



## Off-Label Drugs Educational Material and Consent Form

Patient name \_\_\_\_\_

Facility name: COVA SPINE AND SPINE AND PAIN CENTER

Name of provider conducting informed consent \_\_\_\_\_

The facts in this form will help you learn more about the drug your doctor has prescribed. Please read it carefully. You will be asked to sign the last page of this form.

### Your Health Problem

Your doctor believes that \_\_\_\_\_ is the best drug for treating your \_\_\_\_\_.

The likely results of using this drug for your health problem include:

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### The Purpose of Off-Label Drugs

The term “off-label” means that the drug will be used for a purpose that is not listed on the product label. Off-label treatment is very common. In some cases, it may be the best treatment.

The Food and Drug Administration (FDA) has approved this drug for treatment of certain health problems. Your doctor is prescribing the drug for you in a way that is not *specifically* approved by the FDA.

The lack of FDA approval does not mean that the drug is not safe or that it will not work for you. It means that the FDA does not have the information needed to make formal approvals for treatment of your health problem. Your doctor has talked with you about the scientific data that supports the use of this drug.

## Risks and Common Problems

The most common risks linked to use of this drug for your health problem include but are not limited to:

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If any of the problems listed above happen to you, you may need to have more treatment.

## Other Choices

If you choose not to take this drug, the other option would be to carry on with your current treatment plan.

How well any other treatment works will depend on your specific health problem.

## More Facts

Sometimes, using an off-label drug is the best treatment, based on the latest scientific data. In some patients, the use of an off-label drug may be the only treatment choice.

An off-label drug can be used for:

- a health problem other than the one for which it is approved,
- a different amount of the drug than what is listed on the label,
- a different time schedule for taking the drug, and
- treatment for a child when the drug is FDA approved only for adults.

## Consent to Treatment

\_\_\_\_ **Patient Initial** The first two (2) pages of this form told you the risks, likely results, other choices, and problems that could happen with the use of an off-label drug. If, after you have read and reviewed this form with your doctor, you do not believe that you really understand the risks, likely results, other choices, and possible problems of taking this drug for an off-label purpose, **do not sign the form until all your questions have been answered.**

Because of my special health problem, these extra risks have also been explained to me:

**none**  **list:**

\_\_\_\_\_  
\_\_\_\_\_

I have these allergies:  **none**  **list:**

\_\_\_\_\_  
\_\_\_\_\_

I understand all the facts given to me in the first two (2) pages of this form. I now give my consent to Dr. \_\_\_\_\_ and his/her associates to prescribe an off-label drug for me. I prove with my signature below that my doctor has discussed all of the facts in this form with me, that I have had the chance to ask questions, and that all of my questions have been answered.

\_\_\_\_\_  
Signature of Patient or Responsible Party

\_\_\_\_\_  
Date and Time

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date and Time

### **Physician**

I confirm with my signature that I have given the patient two (2) pages of educational material and have discussed with the above-named patient the risks, likely results, other choices, and possible problems of this off-label drug. The patient has had the chance to ask questions, all questions have been answered, and he or she has expressed understanding. Thus informed, the patient has asked that I prescribe this off-label drug for him or her.

\_\_\_\_\_  
Physician Signature

\_\_\_\_\_  
Date and Time

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date and Time