OFF-LABEL USE OF (name of prescription drug)

Since the early 1960s, the U.S. Food and Drug Administration (FDA) has required that drugs be both safe and effective. The label information on the container, in the package insert, in the Physicians' Desk Reference*, 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 not listed on the label (or 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 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:

-
-
-
-

_____ 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 _____,[professional designation], to prescribe _____,
(drug name)
which is FDA-approved for the treatment of _____, for the purpose of
(condition drug was approved to treat)
_____.
(condition to be treated)

_____ _____
Patient or Legal Representative Signature/Date/Time Relationship to Patient

_____ _____
Print Patient or Legal Representative Name Witness Signature/Date/Time

2001
Revised 8/04, 9/05, 12/05, 1/06, 3/08, J11999 6/19

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.

_____
Prescriber Signature/Date/Time

_____ copy given to patient
initial

_____ original placed in chart
initial

2001
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