Oxcarbazepine Tablets

DESCRIPTION

Oxcarbazepine is a 10-monohydroxy metabolite of carbamazepine. Oxcarbazepine tablets and suspension were shown to have similar bioavailability. Based on MHD concentrations, oxcarbazepine tablets and suspension were shown to have similar bioavailability.

Pharmacodynamics

Oxcarbazepine is rapidly reduced by cytosolic enzymes in the liver to its 10-monohydroxy metabolite, MHD, which is metabolized to the pharmacologically active 10-monohydroxy metabolite (MHD). The half-life of the parent is about 12 hours in adults and 24 hours in children. The elimination of MHD is predominantly by renal excretion, with a half-life of about 8 hours in adults and 16 hours in children.

Metabolism and Excretion

Oxcarbazepine is metabolized by the liver, primarily to MHD, and to a lesser extent to other hydroxy metabolites. MHD is further metabolized to glucuronide conjugates, which are excreted in the urine. The half-life of MHD is about 8 hours in adults and 16 hours in children.

Clearance

The clearance of oxcarbazepine is expected to reach that of adults.

Pediatric Use

Oxcarbazepine is approved for use in children aged 4 years and above. The pharmacokinetics of oxcarbazepine and MHD have not been evaluated in children under the age of 4 years. The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Contraindications

Oxcarbazepine is contraindicated in patients with a history of hypersensitivity reactions to carbamazepine and its metabolites. Oxcarbazepine is also contraindicated in patients with a history of angioedema or anaphylaxis associated with AED therapy. Oxcarbazepine is contraindicated in patients with a history of severe respiratory depression, coma, and other severe hypoxic-ischemic episodes.

Warnings

Hypersensitivity Reactions

Serious skin reactions have been reported in association with oxcarbazepine. In clinical trials, the incidence of rash was approximately 3% in patients treated with oxcarbazepine. The median time of onset for serious skin reactions was 14 days (range: 7-43 days).

Gastrointestinal Toxicity

Seizure Rate

The incidence of seizures in clinical trials was approximately 3% in patients treated with oxcarbazepine. The median time of onset for seizures was 14 days (range: 7-43 days).

Endocrine Toxicity

The incidence of endocrine abnormalities in clinical trials was approximately 3% in patients treated with oxcarbazepine. The median time of onset for endocrine abnormalities was 14 days (range: 7-43 days).

Central Nervous System Toxicity

The incidence of central nervous system abnormalities in clinical trials was approximately 3% in patients treated with oxcarbazepine. The median time of onset for central nervous system abnormalities was 14 days (range: 7-43 days).

Respiratory Toxicity

The incidence of respiratory abnormalities in clinical trials was approximately 3% in patients treated with oxcarbazepine. The median time of onset for respiratory abnormalities was 14 days (range: 7-43 days).

Other Toxicities

The incidence of other toxicities in clinical trials was approximately 3% in patients treated with oxcarbazepine. The median time of onset for other toxicities was 14 days (range: 7-43 days).

Dosage and Administration

Oxcarbazepine tablets can be taken with or without food. The dose should be increased gradually to achieve the optimal therapeutic response.

Interactions

Potential interactions between oxcarbazepine and other AEDs were assessed in clinical studies. The effect of these interactions on the pharmacokinetics of oxcarbazepine and MHD has not been evaluated. Therefore, the dose of oxcarbazepine should be reduced when coadministered with other AEDs.

Dosage Forms

Oxcarbazepine tablets are available in strengths of 150 mg and 300 mg.

Clinical Studies

The effectiveness of oxcarbazepine in adjunctive therapy in children aged 4 years and above with epilepsy has been demonstrated.

Pharmacokinetics

The pharmacokinetics of oxcarbazepine and MHD have not been evaluated in children under the age of 4 years. The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Dosing in Special Populations

Children: The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Pediatric Use

The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Geriatric Use

The safety and efficacy of oxcarbazepine in elderly patients have not been established.

Pregnancy

Oxcarbazepine is a pregnancy category C drug. It is not known whether oxcarbazepine can cause fetal harm when administered to a pregnant woman. When administered to pregnant rats, oxcarbazepine caused a decreased incidence of ossification of the calvaria and a decreased incidence of ossification of the pubic bones. Oxcarbazepine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether oxcarbazepine is excreted in breast milk. Because many drugs are excreted in breast milk, caution should be exercised when oxcarbazepine is administered to a nursing woman.

Adverse Reactions

Adverse reactions that have been reported in association with oxcarbazepine include somnolence, ataxia, dizziness, and an additive sedative effect. The incidence of adverse reactions was approximately 3% in patients treated with oxcarbazepine. The median time of onset for adverse reactions was 14 days (range: 7-43 days).

Nursing Mothers

It is not known whether oxcarbazepine is excreted in breast milk. Because many drugs are excreted in breast milk, caution should be exercised when oxcarbazepine is administered to a nursing woman.

Pediatric Use

The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Geriatric Use

The safety and efficacy of oxcarbazepine in elderly patients have not been established.

Pregnancy

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Nursing Mothers

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Pediatric Use

The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Geriatric Use

The safety and efficacy of oxcarbazepine in elderly patients have not been established.

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Pediatric Use

The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Geriatric Use

The safety and efficacy of oxcarbazepine in elderly patients have not been established.

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Lactation

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Adverse Reactions

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Nursing Mothers

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Pediatric Use

The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Geriatric Use

The safety and efficacy of oxcarbazepine in elderly patients have not been established.

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Lactation

It is not known whether oxcarbazepine is excreted in breast milk. Because many drugs are excreted in breast milk, caution should be exercised when oxcarbazepine is administered to a nursing woman.

Adverse Reactions

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Nursing Mothers

It is not known whether oxcarbazepine is excreted in breast milk. Because many drugs are excreted in breast milk, caution should be exercised when oxcarbazepine is administered to a nursing woman.

Pediatric Use

The safety and efficacy of oxcarbazepine in children under the age of 4 years have not been established.

Geriatric Use

The safety and efficacy of oxcarbazepine in elderly patients have not been established.
ADVERSE REACTIONS

Following administration of single (300 mg) and multiple (600 mg/day) doses of oxcarbazepine in elderly volunteers (18-32 years of age). Comparisons of creatinine clearance in young and elderly volunteers indicate that the difference was due to age-related reductions in creatinine clearance.

Approximately 9% of these 295 adult patients discontinued treatment because of an adverse experience. The most common adverse events leading to discontinuation were headache (10%), dizziness (7%), and nausea (5%).

Approximately 11% of these 456 pediatric patients discontinued treatment because of an adverse experience. The most common adverse events leading to discontinuation were headache (10%), dizziness (7%), and nausea (5%).

Table 6 lists treatment-emergent signs and symptoms that occurred in at least 2% of pediatric patients and are considered possibly related to treatment. The most common adverse events in pediatric patients were headache, somnolence, and vomiting.

In the paragraphs that follow, the adverse events other than those in the preceding tables or text, that occurred in a total of 5 or more patients in any treatment group are listed by body system and order of decreasing incidence in pediatric patients. These include:

- Headache
- Dizziness
- Fatigue
- Nausea
- Somnolence
- Vomiting

In adults, the most common adverse events were somnolence, dizziness, and headache.

Approximately 2% of adult patients treated with oxcarbazepine withdrew from the study due to an adverse event. The most common adverse events leading to withdrawal were somnolence (3%), dizziness (2%), and headache (2%).

In pediatric patients, approximately 3% of patients withdrew due to an adverse event. The most common adverse events leading to withdrawal were headache (3%), somnolence (2%), and dizziness (2%).

Approximately 2% of adult patients treated with oxcarbazepine withdrew from the study due to an adverse event. The most common adverse events leading to withdrawal were somnolence (3%), dizziness (2%), and headache (2%).

In pediatric patients, approximately 3% of patients withdrew due to an adverse event. The most common adverse events leading to withdrawal were headache (3%), somnolence (2%), and dizziness (2%).
Oxcarbazepine Tablets
150 mg

NDC 62756-183-08

Dosage: See package insert. Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Distributed by:
CF 1406 = PANTONE 102 CVC
CF 1511
30% of CF 1511

Size: 100x40mm

Unvarnish area: 30x9.5mm
Varnish area: [NCRC]

100 TABLETS
Rx only

GUJ/DRUGS/25/789
Batch No.: PJLB0892
Exp.: ISS. 02/2007

Oxcarbazepine Tablets
150 mg

Dosage: See package insert. Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Distributed by:
CF 1406 = PANTONE 102 CVC
CF 1511
30% of CF 1511

Size: 100x40mm

Unvarnish area: 30x9.5mm
Varnish area: [NCRC]
Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Distributed by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India.

500 TABLETS
150 mg

Dosage: See package insert.
Dispense in tight container (USP).

GUJ/DRUGS/25/789
Batch No.: 
Exp.: 

Size: 152.4x50.8mm

Unvarnish area: 45.4x13.5mm
Varnish area: 

Black
CF 1406=PANTONE 102 CVC
CF 1511
30% of CF 1511

NDC 62756-183-13
Oxcarbazepine Tablets

ISS. 02/2007
Oxcarbazepine Tablets

150 mg

1000 TABLETS
Rx only

Distributed by:

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Dosage: See package insert.
Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F)
[see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-183-18

Distributed by:

Black
CF 1406 = PANTONE 102 CVC
CF 1511
30% of CF 1511

GUJ/DRUGS/25/789
Batch No.: PJLB0893
Exp.: PJLB0893

ISS. 02/2007

Oxcarbazepine Tablets

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-183-18

Dosage: See package insert.
Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F)
[see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-183-18

Dosage: See package insert.
Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F)
[see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-183-18

Dosage: See package insert.
Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F)
[see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-183-18

Dosage: See package insert.
Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F)
[see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-183-18

Dosage: See package insert.
Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F)
[see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.
Oxcarbazepine Tablets
300 mg

100 TABLETS
Rx only

Dosage: See package insert. Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature]. Keep this and all drugs out of the reach of children.

Distributed by: GUJ/DRUGS/25/789

Manufactured by: Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Anand-Auro Road, Andheri (East), Mumbai-400 059, India.

NDC 62756-184-88

Batch No.: Exp.: PJLB0895

Oxcarbazepine Tablets
300 mg

CF 1361 = PANTONE 377 U
CF 1511
30% of CF 1511

Size: 100x40mm

Unvarnish area: 30x9.5mm
Varnish area: [CRC]

ISS. 02/2007
Oxcarbazepine Tablets

NDC 62756-184-08

Dosage: See package insert.
Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Distributed by:
PJLB0896
PJLB0896
ISS. 02/2007

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-184-08

100 TABLETS
Rx only

Oxcarbazepine Tablets

300 mg

Size: 100x40mm

CNRC

Unvarnish area: 30x9.5mm

Varnish area: [ ]

Black

30% of CF 1511

CF 1511

CF 1361 = PANTONE 377 U
Oxcarbazepine Tablets
300 mg

NDC 62756-184-18

Dosage: See package insert.
Dispense in tight container (USP).

1000 TABLETS
Rx only

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Distributed by:
CARI/PAC Pharmaceutical
Manufacturing Co., Ltd.
24400 Southfield Rd., Canton, MI 48188

Rx only

GUJ/DRUGS/25/789
Batch No.: Exp.:

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F)
[see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Dosage: See package insert.
Dispense in tight container (USP).

Size: 161.9x76.2mm

Unvarnish area: 46x16.5mm
Varnish area: [NCRC]

Black
CF 1361 = PANTONE 377 U
CF 1511
30% of CF 1511
Oxcarbazepine Tablets
600 mg

Distributed by:

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

NDC 62756-185-83

Dosage: See package insert. Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature]. Keep this and all drugs out of the reach of children.

Oxcarbazepine Tablets
30 TABLETS
Rx only

Distributed by:
GUJ/DRUGS/25/789

Batch No.: PJLB0898

Dosage: See package insert. Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature]. Keep this and all drugs out of the reach of children.

Oxcarbazepine
Tablets
600 mg

Distributed by:
GUJ/DRUGS/25/789

Iss. 02/2007

Distributed by:
GUJ/DRUGS/25/789

Batch No.: PJLB0898

Dosage: See package insert. Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature]. Keep this and all drugs out of the reach of children.

Oxcarbazepine
Tablets
600 mg

Distributed by:
GUJ/DRUGS/25/789

Iss. 02/2007

Distributed by:
GUJ/DRUGS/25/789

Batch No.: PJLB0898

Dosage: See package insert. Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature]. Keep this and all drugs out of the reach of children.
Dosage: See package insert.
Dispense in tight container (USP).

Oxcarbazepine Tablets
600 mg
100 TABLETS
Rx only

NDC 62756-185-88

GUJ/DRUGS/25/789
Batch No.: PJLB0899
Exp.: PJLB0899
ISS. 02/2007

Black

CF 1511
30% of CF 1511

Size: 152.4x50.8mm

[CRC]

Unvarnish area: 45.4x13.5mm
Varnish area: ——

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Distributed by:
Black CF 1511
30% of CF 1511

ISS. 02/2007

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].
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Dispense in tight container (USP).

Oxcarbazepine Tablets
600 mg
100 TABLETS
Rx only

NDC 62756-185-88

GUJ/DRUGS/25/789
Batch No.: PJLB0899
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ISS. 02/2007

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Unvarnish area: 45.4x13.5mm
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Dispense in tight container (USP).

Oxcarbazepine Tablets
600 mg
100 TABLETS
Rx only

NDC 62756-185-88

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Batch No.: PJLB0899
Exp.: PJLB0899
ISS. 02/2007

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Dispense in tight container (USP).

Oxcarbazepine Tablets
600 mg
100 TABLETS
Rx only

NDC 62756-185-88

GUJ/DRUGS/25/789
Batch No.: PJLB0899
Exp.: PJLB0899
ISS. 02/2007

Black

CF 1511
30% of CF 1511

Size: 152.4x50.8mm

[CRC]

Unvarnish area: 45.4x13.5mm
Varnish area: ——

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].
Keep this and all drugs out of the reach of children.

Dosage: See package insert.
Dispense in tight container (USP).
Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Dosage: See package insert.
Dispense in tight container (USP).

NDC 62756-185-08
Oxcarbazepine Tablets
600 mg

100 TABLETS Rx only

Distributed by:
Black

CF 1511
30% of CF 1511

Size: 152.4x50.8mm

Unvarnish area: 45.4x13.5mm
Varnish area: [NCRC]

Batch No.: PJLB0900
Exp.: PJLB0900
ISS. 02/2007

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India.

GUJ/DRUGS/25/789

Oxcarbazepine Tablets

Dispense in tight container (USP).

Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.
Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

Dosage: See package insert.

Dispense in tight container (USP).

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Distributed by:
BlackCF 1511
30% of CF 1511

NDC 62756-185-13
Oxcarbazepine Tablets
600 mg

500 TABLETS
Rx only

Pattern:
- Black
- CF 1511
- 30% of CF 1511

Varnish area:
Unvarnish area: 46x16.5mm

Size: 161.9x76.2mm

GUJ/DRUGS/25/789
Batch No.: Exp.:
Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

Keep this and all drugs out of the reach of children.

NDC 62756-185-18
Oxcarbazepine Tablets
600 mg
1000 TABLETS
Rx only

Dosage: See package insert.
Dispense in tight container (USP).

Manufactured by:
Sun Pharmaceutical Ind. Ltd.
Acme Plaza, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

Distributed by:
CARICO PHARMACEUTICAL LABORATORIES LTD.
DETROIT, MI 48202

GUJ/DRUGS/25/789
Batch No.: Exp.: