

Carbatrol® (carbamazepine) Extended-Release Capsules Patient Assistance Program

**P.O. Box 698
Somerville, NJ 08876
Phone 1-866-325-8224
Fax 1-866-838-5831**

Thank you for inquiring about the Carbatrol Patient Assistance Program. This program is designed to assist uninsured, indigent patients. Patients must be US residents and unable to afford the cost of the prescription medication. Patients can neither have nor be eligible for prescription insurance, government assistance, or other sources of funding. Patients should make every effort to seek state assistance before and during the application process.

The licensed practitioner and patient are responsible for completing the application, including pertinent income and insurance coverage. Please include the name and number of an office contact person that can provide information if needed.

Available Products:

**Carbatrol 100 mg, 120 capsules per bottle
Carbatrol 200 mg, 120 capsules per bottle
Carbatrol 300 mg, 120 capsules per bottle**

To enroll in the program, a licensed practitioner must follow the steps outlined below for each eligible patient:

- 1) **Make copies of the blank enrollment form for future use.**
- 2) **Complete the attached application form.**
 - **Form must be completed in full**
 - **Faxed copies will be accepted at 1-866-838-5831**
 - **Patient must meet all requirements to qualify.**
 - **Licensed practitioner's DEA or state license number is required for shipment validation. (If state license, attach a copy.)**
- 3) A **COMPLETED** prescription for a three-month supply must be attached to the form. This program provides medicine **THREE MONTHS AT A TIME ONLY**. You need to reapply to obtain additional supply. (Do not request refills on prescriptions.)
- 4) **To have product shipped directly to the patient** complete the application form and indicate "ship to patient" by checking the appropriate box. This must be mailed with the **ORIGINAL PRESCRIPTION to:**
**Carbatrol Patient Assistance Program
P.O. Box 698
Somerville, NJ 08876**
- 5) **To have product shipped directly to the physician** both the completed form and prescription can be faxed to:
1-866-838-5831

Income criteria:

<u>Household Size</u>	<u>Income Guidelines</u>
1	\$ 27,075
2	\$ 36,425
3	\$ 45,775
4	\$ 55,125
5	\$ 64,475
6	\$ 73,825
7	\$ 83,175
8	\$ 92,525

If you need additional information, please do not hesitate to call us at 1-866-325-8224.

Sincerely,
Carbatrol Patient Assistance Program

Please see Important Safety Information on last page.

The Carbatrol Patient Assistance Program is a service of Shire US Inc.

01/27/09 (MA)

CAR-00240 02/10

FPL2010

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The Carbatrol Patient Assistance Program offers assistance to indigent patients who do not have or qualify for prescription insurance, government assistance or other sources of funding. The program will provide up to a **THREE-MONTH SUPPLY** of Carbatrol, based on confirmation of need by the attending physician. Applications will be considered on a case-by-case basis. While Shire US Inc. will make every effort to grant aid when needed, this program is limited by available resources and may be discontinued or revised at any time.

IF INFORMATION IS NOT CLEARLY AND COMPLETELY FILLED OUT, THIS FORM WILL BE RETURNED.

PATIENT SECTION (To be completed by patient or legal guardian)

1) **Name** _____ **SSN** _____ - _____ - _____
Address _____ **Date of Birth** _____

Phone _____
City _____ **State** _____ **Zip** _____

- 2) A. Is the patient a US resident? Yes No
B. Total **ANNUAL** household income, including Social Security and pension benefits \$ _____ **ANNUAL**
C. Number of persons residing in household (including patient)

D. DOES THE PATIENT HAVE OR QUALIFY FOR PRESCRIPTION COVERAGE IN ANY OF THE FOLLOWING PROGRAMS?

Medicare Part D program	Yes <input type="checkbox"/> No <input type="checkbox"/>	Other state/local government programs.....	Yes <input type="checkbox"/> No <input type="checkbox"/>
If yes, is Carbatrol covered.....	Yes <input type="checkbox"/> No <input type="checkbox"/>	Private insurance/HMO prescription coverage	Yes <input type="checkbox"/> No <input type="checkbox"/>
Medicare prescription coverage.....	Yes <input type="checkbox"/> No <input type="checkbox"/>	Private foundation prescription coverage.....	Yes <input type="checkbox"/> No <input type="checkbox"/>
Medicaid prescription coverage.....	Yes <input type="checkbox"/> No <input type="checkbox"/>	Other prescription coverage.....	Yes <input type="checkbox"/> No <input type="checkbox"/>
Other federal (e.g., Veterans Administration).....	Yes <input type="checkbox"/> No <input type="checkbox"/>	If yes, please specify _____	

- 3) I verify that the information provided in this application is complete and accurate. I certify that I am uninsured and ineligible for any type of public or private reimbursement or coverage of drug costs. I also certify that I am unable to afford the cost of Carbatrol. I understand that Shire reserves the right at any time and without notice to modify the application form or modify or discontinue this program and the related eligibility criteria, or to refuse to distribute any drugs under this program to any patient. Before reapplying every 3 months to the PAP, I understand that I will seek any available state or government assistance before reapplying to the Carbatrol Patient Assistance Program. I authorize Shire to use this form to administer the Carbatrol Patient Assistance Program.

Patient or Legal Guardian Signature

Date

LICENSED PRACTITIONER SECTION (To be completed by the licensed practitioner)

*******ATTACH ORIGINAL SIGNED PRESCRIPTION*******

Prescription will be filled with 100, 200 or 300-mg capsules. The amount of Carbatrol mailed to the licensed practitioner will be that which most closely approximates a three-month supply.

1) **Name** _____ **Phone** _____
Address _____ **FAX#** _____

DEA or State License # _____
City _____ **State** _____ **Zip** _____

(If state license, please attach a copy.)

Contact: _____ **PLEASE CHECK TO SHIP TO PATIENT**

- 2) I represent that the information contained in this application is complete and accurate to the best of my knowledge. I certify that the use of the indicated medication is medically necessary and I will be evaluating the patient's treatment. To the best of my knowledge, this patient has no prescription insurance coverage for the indicated medication, including Medicaid or other public programs, and the patient has insufficient financial resources to pay for the prescribed therapy. I understand that Shire US Inc. reserves the right to modify or terminate this program at any time or to refuse to distribute Carbatrol under this program to any patient or physician. My signature certifies that goods received from Shire are for the use of the above-named patient only. These goods will not be resold nor offered for sale, trade or barter and will not be returned for credit. Shire reserves the right to recall the product when necessary.

Signature of Licensed Practitioner

Date

Important Safety Information

- Carbatrol[®] contains carbamazepine. Please ensure patient is not taking any other form of carbamazepine.
- The most frequently observed adverse reactions, particularly during the initial phases of therapy, are dizziness, drowsiness, unsteadiness, nausea, and vomiting. Initiating therapy at the lowest possible effective dose can minimize adverse reactions.
- Antiepileptic drugs, including Carbatrol[®], increase the risk of suicidal thoughts or behavior in patients taking these drugs. Patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.
- **Toxic epidermal necrolysis and Stevens-Johnson syndrome have been reported with use of carbamazepine. These skin disorders are rare, but appear to be more common in patients of Asian ancestry. A strong association between Asian ancestry and the presence of HLA-B*1502 allele in the development of toxic epidermal necrolysis and Stevens-Johnson syndrome has been reported. Patients of ancestry in genetically at-risk populations should be screened for the presence of HLA-B*1502 prior to initiating Carbatrol. Patients testing positive for the allele should not be treated with Carbatrol unless the benefit clearly outweighs the risk.**
- **Aplastic anemia and agranulocytosis have been reported in association with the use of carbamazepine. Reports of transient or persistent decreased platelet or white blood cell counts are not uncommon in association with the use of carbamazepine. However, the vast majority of the cases of leukopenia have not progressed to the more serious conditions of aplastic anemia or agranulocytosis. Nonetheless, complete pretreatment hematological testing should be obtained as a baseline. If a patient in the course of treatment exhibits low or decreased white blood cell or platelet counts, the patient should be monitored closely. Discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops.**
- Carbamazepine should not be used in patients with a history of previous bone marrow depression, hypersensitivity to the drug, or known sensitivity to any of the tricyclic compounds.
- Carbamazepine is Pregnancy Category D. Patients should be encouraged to enroll in the North American Antiepileptic Drug Pregnancy Registry if they become pregnant by calling the toll free number 1-888-233-2334.
- Absence seizures (petit mal) do not appear to be controlled by carbamazepine.

Please see Full Prescribing Information, including Boxed Warning, enclosed.

Carbatrol[®] is registered in the United States Patent and Trademark Office.