine Tablets BP is not recommended in breast-feeding women.

7. Effects on ability To Drive and use Machines

The patient's ability to react may be impaired by dizziness and drowsiness caused by carbamazepine, especially at the start of treatment or in connection with the dose adjustments; patient should therefore exercise due caution when driving a vehicle or operating a machine.

8. Undesirable Effects

Cardiovascular: Arrhythmias, bradycardia, chest pain, edema, hypertension, hypotension.

Central nervous system: anxiety, ataxia, confusion, depression, dizziness, fatigue, headache, sedation, slurred speech.

Dermatologic: Alopecia, alterations in skin pigmentation, photosensitivity reaction, pruritus, rash, Stevens-Johnson syndrome.

Endocrine & metabolic: Chills, fever, hyponatremia.

Gastrointestinal: Abdominal pain, anorexia, constipation, diarrhea, dyspepsia, gastric distress, nausea, pancreatitis, vomiting.

Genitourinary: Azotemia, impotence, renal failure, urinary frequency, urinary retention.

Hematologic: Agranulocytosis, aplastic anemia, bone marrow suppression.

Hepatic: Abnormal liver function tests, hepatic failure, hepatitis, jaundice.

Neuromuscular & skeletal: Back pain, pain, weakness.

Ocular: Blurred vision, conjunctivitis, lens opacities.

Otic: tinnitus.

Miscellaneous: Diaphoresis, hypersensitivity.

9. Overdose

Carbamazepine overdose is extremely hazardous, and the severity of toxic symptoms depends on the amount ingested. In small children the lethal dose is much lower than for an adult.

Early symptoms of Carbamazepine toxicity include neuromuscular disturbances, such as jerky eye movements, muscle jerks, increased reflex reactions and severe nausea and vomiting.

Symptoms of higher overdose, including respiratory depression, convulsions, cardiac arrhythmia, shock, and coma, may result in death, especially in small children.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency department for observation and treatment.

5. Pharmacological Properties

1. Pharmacodynamics Properties

Carbamazepine is a dibenzapine derivative with antiepileptic and anticonvulsant properties. Carbamazepine appears to act by reducing polysynaptic response and blocking the posttetanic potentiation. Carbamazepine greatly reduces or abolishes pain induced by stimulation of the infraorbital nerve. The principal metabolite of Carbamazepine-10, 11-epoxide, has anticonvulsant activity as demonstrated in several in vivo animal models of seizures.

2. Pharmacokinetic Properties

Absorption: Absorption from the gastrointestinal tract is relatively slow. Plasma levels of Carbamazepine are variable and may range from 0.5 to 25 mcg/mL. The bioavailability of the Carbamazepine is 89%.

Distribution: Carbamazepine is 76% bound to plasma proteins. The concentration of unchanged drug in the CSF and saliva is approximately 20% to 30% of that attained in plasma. Carbamazepine readily crosses the placenta. The apparent volume of distribution was found to be 0.8 to 1.9 L/kg.

Metabolism and Excretion: Carbamazepine is metabolized in the liver via the epoxide-diol pathway, the main metabolite (Carbamazepine -10, 11-epoxide) being pharmacologically active. The elimination half-life of unchanged Carbamazepine following a single oral dose averaged 36 hours whereas, after repeated administration which leads to hepatic enzyme induction, it averaged 16 to 24 hours, depending on the duration of treatment. Following a single dose, 72% was excreted in the urine mainly in the form epoxidated, hydroxylated and conjugated metabolites. Some 28% of the dose was excreted in the feces.

3. Preclinical Safety Data

Non-clinical data reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity, local tolerance, genotoxicity and carcinogenic potential. Reproductive toxicity studies in animals were insufficient to rule out a teratogenic effect of carbamazepine in humans.

Carcinogenicity

In rats treated with carbamazepine for two years, there was an increased incidence of hepatocellular tumours in females and benign testicular tumours in males. However, there is no evidence to date that these observations are of any relevance to the therapeutic use of carbamazepine in humans.

Reproductive toxicity

Animal data

The cumulative evidence from various animal studies in mice, rats and rabbits indicates that carbamazepine has no or only minor teratogenic potential at doses relevant to man. However, the animal studies were insufficient to rule out a teratogenic effect of carbamazepine. In a reproduction study in rats, nursing offspring demonstrated a reduced weight gain at a maternal dosage level of 192 mg/kg/day.

Fertility

In chronic toxicity studies dose related testicular atrophy and aspermatogenesis occurred in rats receiving carbamazepine. The safety margin for this effect is not known.

6. Pharmaceutical Particulars

1. List of Excipients

Maize starch
Calcium Hydrogen Phosphate
Maize starch
Magnesium Stearate
Purified talc
Sodium Starch Glycolate (TYPE-A)
Microcrystalline Cellulose (PH102)
Purified water

2. Incompatibilities

Not applicable.

3. Shelf Life

36.months

6.4 Special Precautions for Storage

Do not store above 30°C. Protect from light.

5. Nature and Contents of Container

10 tablets are packed in Alu-PVC blister pack. Such 10 blisters are packed in printed carton with package insert.

6. Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder And Manufacturing Site Addresses

1. Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

2. Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

8. Marketing Authorization Number

TAN 22 HM 0307

9. Date of First <Registration> / Renewal of The <Registration>

04/08/2022

10. Date of Revision of the Text

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