# NEW OFFER

Equetro®
(carbamazepine)
Extended-Release Capsules
100 mg • 200 mg • 300 mg

# $10 COPAY (30-DAY SUPPLY)

Please See Important Safety Information, Including Boxed Warning Below


## Congratulations!

Eligible* patients pay a minimum of **$10 for a 30-day supply** and receive up to $100 off (maximum out of pocket $75). For a 60-day supply, patients pay a minimum of $20 and receive up to $150 off (maximum out of pocket $100). For a 90-day supply, patients pay a minimum of $20 and receive up to $200 off (maximum out of pocket $150) for Equetro® (carbamazepine) Extended-Release Capsules.

### Here's how it works:

**You pay the first $10** of your copay, and then **we'll pay up to the next $100**.

Print your copay card and present it whenever you fill your prescription at the pharmacy.

*Limitations and restrictions apply. To view eligibility requirements and terms and conditions, please **visit equetro.com** or call **1-866-297-6945** for more information.

**Patient Instructions:** To redeem this copay card, you must have a valid prescription for **Equetro® (carbamazepine) Extended-Release Capsules**. Follow the dosage instructions given by your doctor. For up to a 30-day supply, you will be required to pay the first $10 of your copay, after which this copay card will deduct up to $100 off from your remaining balance (maximum out of pocket $75). For up to a 60-day supply, you will be required to pay the first $20 of your copay, after which this copay card will deduct up to $150 off from your remaining balance (maximum out of pocket $100). For up to a 90-day supply, you will be required to pay the first $20 of your copay, after which this copay card will deduct up to $200 off from your remaining balance (maximum out of pocket $150). The pharmacist will process your insurance information and this copay card and then inform you of your copay amount. This offer may not be redeemed for cash. By using this copay card, you are certifying that you meet the eligibility criteria and will comply with the terms and conditions described in the Restrictions section below. Limitations and restrictions apply. To view eligibility requirements and terms and conditions, please visit **equetro.com** or call **1-866-297-6945** for more information.

**Pharmacist instructions for a Patient paying with an Eligible Third-Party Payer:** First submit this claim to the eligible Third-Party Payer as the primary payer, then submit the balance due to **CHANGE HEALTHCARE** as a Secondary Payer COB [coordination of benefits] with the patient responsibility amount and a valid Other Coverage Code **(e.g., 8)**. For up to a 30-day supply, the patient is responsible for the first $10 and this copay card pays up to the next $100 off (maximum out of pocket $75). For up to a 60-day supply, the patient is responsible for the first $20 and this copay card pays up to the next $150 off (maximum out of pocket $100). For up to a 90-day supply, the patient is responsible for the first $20 and this copay card pays up to the next $200 off (maximum out of pocket $150). Reimbursement will be received from **CHANGE HEALTHCARE**.

**Pharmacist instructions for a Cash-Paying Patient:** Submit this claim to **CHANGE HEALTHCARE**. A valid Other Coverage Code **(e.g., 1)** is required. For up to a 30-day supply, the patient is responsible for the first $10 and this copay card pays up to the next $100 off (maximum out of pocket $75). For up to a 60-day supply, the patient is responsible for the first $20 and this copay card pays up to the next $150 off (maximum out of pocket $100). For up to a 90-day supply, the patient is responsible for the first $20 and this copay card pays up to the next $200 off (maximum out of pocket $150). Reimbursement will be received from **CHANGE HEALTHCARE**.

Valid Other Coverage Code required. For any questions regarding **CHANGE HEALTHCARE** online processing, please call the Help Desk at **1-800-422-5604**.

**Restrictions:** This promotion cannot be combined with any other programs, offers, or discounts. A prescription for Equetro must be filled in order to use this copay card. **THIS OFFER IS NOT VALID FOR PRESCRIPTIONS THAT ARE ELIGIBLE TO BE REIMBURSED, IN WHOLE OR IN PART, BY MEDICAID, MEDICARE (INCLUDING MEDICARE PART D), OR OTHER FEDERAL OR STATE HEALTHCARE PROGRAMS.** Patients are responsible for reporting receipt of any program rewards to any private insurer or health or pharmacy benefit programs that reimburse the entire cost of the prescription. Void where prohibited by law or restricted. Void outside the U.S. This card is the property of Validus Pharmaceuticals LLC and must be returned upon request.

This offer is not transferable. Not valid if reproduced. Void where prohibited by law. Program managed by ConnectiveRx on behalf of Validus Pharmaceuticals LLC. The parties reserve the right to rescind, revoke, or amend this offer without notice at any time.

ConnectiveRx

# Equetro® (carbamazepine) Extended-Release Capsules 100 mg • 200 mg • 300 mg

**WARNING: SERIOUS DERMATOLOGIC REACTIONS and APLASTIC ANEMIA AND AGRANULOCYTOSIS**

**Serious Dermatologic Reactions and HLA-B*1502 Allele**

**Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have occurred in patients treated with carbamazepine. These syndromes may be accompanied by mucous membrane ulcers, fever, or painful rash. These reactions are estimated to occur in 1 to 6 per 10,000 new users in countries with mainly Caucasian populations, but the risk in patients of Asian descent is estimated to be about 10 times higher. There is a strong association between the risk of developing SJS/TEN and the presence of HLA-B*1502, an inherited allelic variant of the HLA-B gene. Test for HLA-B*1502 prior to initiating EQUETRO in patients with an increased likelihood of carrying this allele. Avoid use of EQUETRO in patients testing positive for the allele unless the benefit clearly outweighs the risk. Discontinue EQUETRO if you suspect that the patient has a serious dermatologic reaction *[see Warnings and Precautions]*.**

**Aplastic Anemia and Agranulocytosis**

**Aplastic anemia and agranulocytosis can occur during treatment with EQUETRO. The risk of developing these reactions with EQUETRO is 5 to 8 times greater than in the general population. However, the overall risk in the general population is low (6 cases in a population of one million per year for agranulocytosis and two cases in a population of one million per year for aplastic anemia). Obtain a complete blood count before beginning treatment with EQUETRO, and monitor CBC periodically.**

**Consider discontinuing EQUETRO if significant bone marrow depression develops *[see Warnings and Precautions]*.**

## INDICATIONS AND USAGE

1. A mood stabilizer indicated for the treatment of acute manic or mixed episodes associated with bipolar I disorder.
2. Indicated for the treatment of the pain associated with trigeminal neuralgia.
3. An antiepileptic drug (AED) indicated for the treatment of partial seizures with complex symptomatology, generalized tonic-clonic seizures, and mixed seizures. EQUETRO is not indicated for the treatment of absence seizures (petit mal). Carbamazepine has been associated with increased frequency of generalized convulsions in these patients.

## DOSAGE AND ADMINISTRATION

Prior to initiating treatment with EQUETRO, test patients with ancestry in genetically at-risk populations for the presence of the HLA-B*1502 allele. Avoid use of EQUETRO in patients testing positive for the allele, unless the benefit clearly outweighs the risk. Complete pretreatment blood counts should be obtained as a baseline. Baseline and periodic evaluations of liver function, eye examination, urinalysis, and BUN determinations should be performed. **See Full Prescribing Information for dosing instructions.**

## CONTRAINDICATIONS

EQUETRO is contraindicated in patients with bone marrow depression; known hypersensitivity to carbamazepine, such as anaphylaxis or serious hypersensitivity reaction; known hypersensitivity to any of the tricyclic antidepressants, such as amitriptyline, desipramine, imipramine, protriptyline, and nortriptyline, hypersensitivity reactions include anaphylaxis and serious rash; concomitant use with delavirdine or other non-nucleoside reverse transcriptase inhibitors (NNRTIs) that are substrates for CYP3A4. EQUETRO decreases efficacy of these drugs by substantially reducing the concentrations of these drugs through induction of CYP3A4. This can lead to loss of virologic response and possible resistance to these medications. Concomitant use of monoamine oxidase inhibitors (MAOIs) can cause serotonin syndrome. Before beginning treatment with EQUETRO, MAOIs should be discontinued for a minimum of 14 days. Concomitant use with nefazodone may result in insufficient plasma concentrations of nefazodone and its active metabolite to achieve a therapeutic effect.

## WARNINGS AND PRECAUTIONS

**Serious Dermatologic Reactions.** Serious and sometimes fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS), have been reported with carbamazepine treatment. *Discontinue EQUETRO if you suspect that the patient has a serious dermatologic reaction. If signs or symptoms suggest SJS/TEN, do not resume treatment with EQUETRO.*

**Aplastic Anemia and Agranulocytosis.** Aplastic anemia and agranulocytosis have occurred in patients treated with carbamazepine.

**Drug Reaction with Eosinophilia and Systemic Symptoms/Multiorgan Hypersensitivity.** Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as Multiorgan Hypersensitivity, have occurred with carbamazepine. Some of these events have been fatal or life threatening. DRESS typically, though not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling, in association with other organ system involvement sometimes resembling an acute viral infection. Eosinophilia is often present. Early manifestations of hypersensitivity (fever, lymphadenopathy) may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. *Discontinue EQUETRO if an alternative etiology for the signs and symptoms cannot be established.*

Hypersensitivity reactions to carbamazepine have been reported in patients who previously experienced this reaction to anticonvulsants, including phenytoin, primidone, and phenobarbital. If such history is present, benefits and risks should be carefully considered, and, if EQUETRO is initiated, the signs and symptoms of hypersensitivity should be carefully monitored.

**Suicidal Behavior and Ideation.** Antiepileptic drugs (AEDs), including EQUETRO, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Anyone considering prescribing EQUETRO must balance the risk of suicidal thoughts or behavior with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, the prescriber needs to consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Patients, their caregivers, and families should be informed that AEDs increase the risk of suicidal thoughts and behaviors and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

**Embryofetal Toxicity.** EQUETRO can cause fetal harm when administered to pregnant women. Apprise women of childbearing potential of this risk. Use in pregnancy only if the potential benefits of treatment outweigh the risks. Epidemiological data suggest that there may be an association between the use of carbamazepine during pregnancy and congenital malformations, including spina bifida.

To provide additional information regarding the effects of in utero exposure to EQUETRO, physicians are advised to recommend that pregnant patients taking EQUETRO enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry by calling the toll-free number 1-888-233-2334, and must be done by patients themselves. Information on the registry can also be found at the website http://www.aedpregnancyregistry.org.

**Abrupt Discontinuation and Risk of Seizure.** Do not discontinue EQUETRO abruptly because of the risk of seizure and other withdrawal signs/symptoms. Patients with seizure disorder are at increased risk of developing seizure and status epilepticus with attendant hypoxia and threat to life. In the event of an allergic or hypersensitivity reaction, more rapid substitution of alternative therapy may be necessary.

**Hyponatremia.** Hyponatremia can occur as a result of treatment with EQUETRO. In many cases, the hyponatremia appears to be caused by the syndrome of inappropriate antidiuretic hormone secretion (SIADH). The risk of developing SIADH with EQUETRO treatment appears to be dose-related. Elderly patients and patients treated with diuretics are at greater risk of developing hyponatremia. Signs and symptoms of hyponatremia include headache, new or increased seizure frequency, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness, which can lead to falls. Consider discontinuing EQUETRO in patients with symptomatic hyponatremia.

**Potential for Cognitive and Motor Impairment.** EQUETRO has the potential to cause impairment in judgment, cognition, and motor function. Caution patients about operating hazardous machinery, including automobiles, until they are reasonably certain that EQUETRO does not affect them adversely.

**Potential for Loss of Virologic Response to Non-nucleoside Reverse Transcriptase Inhibitors that are substrates for CYP3A4 with Concomitant use of EQUETRO.** Co-administration of EQUETRO with NNRTIs, including delavirdine, is contraindicated because it may lead to loss of virologic response and possible resistance. Co-administration of delavirdine, an NNRTI and a substrate of CYP3A4, and EQUETRO can decrease delavirdine concentrations by 90%.

**Liver Damage.** Hepatic effects, ranging from slight elevations in liver enzymes to rare cases of hepatic failure have been reported. In some cases, hepatic effects may progress despite discontinuation of the drug. Rare instances of vanishing bile duct syndrome have also been reported.

**AV Heart Block.** AV heart block, including second- and third-degree block, have been reported following carbamazepine treatment.

**Hepatic Porphyria.** The use of EQUETRO should be avoided in patients with a history of hepatic porphyria. Acute attacks have been reported in such patients receiving carbamazepine therapy.

**Increased Intraocular Pressure.** Carbamazepine has mild anticholinergic activity. In patients with a history of increased intraocular pressure, consider assessing intraocular pressure before initiating treatment and periodically during therapy.

## DRUG INTERACTIONS

EQUETRO is metabolized primarily by CYP3A4 to the active carbamazepine-10,11-epoxide, which is further metabolized to the trans-diol by epoxide hydrolase. Inhibitors of CYP3A4 and/or epoxide hydrolase can increase plasma levels of EQUETRO and its active metabolites, increasing plasma concentrations of EQUETRO and the risk of adverse reactions.

**See Full Prescribing Information for Potential Drug Interactions.**

## USE IN SPECIFIC POPULATIONS

**Pregnancy and Lactation.** EQUETRO can cause fetal harm when administered to pregnant women. Carbamazepine and its epoxide metabolite are transferred to breast milk during lactation. There is a potential for serious adverse reactions in nursing infants exposed to carbamazepine. Nursing mothers should consider the potential benefits and risks of treatment when deciding on whether to discontinue nursing or discontinue treatment with EQUETRO, considering the importance of the drug to the mother.

**Pediatric.** The safety and effectiveness of EQUETRO have not been established in pediatric patients for indications other than Epilepsy.

**Geriatric.** Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

**ADVERSE REACTIONS.** To avoid Adverse Reactions, refer to the Warnings and Precautions provided. To report suspected Adverse Reactions, call Validus Pharmaceuticals LLC at 1-866-982-5438 or info@validuspharma.com or the FDA at 1-800-FDA-1088 or www.fda/gov/medwatch.

**See Full Prescribing Information for Potential Adverse Reactions.**

**Please see Full Prescribing Information available at www.equetro.com.**


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