	HOSPITAL MONUMENT OF THE BAPTISM OF POLAND St. John's Street 9 62-200 Gniezno	**PATIENT INFORMATION AND INFORMED CONSENT FORM OFF-LABEL USE OF DRUG THERAPY**
Patient's name and surname		

PESEL												**Book Number Main**	

1. APPLICATION OF DRUG THERAPY

Drugs are tested and approved for specific indications. However, in some situations, a drug may be effective for other conditions even if it has not been approved for that use. A doctor may decide to use it "off-label," for example, when traditional treatments are ineffective or when a patient has a condition not covered by the approved indication. After analyzing the clinical situation, we recommend that you use the following medication:

.....

(international name of the active substance / trade name of the drug)

which aims to .....

2. FORESEEABLE CONSEQUENCES

a) EXPECTED BENEFITS

Off-label drug use allows for the treatment of rare or resistant diseases when other effective options are lacking. It allows for the utilization of current medical knowledge and tailoring therapy to individual patient needs.

b) POSSIBILITY OF COMPLICATIONS:

This method of prescribing a drug is used in exceptional circumstances. It falls outside the scope of the registered indications for a given drug, which carries a potential risk of adverse effects or complications. The following adverse effects may occur when using the drug:

.....

.....

PATIENT! If any disturbing symptoms occur during drug therapy, notify the medical staff immediately.

c) LONG-TERM EFFECTS OF THE USE OF THE DRUG:

.....

d) RISK OF COMPLICATIONS:

[ ] small [ ] medium [ ] large

3. PROGNOSIS

The probability of success of the proposed treatment in your case is:

[ ] big [ ] medium [ ] limited

4. ALTERNATIVE METHODS OF PROCEDURE

An alternative to the proposed procedure is .....

.....

5. CONSEQUENCES OF REFUSING THERAPY

Refusing proposed treatment may result in no improvement or worsening of the patient's condition. It may prolong the duration of the illness or limit the effectiveness of other available therapies. In some cases, it may be life-threatening.

6. CONVERSATION WITH A DOCTOR

Please feel free to ask us anything you would like to know about your treatment with this medication. Any additional information regarding your planned use of the medication and any clarifications you may require can be obtained from any physician providing healthcare services at our facility.

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7. PATIENT STATEMENT

- After reviewing the content of this form and having an explanatory conversation with the medical staff, all my requirements regarding information about my health condition and the diagnosed disease, the justification and course of drug therapy have been met.outside the registered indications and possible complications and consequences related to the use of the procedure, as well as consequences related to its predicted consequences.
- I declare that I am not participating in a clinical trial using the above-mentioned drug.
- Furthermore, I declare that I have been informed about the possibility of withdrawing consent.

☐ **I CONSENT to off-label drug therapy and I am aware that I may discontinue further treatment at any time.**

☐ **I DO NOT AGREE to the proposed use of off-label drug therapy. I have been informed about the possible consequences of such a decision for my health and life.**

Date and signature of the patient or legal representative	
Date, signature and doctor's stamp (in case of refusal also indicate the time)	

The patient or her legal representative cannot sign the form due to:

.....

Date, signature and doctor's stamp	

8. DECLARATION OF THE PHYSICIAN RESPONSIBLE FOR OFF-LABEL USE

- I have discussed the presented studies with the patient using understandable, possibly simple terms and have provided information on the nature and importance of off-label drug therapy (indicated in point 1 of this form).
- Mr./Ms. (name and surname - in capital letters) ..... was not qualified for a clinical trial at the place where services were provided during the period of therapy with the use of the above-mentioned medicinal product and I am not aware of the fact that the above-mentioned beneficiary participated in a sponsored clinical trial with the use of the above-mentioned medicinal product.

Date, signature and doctor's stamp	