

PATIENT INFORMATION/CONSENT

FELBATOL® (felbamate) SHOULD NOT BE USED BY PATIENTS UNTIL THERE HAS BEEN A COMPLETE DISCUSSION OF THE RISKS AND WRITTEN INFORMED CONSENT HAS BEEN OBTAINED.

IMPORTANT INFORMATION AND WARNING:

Felbatol®, taken by itself or with other prescription and/or nonprescription drugs, can result in severe, potentially fatal blood abnormality (“aplastic anemia”) and/or severe, potentially fatal liver damage.

PATIENT CONSENT:

My [My son, daughter, ward, _____] _____’s]

treatment with Felbatol® has been personally explained to me by Dr. _____. The following points of information, among others, have been specifically discussed and made clear and I have had the opportunity to ask any questions concerning this information:

1. I, _____ (Patient’s Name), understand that Felbatol® is used to treat certain types of seizures and my physician has told me that I have this type(s) of seizures;

INITIALS: _____

2. I understand that Felbatol® is being used since my seizures have not been satisfactorily treated with other antiepileptic drugs;

INITIALS: _____

3. I understand that there is a serious risk that I could develop aplastic anemia and/or liver failure, both of which are potentially fatal, by using Felbatol®;

INITIALS: _____

4. I understand that there are no laboratory tests which will predict if I am at an increased risk for one of the potentially fatal conditions;

INITIALS: _____

5. I understand that I should have the recommended blood work before my treatment with Felbatol® is begun (baseline) and periodically thereafter as clinical judgment warrants. I understand that although this blood work may help detect if I develop one of these conditions, it may do so only after significant, irreversible and potentially fatal damage has already occurred;

INITIALS: _____

6. If I am currently taking another antiepileptic drug, I understand that the manufacturer of Felbatol® recommends that the dosage of these other drugs be decreased by a certain amount when Felbatol® is started; if my physician determines that this should not be done in my case, he/she has explained the reason(s) for this decision;

INITIALS: _____

7. I understand that I must immediately report any unusual symptoms to Dr. _____ and be especially aware of any rashes, easy bruising, bleeding, sore throats, fever, and/or dark urine;

INITIALS: _____

I now authorize Dr. _____ to begin my treatment with Felbatol®; OR, if my treatment has already begun with Felbatol®, to continue such treatment.

Patient, Parent, or Guardian

Address

Telephone

PHYSICIAN STATEMENT:

I have fully explained to the patient, _____,

_____ the nature and purpose of the treatment with Felbatol® (felbamate) and the potential risks associated with this treatment. I have asked the patient if he/she has any questions regarding this treatment or the risks and have answered those questions to the best of my ability. I also acknowledge that I have read and understand the prescribing information listed above.

Physician Date

NOTE TO PHYSICIAN: It is strongly recommended that you retain a signed copy of the informed consent with the patient’s medical records.

SUPPLY OF PATIENT INFORMATION/CONSENT FORMS:

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