Before Prescribing Felbatol® (felbamate), the physician should be thoroughly familiar with the details of this prescribing information. Felbatol® SHOULD NOT BE USED BY PATIENTS UNTIL THERE HAS BEEN A COMPLETE DISCUSSION OF THE RISKS AND THE PATIENT, PARENT, OR GUARDIAN HAS BEEN PROVIDED THE FELBATOL WRITTEN ACKNOWLEDGMENT (SEE PATIENT/PHYSICIAN ACKNOWLEDGMENT FORM).

The mechanism by which felbamate exerts its anticonvulsant activity is unknown, but in animal test systems designed to study anticonvulsant activity, felbamate is active in both electroshock-induced and maximal electroshock-induced seizures. Felbatol® is effective in the electroshock-induced seizure test in rats and in the maximal electroshock test in mice.

2. EVALUATION OF MARKETED EXPERIENCE

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maximal electroshock-induced seizures suggests that felbamate may reduce seizure spread, an effect possibly predictive of efficacy in general tonic-clonic or partial seizures. Protection against pentyleneetetrazol-induced seizures suggests that felbamate may also reduce the propagation of seizures. Felbatol® is effective in the pentylenetetrazol-induced seizure test, and this test has been used to evaluate the anti-epileptic activity of a variety of new drug candidates.

In a 28-day double-blind placebo-controlled trial, the primary efficacy variable was the percentage of patients in each treatment group who met escape criteria. In the Felbatol® and placebo groups, 14% (26/189) and 14% (26/187), respectively, of the patients met escape criteria.

FELBATOL® Monotherapy Therapy in Adults

FELBATOL® should be administered as single 400 mg tablets as needed to control seizures. The recommended initial dose is 400 mg twice a day with meals. If needed, the dosage may be increased by 400 mg at weekly intervals up to a maximum of 3,600 mg/day in divided doses.
The complete text of the Medication Guide is reprinted at the end of this document.

When efficacy was analyzed by gender in four well-controlled trials of felbamate as adjunctive and monotherapy for partial-onset seizures and Lennox-Gastaut syndrome, a similar response was seen in 122 males and 142 females.

INDICATIONS AND USAGE

Felbamate is not indicated as a first line antiepileptic treatment (see Warnings). Felbamate is recommended for use only in those patients who respond inadequately to alternative treatments and whose epilepsy is so severe that a substantial risk of convulsive status epilepticus and other drug therapy-related complications is present. If these criteria are met and the patient has been fully advised of the risk and has provided written acknowledgment, Felbatol® can be considered for either monotherapy or adjunctive therapy in the treatment of partial seizures, with and without secondary generalization, and in the treatment of Lennox-Gastaut syndrome children.

CONTRAINdications

Felbatol® is contraindicated in patients with known hypersensitivity to Felbatol®, its ingredients, or known sensitivity to other carbamates.

It should not be used in patients with a history of any blood dyscrasia or hepatic dysfunction.

WARNings

See Warnings regarding aplastic anemia and hepatic failure.

Antiepileptic drugs should not be suddenly discontinued because of the possibility of increasing seizure frequency.

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including Felbatol®, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of suicidal thoughts or behavior. All patients being treated with Felbatol® should be observed for clinical indications of suicidal ideation and behavior, such as a change in mood or interest, loss of interest in previously enjoyed activities, or talk of suicidal ideation.

Pooled analyses of 198 placebo-controlled clinical trials (monoh- and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.9, 95% CI 1.7 to 2.2) of being treated with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk of suicide is a class effect of AEDs.

Patients should be advised to report any symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal ideation, plan, or behavior, to their health care provider at once.

Use of Felbatol® in pregnant women and children under 18 years of age has been reported.

Specific Effects of Felbatol® on Other Antiepileptic Drugs:

Felbatol® causes an increase in steady-state phenytoin concentrations. In 10 other healthy subjects treated with phenytoin, the steady-state Cmin concentration was increased from 21.8±3.8 to 35.4±7.4 micrograms/mL and the time to reach steady-state increased from 10.5±2.1 days to 16.1±2.6 days. In 13 other patients treated with phenytoin, the steady-state Cmin concentration increased from 31.5±5.1 to 47.3±9.8 micrograms/mL and the time to reach steady-state increased from 11.3±2.5 days to 19.0±4.0 days. In 12 other patients treated with phenytoin, the steady-state Cmin concentration increased from 1.9±0.6 to 3.3±0.9 micrograms/mL and the time to reach steady-state increased from 0.6±0.1 days to 1.8±0.4 days, with the addition of felbamate.

In clinical trials, similar changes in carbamazepine and phenobarbital were seen.

Felbatol®: It appears that phenobarbital may reduce plasma felbamate concentrations. Steady-state plasma felbamate concentrations decreased in studies of patients taking felbamate with other AEDs; effects of AEDs on trough felbamate levels were not reported.

Effects of Antiepilptic Drugs on Felbatol®:

Felbatol® does not appear to affect the steady-state plasma concentrations of carbamazepine, phenytoin, and phenobarbital.

Phenobarbital: It appears that phenobarbital may increase plasma felbamate concentrations. Steady-state plasma felbamate concentrations increased in studies of patients taking felbamate with other AEDs; effects of AEDs on trough felbamate levels were not reported.

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ADVERSE REACTIONS

To report SUSPECTED ADVERSE REACTIONS, contact Mea Pharmaceuticals Inc. at 1-800-567-2204 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

The most common adverse reactions seen in association with Felbatol® (felbamate) in adults during monotherapy are anorexia, vomiting, insomnia, nausea, and headache. The most common adverse reactions seen in association with Felbatol® in adults during adjunctive therapy are anorexia, vomiting, insomnia, headache, somnolence, and headache.

The most common adverse reactions seen in association with Felbatol® in children during adjunctive therapy are anorexia, vomiting, insomnia, headache, and somnolence.

The dropout rate because of adverse experiences or intercurrent illnesses among adult felbamate patients was 12 percent (120/97). The dropout rate because of adverse experiences or intercurrent illnesses among pediatric felbamate patients was six percent (22/357). In adults, the body systems associated with causing these withdrawals in order of frequency were: digestive (4.3%), psychologic (0.2%), whole body (1.1%), neurological (0.5%), and dermatologic (1.5%). In children, the body systems associated with causing these withdrawals in order of frequency were: digestive (1.7%), neurological (1.4%), dermatologic (1.1%), and whole body (1.0%). In adults, specific events with an incidence of 1% or greater associated with causing these withdrawals, in order of frequency were: rash (1.4%), nausea (0.5%), and weight decrease (1.0%). In children, specific events with an incidence of 1% or greater associated with causing these withdrawals, in order of frequency were: rash (1.4%), nausea (0.5%), and weight decrease (1.0%).

Incidence in Clinical Trials:
The prescriber should be aware that the figures cited in the following table cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those prevalent in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different investigators, treatments, and uses including the use of Felbatol® (felbamate) as adjunctive therapy where the incidence of adverse events may be higher due to drug interactions. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence rate in the population studied.

Incidence in Controlled Clinical Trials – Monotherapy Studies in Adults:
The table that follows enumerates adverse events that occurred at an incidence of 2% or more among 58 adult patients who received Felbatol® (felbamate) therapy at dosages of 3800 mg/day in double-blind controlled trials. Table 3 presents reported adverse events that were classified using standard WHO-based dictionary terminology.
Dosage Adjustment in the Renally Impaired: Felbatol® may be used with caution in patients with renal dysfunction. In the renally impaired, starting and maintenance doses should be reduced by one-half (see CLINICAL PHARMACOLOGY/Pharmacodynamics and PRECAUTIONS). Adjunctive therapy with medications which affect felbamate plasma concentrations, especially AEDs, may warrant further reductions in felbamate daily doses in patients with renal dysfunction.

Adults (14 years of age and over)

The majority of patients received 3600 mg/day in clinical trials evaluating its use as both monotherapy and adjunctive therapy.

Monotherapy: Initiate Felbatol® (felbamate) has not been systematically evaluated as initial monotherapy. Initiate Felbatol® at 1200 mg/day in divided doses three or four times daily. The prescriber is advised to titrate previously untreated patients under close clinical supervision, increasing the dosage in 600-mg increments every 2 weeks to 2400 mg/day based on clinical response thereafter to felbamate clinically indicated.

Conversion to Monotherapy: Initiate Felbatol® at 1200 mg/day in divided doses three or four times daily. Reduce the dosage of concomitant AEDs by one-third at initiation of Felbatol® therapy. At week 2, increase the Felbatol® dosage to 2400 mg/day while reducing the dosage of other AEDs up to an additional one-third of their original dosage. At week 3, increase the Felbatol® dosage up to 3600 mg/day and continue to reduce the dosage of other AEDs as clinically indicated.

Adjuvantive Therapy: Felbatol® should be added to the daily dose of other AEDs in increments of 15 mg/kg/day as clinically indicated; do not exceed 45 mg/kg/day. Felbatol® may be reduced as the dosage of concomitant AEDs is decreased. Most side effects seen during Felbatol® adjunctive therapy resolve as the dosage of concomitant AEDs is decreased.

Table 6 Dosage Table (adults)

<table>
<thead>
<tr>
<th>Dosage reduction of concomitant AEDs</th>
<th>WEEK 1: REDUCE original dose by 20-30%*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Felbatol® dosage</td>
<td>1200 mg/day initial dose</td>
</tr>
<tr>
<td></td>
<td>2400 mg/day therapeutic dosage range</td>
</tr>
<tr>
<td></td>
<td>3600 mg/day Therapeutic dosage range</td>
</tr>
</tbody>
</table>

*See Adjunctive and Conversion to Monotherapy sections.

While the above Felbatol® conversion guidelines may result in a Felbatol® 3600 mg/day dose within 3 weeks, in some patients titration to a 3600 mg/day Felbatol® dose has been achieved in as little as 3 days with appropriate adjustment of other AEDs.

Children with Lennox-Gastaut Syndrome (Ages 2–14 years)

Adjuvantive Therapy: Felbatol® should be added at 15 mg/kg/day in divided doses three or four times daily while reducing present AEDs by 20% in order to control plasma levels of concurrent phenytoin, valproic acid, phenobarbital, and carbamazepine and its metabolites. Further reductions of the concomitant AEDs dosage may be necessary to minimize side effects due to drug interactions. Increase the dosage of Felbatol® by 15 mg/kg/day increments at weekly intervals to 45 mg/kg/day. Most side effects seen during Felbatol® adjunctive therapy resolve as the dosage of concomitant AEDs is decreased.

HOW SUPPLIED

Felbatol® (felbamate) Tablets, 400 mg, are yellow, scored, capsule-shaped tablets, debossed 0430 on one side and FELBATOL 400 on the other; available in bottles of 100 (NDC 0037-0430-01). Felbatol® (felbamate) Tablets, 600 mg, are peach-colored, scored, capsule-shaped tablets, debossed 0431 on one side and FELBATOL 600 on the other; available in bottles of 100 (NDC 0037-0431-01). Felbatol® Oral Suspension, 600 mg in 5 mL, is peach-colored, available in 8 or 32 oz bottles (NDC 0037-0442-67) and 32 oz bottles (NDC 0037-0442-17). Shake suspension well before using. Store at controlled room temperature 20°–25°C (68°–77°F). Dispense in tight container.

To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-800-526-3840 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

PATIENT/PHYSICIAN ACKNOWLEDGMENT FORM

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

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

IMPORTANT INFORMATION AND WARNING:

Felbatol®, 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 ACKNOWLEDGMENT:

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 [Name of Patient], understand that Felbatol® is used to treat certain types of seizures and my physician has told me that I have this type of seizure.

INITIALS: [ ]

1. [ ] 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: [ ]

7. [ ] 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: [ ]

Physician: [ ]

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 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: [ ]

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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.

In the nature and purpose of the treatment with Felbatol® (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: [ ]

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SUPPORT OF PATIENT/PHYSICIAN ACKNOWLEDGMENT FORMS:

A supply of “Patient/Physician Acknowledgment” Forms as printed above is available, free of charge, from your local MEDA Pharmaceuticals representative, or may be obtained by calling 1-800-526-3840. Permission to use the above Patient/Physician Acknowledgment Form by photocopy reproduction is also hereby granted by MEDA Pharmaceuticals Inc.
Read this Medication Guide before you start taking FELBATOL and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

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

Do not stop taking FELBATOL without first talking to your healthcare provider. Stopping FELBATOL suddenly can cause serious problems.

FELBATOL can cause serious side effects, including:

1. FELBATOL may cause serious blood problems that may be life-threatening. Call your healthcare provider right away if you have any of the following symptoms:
   - Fever, sore throat or other infections that come and go or do not go away
   - Frequent infections or an infection that does not go away
   - Easy bruising
   - Red or purple spots on your body
   - Bleeding gums or nose bleeds
   - Severe fatigue or weakness

2. Liver problems that may be life-threatening. Call your healthcare provider right away if you have any of these symptoms:
   - Yellowing of your skin or the whites of your eyes (jaundice)
   - Dark urine
   - Nausea or vomiting
   - Loss of appetite
   - Pain on the right side of your stomach (abdomen)

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

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

- Thoughts about suicide or dying
- New or worse depression
- Attempts to commit suicide
- Feeling agitated or restless
- New or worse anxiety
- Panic attacks
- New or worse irritability
- Acting aggressive, being angry, or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood

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

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Do not stop FELBATOL without first talking to a healthcare provider. Stopping FELBATOL suddenly can cause serious problems. You should talk to your healthcare provider before stopping. Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures.

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

What is FELBATOL?

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

- Adults alone or with other medicines to treat:
  - Partial seizures with and without generalization
- Children with other medicines to treat:
  - Seizures associated with Lennox-Gastaut syndrome

Who should not take FELBATOL?

Do not take FELBATOL if you:

- Are allergic to felbamate, carbamates or any of the ingredients in FELBATOL.
- Have or have had blood problems
- Have or have had liver problems

What should I tell my healthcare provider before taking FELBATOL?

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

- Have kidney problems
- Have or have had depression, mood problems, or suicidal thoughts or behavior
- Have any other medical conditions
- Are pregnant or plan to become pregnant. It is not known if FELBATOL can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking FELBATOL. You and your healthcare provider will decide if you should take FELBATOL while you are pregnant.
  - If you become pregnant while taking FELBATOL, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- Are breastfeeding or plan to breastfeed. FELBATOL may pass into your breast milk. You and your healthcare provider should decide if you should take FELBATOL while you breastfeed.
Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking FELBATOL with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

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

**How should I take FELBATOL?**

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

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

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

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

See “What is the most important information I should know about FELBATOL?” FELBATOL may cause serious side effects including:

The most common side effects of FELBATOL include:

- weight loss
- trouble sleeping
- sleepiness
- vomiting
- nausea
- headache
- changes in the way that food tastes
- dizziness
- double-vision

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

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

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

**How should I store FELBATOL?**

- Store FELBATOL at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep FELBATOL and all medicines out of the reach of children.

**General information about FELBATOL.**

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

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

**What are the ingredients in FELBATOL?**

**Active Ingredient:** felbamate

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

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

For more information, go to www.FELBATOL.com or call 1-800-526-3840. This Medication Guide has been approved by the U.S. Food and Drug Administration. MEDA Pharmaceuticals Inc., Somerset, NJ 08873 FELBATOL is a registered trademark of Meda Pharmaceuticals Inc.

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