PATIENT/PHYSICIAN ACKNOWLEDGEMENT FORM

FELBAMATE SHOULD NOT BE USED BY PATIENTS UNTIL THERE HAS BEEN A COMPLETE DISCUSSION OF THE RISKS.

All patients treated with felbamate should acknowledge that they understand the risks and other information about felbamate discussed below, and physicians should acknowledge this discussion.

IMPORTANT INFORMATION AND WARNING:

Felbamate, taken by itself or with other prescription and/or non-prescription drugs, can result in a severe, potentially fatal blood abnormality ("aplastic anemia") and/or severe, potentially fatal liver damage.

PATIENT ACKNOWLEDGEMENT:

Do not sign this form if there is anything you do not understand about the information you have received. Ask your doctor about anything you do not understand before you initial any of the items below or sign this form.

My [My son, daughter, ward _____'s] treatment with felbamate tablets 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 felbamate 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 felbamate is being used because 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 felbamate;
   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 felbamate is begun (baseline) and periodically thereafter as clinical judgement 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 other antiepileptic drugs, I understand that the manufacturer of felbamate recommends that the dosage of these other drugs be decreased by a certain amount when felbamate 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: _____

Size : 130 x 210 mm (L x H) Substrate : 60 GSM Maplitho paper Form Of Supply : 24's bundle form, Folded size : Not Applicable
\\MFGfilecl\PTC\Pkg. Dev\Commercial\ARTWORKS_COM\US_VIONA\Felbamate Tablets_VIONA\
XXXXXXX_PPAF FELBAMATE TABLETS USP US VIONA_1222\XXXXXXX_MG FELBAMATE TABLETS USP US VIONA_1222.indd

8. I understand that antiepileptic drugs such as felbamate may increase the risk of suicidal thoughts and behavior. I understand that I must immediately report any unusual changes in mood or behavior, symptoms of depression or thoughts about self-harm to Dr. _____.

   INITIALS: _____

_____

Patient, Parent, or Guardian

_____

Address

_____

Telephone

PHYSICIAN STATEMENT:

I have fully explained to the patient, _____, the nature and purpose of the treatment with felbamate and the potential risks associated with that 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.

_____

Physician Date

NOTE TO PHYSICIAN:

It is strongly recommended that you retain a signed copy of the Patient/Physician Acknowledgment Form with the patient's medical records.

SUPPLY OF PATIENT/PHYSICIAN ACKNOWLEDGMENT FORMS:

A supply of "Patient/Physician Acknowledgment" Forms as printed above is available, free of charge, on our website, https://vionausa.com/products/felbamate-tablets-usp/, or may be obtained by calling 1-888-304-5011. Permission to use the above Patient/Physician Acknowledgment Form by photocopy reproduction is also hereby granted by Viona Pharmaceuticals Inc.

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