

OFF-LABEL USE OF (name of prescription drugs)

Since the early 1960s, the 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 the Physicians' Desk Reference (PDR), 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 disease 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. Physicians, based on their knowledge and on available current information, may use a drug for a use not indicated in the "approved" labeling if it seems reasonable or appropriate.

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:
- -
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- _____ I have informed the doctor of all my known allergies.
- _____ I have informed the doctor 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.
- _____ The doctor 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 _____, M.D./D.O., to prescribe _____, which is
(drug name)
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

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

Physician Signature/Date/Time

initial copy given to patient

initial original placed in chart

SAMPLE