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877 **Medication Guide**

878 **FELBATOL (Fel-ba-taal)**

879 **(felbamate)**

880 **Tablets and Oral Suspension**

881 IS-00431-01

Rev. 7/11

882 Read this Medication Guide before you start taking FELBATOL and each time you get a refill.
883 There may be new information. This information does not take the place of talking to your
884 healthcare provider about your medical condition or treatment.

885

886 **What is the most important information I should know about FELBATOL?**

887 **Do not stop taking FELBATOL without first talking to your healthcare provider.**

888 **Stopping FELBATOL suddenly can cause serious problems.**

889

890 FELBATOL can cause serious side effects, including:

891 **1. FELBATOL may cause serious blood problems that may be life-threatening.**

892 **Call your healthcare provider right away if you have any of the following symptoms:**

893 • Fever, sore throat or other infections that come and go or do not go away

894 • Frequent infections or an infection that does not go away

895 • Easy bruising

896 • Red or purple spots on your body

897 • Bleeding gums or nose bleeds

898 • Severe fatigue or weakness

899

900 **2. Liver problems that may be life-threatening. Call your healthcare provider right**
901 **away if you have any of these symptoms:**

902 • yellowing of your skin or the whites of your eyes (jaundice)

903 • dark urine

904 • nausea or vomiting

905 • loss of appetite

906 • pain on the right side of your stomach (abdomen)

907

908 **3. Like other antiepileptic drugs, FELBATOL may cause suicidal thoughts or actions**
909 **in a very small number of people, about 1 in 500.**

910 **Call your healthcare provider right away if you have any of these symptoms,**
911 **especially if they are new, worse, or worry you:**

- 912 • thoughts about suicide or dying
- 913 • attempts to commit suicide
- 914 • new or worse depression
- 915 • new or worse anxiety
- 916 • feeling agitated or restless
- 917 • panic attacks
- 918 • trouble sleeping (insomnia)
- 919 • new or worse irritability
- 920 • acting aggressive, being angry, or violent
- 921 • acting on dangerous impulses
- 922 • an extreme increase in activity and talking (mania)
- 923 • other unusual changes in behavior or mood

924 **How can I watch for early symptoms of suicidal thoughts and actions?**

- 925 • Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts,
926 or feelings.
- 927 • Keep all follow-up visits with your healthcare provider as scheduled.

928 Call your healthcare provider between visits as needed, especially if you are worried about
929 symptoms.

930 **Do not stop FELBATOL without first talking to a healthcare provider.**

931 Stopping FELBATOL suddenly can cause serious problems. You should talk to your healthcare
932 provider before stopping. Stopping a seizure medicine suddenly in a patient who has epilepsy
933 can cause seizures.

934 Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal
935 thoughts or actions, your healthcare provider may check for other causes.

936

937 **What is FELBATOL?**

938 FELBATOL is a prescription medicine used when other treatments have failed in:

- 939 • adults alone or with other medicines to treat:

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940 ▪ partial seizures with and without generalization

941 • children with other medicines to treat:

942 ▪ seizures associated with Lennox-Gastaut syndrome

943

944 **Who should not take FELBATOL?**

945 **Do not take FELBATOL if you:**

946 • are allergic to felbamate, carbamates or any of the ingredients in FELBATOL. See the
947 end of this Medication Guide for a complete list of ingredients in FELBATOL.

948 • have or have had blood problems

949 • have or have had liver problems

950 **What should I tell my healthcare provider before taking FELBATOL?**

951 **Before you take FELBATOL, tell your healthcare provider if you:**

952 • have kidney problems

953 • have or have had depression, mood problems, or suicidal thoughts or behavior

954 • have any other medical conditions

955 • are pregnant or plan to become pregnant. It is not known if FELBATOL can harm your
956 unborn baby. Tell your healthcare provider right away if you become pregnant while
957 taking FELBATOL. You and your healthcare provider will decide if you should take
958 FELBATOL while you are pregnant.

959 ▪ If you become pregnant while taking FELBATOL, talk to your healthcare provider
960 about registering with the North American Antiepileptic Drug (NAAED) Pregnancy
961 Registry. The purpose of this registry is to collect information about the safety of
962 antiepileptic medicine during pregnancy. You can enroll in this registry by calling
963 1-888-233-2334.

964 • are breastfeeding or plan to breastfeed. FELBATOL may pass into your breast milk. You
965 and your healthcare provider should decide if you should take FELBATOL while you
966 breastfeed.

967

968 **Tell your healthcare provider about all the medicines you take**, including prescription
969 and non-prescription medicines, vitamins, and herbal supplements.

970 Taking FELBATOL with certain other medicines can cause side effects or affect how well they
971 work. Do not start or stop other medicines without talking to your healthcare provider.

972 Know the medicines you take. Keep a list of them and show it to your healthcare provider and
973 pharmacist when you get a new medicine.

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975 **How should I take FELBATOL?**

- 976 • Take FELBATOL exactly as your healthcare provider tells you. Your healthcare provider
977 will tell you how much FELBATOL to take and when to take it.
- 978 • Your healthcare provider may change your dose of FELBATOL. Do not change your dose
979 of FELBATOL without talking to your healthcare provider.
- 980 • Because of the risk of serious blood and liver problems, your healthcare provider may do
981 blood tests before you start and while you take FELBATOL.
- 982
- 983 • If you take too much FELBATOL, call your healthcare provider or local Poison Control
984 Center right away.
- 985
- 986 • Do not stop FELBATOL without first talking to your healthcare provider.

987 **What should I avoid while taking FELBATOL?**

- 988 • FELBATOL can cause drowsiness and dizziness. Do not drink alcohol or take
989 other medicines that make you sleepy or dizzy while taking FELBATOL, until you
990 talk with your doctor. Taking FELBATOL with alcohol or drugs that cause
991 sleepiness or dizziness may make your sleepiness or dizziness worse.

992 **What are the possible side effects of FELBATOL?**

993 See **“What is the most important information I should know about FELBATOL?”**

994 **FELBATOL may cause serious side effects including:**

995 The most common side effects of FELBATOL include:

- 996 • weight loss
997 • vomiting
- 998 • trouble sleeping
- 999 • nausea
- 1000 • dizziness
- 1001 • sleepiness
- 1002 • headache
- 1003 • double-vision
- 1004 • changes in the way that food tastes

1005 These are not all the possible side effects of FELBATOL. For more information, ask your
1006 healthcare provider or pharmacist.

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1008 Tell your healthcare provider if you have any side effect that bothers you or that does not go
1009 away.

1010

1011 **Call your doctor for medical advice about side effects. You may report side effects to**
1012 **FDA at 1-800-FDA-1088.**

1013

1014 **How should I store FELBATOL?**

1015 • Store FELBATOL at room temperature between 68°F to 77°F (20°C to 25°C).

1016 **Keep FELBATOL and all medicines out of the reach of children.**

1017 **General information about FELBATOL.**

1018 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
1019 Do not use FELBATOL for a condition for which it was not prescribed. Do not give FELBATOL to
1020 other people, even if they have the same symptoms that you have. It may harm them.

1021

1022 This Medication Guide summarizes the most important information about FELBATOL. If you
1023 would like more information, talk with your healthcare provider. You can ask your pharmacist or
1024 healthcare provider for information about FELBATOL that is written for health professionals.

1025 **What are the ingredients in FELBATOL?**

1026 **Active Ingredient:** felbamate

1027 **Tablet Inactive Ingredients:** starch, microcrystalline cellulose, croscarmellose sodium,
1028 lactose, magnesium stearate, FD&C Yellow No. 6, D&C Yellow No. 10, and FD&C Red No. 40
1029 (600 mg tablets only).

1030 **Suspension Inactive Ingredients:** sorbitol, glycerin, microcrystalline cellulose,
1031 carboxymethylcellulose sodium, simethicone, polysorbate 80, methylparaben, saccharin sodium,
1032 propylparaben, FD&C Yellow No. 6, FD&C Red No. 40, flavorings, and purified water.

1033 For more information, go to www.FELBATOL.com or call 1-800-526-3840.

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1036 This Medication Guide has been approved by the U.S. Food and Drug Administration.

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