

## OFF-LABEL USE OF PRESCRIPTION DRUG

*The U.S. Food and Drug Administration (FDA) has required that drugs used in the United States be both safe and effective. The label information on the container, in the package insert, in published drug references, and in any advertising can indicate a drug's use only in certain "approved" doses and routes of administration for a particular condition. The use of a drug for a condition, in a dose, or by a route not listed on the label is considered to be a "nonapproved" or "off-label" use of the drug. Prescribers—based on their knowledge, education, training, experience, and available current information—may use a drug for a use, in a dose, or by a route not indicated in the "approved" labeling if it seems reasonable or appropriate in the prescriber's professional judgment.*

Patient's  
Initials

- \_\_\_\_\_ I understand that this is an experimental use of this medication, therefore no one can be fully aware of all possible side effects and complications.
- \_\_\_\_\_ The details of this treatment including anticipated benefits, material risks, and disadvantages have been explained to me in terms I understand.
- \_\_\_\_\_ Alternative treatments, prescriptions and therapies, their benefits, material risks, and disadvantages have been explained to me in terms I understand.
- \_\_\_\_\_ I understand and accept that the most likely material risks and complications of using (Name of Prescription Drug) for off-label use have been discussed with me and may include but are not limited to:
- - (Include common complications/risks)
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- \_\_\_\_\_ I have informed my healthcare provider of all my known allergies.
- \_\_\_\_\_ I have informed my healthcare provider of all medications I am currently taking, including prescriptions, over-the-counter remedies, herbal therapies and supplements, aspirin, and other recreational drug or alcohol use.
- \_\_\_\_\_ I have been advised whether I should take any or all of these medications while I am taking the above prescribed medication.
- \_\_\_\_\_ I am aware and accept that no guarantees about the results of this medication have been made.
- \_\_\_\_\_ My healthcare provider has answered all of my questions regarding this treatment/ medication.

I certify that I have read and understand this treatment agreement and that all blanks were filled in prior to my signature.

I authorize and direct \_\_\_\_\_ to prescribe  
(Name of healthcare provider)

\_\_\_\_\_ (Drug name)

which is FDA-approved for the treatment of \_\_\_\_\_  
(Condition drug was approved to treat)

for the purpose of \_\_\_\_\_  
(Condition to be treated)

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Patient or Legal Representative Signature/Date/Time

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Print Patient's or Legal Representative's Name

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Patient's Date of Birth

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Legal Representative's Relationship to Patient

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Witness Signature/Date/Time

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Print Witness's Name

I certify that I have explained the nature, purpose, anticipated benefits, material risks, complications, and alternatives to the proposed therapy to the patient or the patient's legal representative. I have answered all questions fully, and I believe that the patient/legal representative (circle one) fully understands what I have explained.

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Prescriber Signature/Date/Time

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