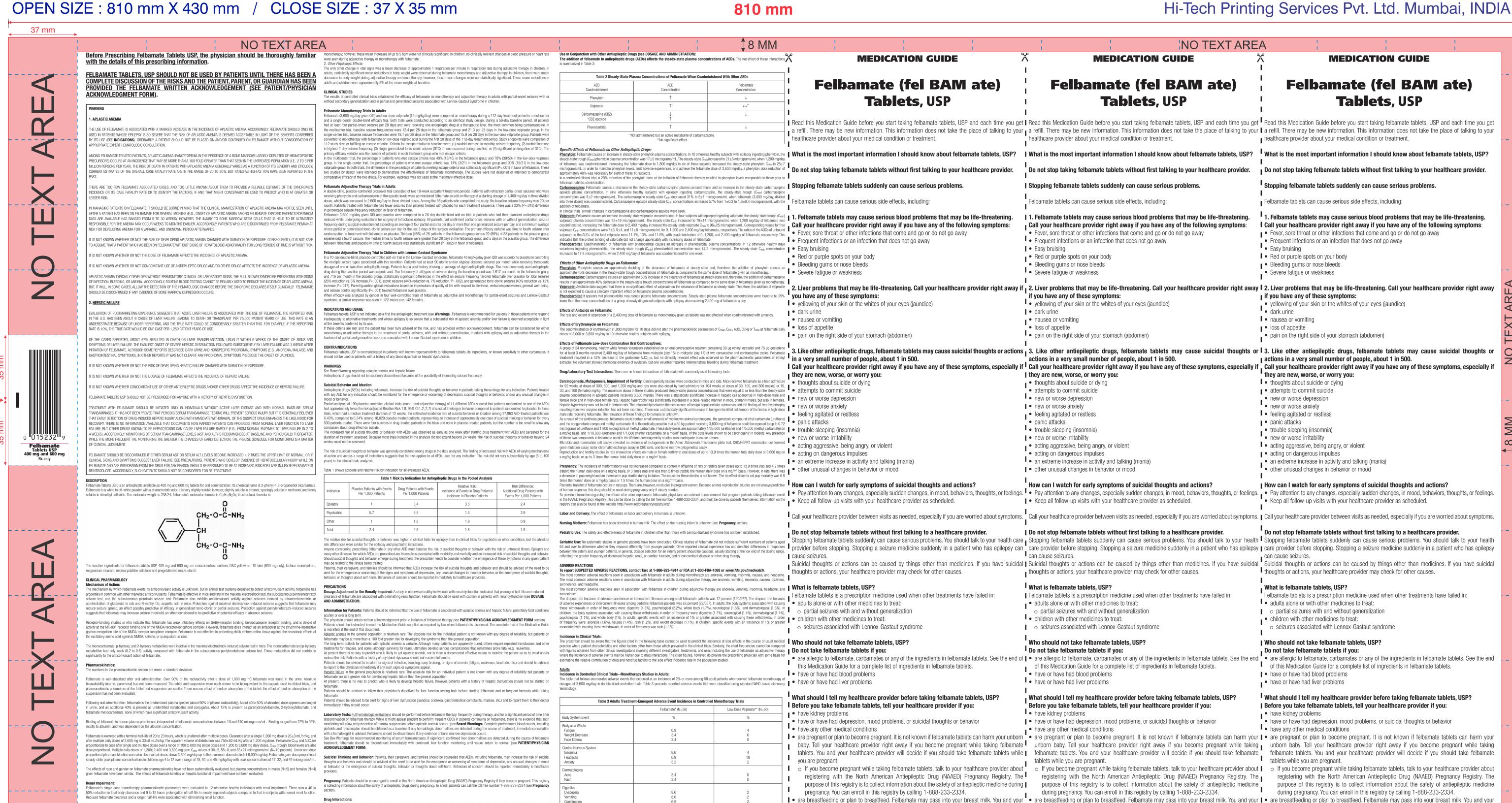
The drug interaction data described in this section were obtained from controlled clinical trials and studies involving otherwise healthy adults with epilepsy.

healthcare provider should decide if you should take felbamate tablets while you breastfeed.

'NO TEXT AREA



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healthcare provider should decide if you should take felbamate tablets while you breastfeed.

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I I I I I I I I I I I I I I I I I I I	NO¦TEXT AREA¦	I I	\$8 MM	I I	I.	1	1	ı N	NO TEXT AREA
		Tell your healthcare provider about all the medicines you take, including prescription and ₩	Metabolic/Nutritional	1 1		Vernities	20.7	14.9	PATIENT/PHYSICIAN ACKNOWLEDGMENT FORM
rescription medicines, vitamins, and herbal supplements.	non-prescription medicines, vitamins, and herbal supplements.	non-prescription medicines, vitamins, and herbal supplements.	Hypophosphatemia	3.4	0	Vomiting	12.9	14.8	
	Taking felbamate tablets with certain other medicines can cause side effects or affect how well	Taking felbamate tablets with certain other medicines can cause side effects or affect how well they	Respiratory Upper Respiratory Tract Infection	8.6	4	Hiccup	9.7	3.7	FELBAMATE SHOULD NOT BE USED BY PATIENTS UNTIL THERE HAS BEEN A COMPLETE DISCUSSION OF THE RISKS.
		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	Rhinitis Special Senses	6.9	0	Nausea	6.5	0	All patients treated with felbamate should acknowledge that they understand the risks and other
icist when you get a new medicine.		pharmacist when you get a new medicine.	Diplopia Otitis Media	3.4	4	Dyspepsia	6.5	3.7	information about felbamate discussed below, and physicians should acknowledge this discussion.
		ji i i i i i i i i i i i i i i i i i i	Urogenital	0.4		Hematologic			I Important information and warning:
	•	How should I take felbamate tablets, USP? • Take felbamate tablets exactly as your healthcare provider tells you. Your healthcare provider will	Intramenstrual Bleeding Urinary Tract Infection	3.4 3.4	0 2	Purpura	12.9	7.4	Felbamate, taken by itself or with other prescription and/or non-prescription drugs, can result in a
tell you how much felbamate tablets to take and when to take it.		tell you how much felbamate tablets to take and when to take it.	*3,600 mg/day; **15 mg/kg/day			Leukopenia	6.5	0	severe, potentially fatal blood abnormality ("aplastic anemia") and/or severe, potentially fatal liver
,	Your healthcare provider may change your dose of felbamate tablets. Do not change your dose	 Your healthcare provider may change your dose of felbamate tablets. Do not change your dose of 	Incidence in Controlled Add-On Clinical Studi	ies in Adults: at an incidence of 2% or more among 114 adult patients who received felba	elbamate adjunctive therapy in add-on	Respiratory			damage.
bamate without talking to your healthcare provider.	of felbamate without talking to your healthcare provider.	felbamate without talking to your healthcare provider.	controlled trials at dosages up to 3,600 mg/day. Re Many adverse experiences that occurred during ac	eported adverse events were classified using standard WHO-based dictional djunctive therapy may be a result of drug interactions. Adverse experiences	onary terminology.	Upper Respiratory Tract Infection	45.2	25.9	PATIENT ACKNOWLEDGMENT:
use of the risk of serious blood and liver problems, your healthcare provider may do blood before you start and while you take felbamate tablets.	Because of the risk of serious blood and liver problems, your healthcare provider may do blood tests before you start and while you take felbamate tablets.	 Because of the risk of serious blood and liver problems, your healthcare provider may do blood tests before you start and while you take felbamate tablets. 	resolved with conversion to monotherapy, or with a	djustment of the dosage of other antiepileptic drugs.		Pharyngitis	9.7	3.7	Do not sign this form if there is anything you do not understand about the information
		If you take too much felbamate tablets, call your healthcare provider or local Poison Control Center	Table 4 Adults Tre	atment-Emergent Adverse Event Incidence in Controlled Add-On Tr	Trials	Coughing	6.5	0	you have received. Ask your doctor about anything you do not understand before you
r right away.	Center right away.	right away.		Felbamate	Placebo	Special Senses		-	initial any of the items below or sign this form.
stop felbamate tablets without first talking to your healthcare provider.	Do not stop felbamate tablets without first talking to your healthcare provider.	Do not stop felbamate tablets without first talking to your healthcare provider.		(N=114)	(N=43)	Otitis Media	9.7	0	My [My son, daughter, ward''s]
hould I avoid while taking felbamate tablets, USP?	What should I avoid while taking felbamate tablets, USP?	What should I avoid while taking felbamate tablets, USP?	Body System/Event	%	%		han those in the preceding tables, that occurred in a total of 977		treatment with felbamate has been personally explained to me by
nate tablets can cause drowsiness and dizziness. Do not drink alcohol or take other	Felbamate tablets can cause drowsiness and dizziness. Do not drink alcohol or take other	• Felbamate tablets can cause drowsiness and dizziness. Do not drink alcohol or take other	Body as a Whole			to telearate and that are reasonably associated with its use and observed in open-label and uncontrolled studies, the role of fellowers are classified within both contract extension and appropriate the contract of the cont	re presented. They are listed in order of decreasing frequency. namate in their causation cannot be reliably determined.	cy. Because the reports cite events	The following points of information, among others, have been specifically discussed and made clear
nes that make you sleepy or dizzy while taking felbamate tablets, until you talk with your	medicines that make you sleepy or dizzy while taking felbamate tablets, until you talk with your	medicines that make you sleepy or dizzy while taking felbamate tablets, until you talk with your	Fatigue	16.8	7	defined as those occurring on one or more occasions in at least 1 rare events are those occurring in fewer than 1/1.000 patients.	1/100 patients; infrequent adverse events are those occurring.	in 1/100 to 1/1,000 patients; and	
Taking felbamate tablets with alcohol or drugs that cause sleepiness or dizziness may your sleepiness or dizziness worse.	doctor. Taking felbamate tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.	doctor. Taking felbamate tablets with alcohol or drugs that cause sleepiness or dizziness may make your sleepiness or dizziness worse.	Fever	2.6	4.7	Event frequencies are calculated as the number of patients report Body as a Whole: Frequent: Weight increase, asthenia, malaise,			1. I, (Patient's Name),
our sieepiness or dizziness worse.	make your steepiness or dizziness worse.	make your steephness or dizziness worse.	Chest Pain	2.6	0	Cardiovascular: Frequent: Palpitation, tachycardia; Rare: suprav Central Nervous System: Frequent: Agitation, psychological dis	aventricular tachycardia.	,	understand that felbamate is used to treat certain types of seizures and my physician has told me
e the possible side effects of felbamate tablets, USP?		What are the possible side effects of felbamate tablets, USP?	Central Nervous System	20.0	0.2	<u>Digestive</u> : Frequent: SGOT increased; Infrequent: esophagitis, ap <u>Hematologic</u> : Infrequent: Lymphadenopathy, leukopenia, leukod	appetite increased; Rare: GGT elevated.		that I have this type(s) of seizures:
hat is the most important information I should know about felbamate tablets,	, , , , , , , , , , , , , , , , , , , ,	See "What is the most important information I should know about felbamate tablets,	Headache Somnolence	36.8	9.3	platelet disorder, agranulocytosis. Metabolic/Nutritional: Infrequent: Hypokalemia, hyponatrem		, , ,	INITIALS:
	USP?"	USP?"	Dizziness	18.4	14	phosphokinase increased. Musculoskeletal: Infrequent: Dystonia.			2. I understand that felbamate is being used because my seizures have not been satisfactorily
nate tablets may cause serious side effects including:	Felbamate tablets may cause serious side effects including:	Felbamate tablets may cause serious side effects including:	Insomnia	17.5	7	Dermatological: Frequent: Pruritus; Infrequent: urticaria, bullous Special Senses: Rare: Photosensitivity allergic reaction.	s eruption; Rare: buccal mucous membrane swelling, Stevens-	s-Johnson Syndrome.	treated with other antiepileptic drugs;
st common side effects of felbamate tablets include:	The most common side effects of felbamate tablets include:	The most common side effects of felbamate tablets include:	Nervousness	7	2.3	Postmarketing Adverse Event Reports:	According to the second of the	ataua and Aries	INITIALS:
	• weight loss	• weight loss	Tremor	6.1	2.3	Voluntary reports of adverse events in patients taking felbamate (have no causal relationship with the drug(s). These include the fol	following by body system:	since market introduction and may	3. I understand that there is a serious risk that I could develop aplastic anemia and/or liver failure,
miting uble sleeping	vomitingtrouble sleeping	vomiting trouble sleeping	Anxiety	5.3	4.7	Body as a Whole: neoplasm, sepsis, L.E. syndrome, SIDS, sudde Cardiovascular: atrial fibrillation, atrial arrhythmia, cardiac arre	rrest, torsade de pointes, cardiac failure, hypotension, hyperten	tension, flushing, thrombophlebitis,	both of which are potentially fatal, by using felbamate;
uble sleeping usea	• trouble sleeping • nausea	• trouble sleeping • nausea	Gait Abnormal	5.3	0	ischemic necrosis, gangrene, peripheral ischemia, bradycardia, H <u>Central & Peripheral Nervous System</u> : delusion, paralysis, m	mononeuritis, cerebrovascular disorder, cerebral edema, coma,		INITIALS:
	• dizziness	dizziness	Depression	5.3	0	paranoid reaction, nystagmus, choreoathetosis, extrapyramidal d apathy, concentration impaired. Dermatological: abnormal body odor, sweating, lichen planus, li		uysaruma, respiratory depression,	4. I understand that there are no laboratory tests which will predict if I am at an increased risk for
piness	• sleepiness	• sleepiness	Paraesthesia	3.5	2.3	Digestive: (Refer to WARNINGS) hepatitis, hepatic failure, G flatulence, gingival bleeding, acquired megacolon, ileus, intestina	G.I. hemorrhage, hyperammonemia, pancreatitis, hematemes		
dache ble-vision	headache double-vision	headachedouble-vision	Ataxia	3.5	0	dilatation, gastroesophageal reflux. Fetal Disorders: fetal death, microcephaly, genital malformation		agra, jauridioo, gastrio dioor, gastrio	INITIALO.
	changes in the way that food tastes	changes in the way that food tastes	Mouth Dry	2.6	0	Hematologic: (Refer to WARNINGS) increased and decreased pr syndrome, increased mean corpuscular volume (mcv) with and	prothrombin time, anemia, hypochromic anemia, aplastic anemia		o. I diladiotalia tilat i oliodia fiavo tilo rocommonaca bioda work boloro my troatmont with robbamato
		I	Stupor	2.6	0	eosinophilia, hemolytic anemia, leukemia, including myelogenous Metabolic/Nutritional: hypernatremia, hypoglycemia, SIADH, hy			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
		These are not all the possible side effects of felbamate tablets. For more information, ask your	Dermatological			Musculoskeletal: arthralgia, muscle weakness, involuntary mus Respiratory: dyspnea, pneumonia, pneumonitis, hypoxia, epista	axis, pleural effusion, respiratory insufficiency, pulmonary hemor	norrhage, asthma.	significant, irreversible and potentially fatal damage has already occurred;
		healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.	Rash	3.5	4.7	Special Senses: hemianopsia, decreased hearing, conjunctivitis Urogenital: menstrual disorder, acute renal failure, hepatorenal s		morrhage, abnormal renal function,	INITIALS:
	1		Digestive			dysuria, placental disorder. DRUG ABUSE AND DEPENDENCE			6. If I am currently taking other antiepileptic drugs, I understand that the manufacturer of felbamate
		Call your doctor for medical advice about side effects. You may report side effects to FDA	Nausea	34.2	2.3	Abuse: Abuse potential was not evaluated in human studies. Dependence: Rats administered felbamate orally at doses 8.3 ti	times the recommended human does 6 days each week for F	5 consecutive weeks demonstrated	recommends that the dosage of these other drugs be decreased by a certain amount when
at 1-800-FDA-1088.	FDA at 1-800-FDA-1088.	at 1-800-FDA-1088.	Vomiting	19.3	4.7	no signs of physical dependence as measured by weight loss folk		o consecutive weeks demonstrated	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;
should I store felbamate tablets, USP?	How should I store felbamate tablets, USP?	How should I store felbamate tablets, USP?	Dysnensia	12.3	7	OVERDOSAGE Four subjects inadvertently received felbamate as adjunctive there	rapy in dosages ranging from 5.400 to 7.200 mg/day for dura	ations between 6 and 51 days. One	INITIALS:
ore felbamate tablets at room temperature between 68°F to 77°F (20°C to 25°C).		• Store felbamate tablets at room temperature between 68°F to 77°F (20°C to 25°C).	Constipation	11.4	2.3	subject who received 5,400 mg/day as monotherapy for 1 week refelbamate in a 12-hour period. The only adverse experiences report	reported no adverse experiences. Another subject attempted su	suicide by ingesting 12,000 mg of	
		, , , , , , , , , , , , , , , , , , ,	Diarrhea	5.3	2.3	have been reported. General supportive measures should be emp	ployed if overdosage occurs. It is not known if felbamate is dial	alyzable.	7. I understand that I must immediately report any unusual symptoms to Drand be especially aware of any rashes, easy bruising,
o felbamate tablets and all medicines out of the reach of children.	Keep felbamate tablets and all medicines out of the reach of children.	Keep felbamate tablets and all medicines out of the reach of children.	Abdominal Pain	Abdominal Pain 5.3 0 DOSAGE AND ADMINISTRATION Felbamate has been studied as monotherapy and adjunctive therapy in adults and as adjunctive therapy in children with seizures associated with Lennox-Gastaut bleeding, sore throats, fever, and/or dark urine;	bleeding, sore throats, fever, and/or dark urine;				
eral information about felbamate tablets.	General information about felbamate tablets.	General information about felbamate tablets.	SGPT Increased	3.5	0	syndrome. As felbamate is added to or substituted for existing AE to minimize side effects (see Drug Interactions subsection).	.Ds, it is strongly recommended to reduce the dosage of those	se AEDs in the range of 20 to 33%	NITIALS:
	· · · · ·	Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.	Musculoskeletal			Dosage Adjustment in the Renally Impaired: Felbamate sh	nould be used with caution in patients with renal dysfunction	n. In the renally impaired, starting	8. I understand that antiepileptic drugs such as felbamate may increase the risk of suicidal thoughts
· · · · · · · · · · · · · · · · · · ·	·	Do not use felbamate tablets for a condition for which it was not prescribed. Do not give felbamate	Myalgia	2.6	0	and maintenance doses should be reduced by one-half (see CLII medications which affect felbamate plasma concentrations, esp			
	tablets to other people, even if they have the same symptoms that you have. It may harm them. This Medication Guide symmatizes the most important information about felbamate tablets. If you	This Medication Guide summarizes the most important information about felbamate tablets. If you	Respiratory			dysfunction. Adults (14 years of age and over)			symptoms of depression or thoughts about self-harm to Dr
	would like more information, talk with your healthcare provider. You can ask your pharmacist or		Upper Respiratory Tract Infection	5.3	7	The majority of patients received 3,600 mg/day in clinical trials e Monotherapy: (Initial therapy) felbamate has not been systematis			INITIALS:
· · · · · · · · · · · · · · · · · · ·	<u> </u>	- Houriloure provider for information about following to table that to written for houril professionals.	Sinusitis	3.5	0	or four times daily. The prescriber is advised to titrate previously u every 2 weeks to 2,400 mg/day based on clinical response and ti	untreated patients under close clinical supervision, increasing th		
nore information call Taro at 1-866-923-4914.	For more information call Taro at 1-866-923-4914.	For more information call Taro at 1-866-923-4914.	Pharyngitis	2.6	0	Conversion to Monotherapy: Initiate felbamate at 1,200 mg/da at initiation of felbamate therapy. At week 2, increase the felbamate	day in divided doses three or four times daily. Reduce the dosage of		Patient, Parent, or Guardian
t are the ingredients in felbamate tablets USP, 400 mg and 600 mg?	What are the ingredients in felbamate tablets USP, 400 mg and 600 mg?	What are the ingredients in felbamate tablets USP, 400 mg and 600 mg?	Special Senses			of their original dosage. At week 3, increase the felbamate dosage Adjunctive Therapy: Felbamate should be added at 1,200 mg/da			
ve Ingredient: felbamate	Active Ingredient: felbamate	Active Ingredient: felbamate	Diplopia	6.1	0	plasma concentrations of concurrent phenytoin, valproic acid, phe dosage may be necessary to minimize side effects due to drug int	nteractions. Increase the dosage of felbamate by 1,200 mg/day	ay increments at weekly intervals to	o Telenhone
		1	Taste Perversion	6.1	0	3,600 mg/day. Most side effects seen during felbamate adjunctiv		reased.	
	Inactive Ingredients: croscarmellose sodium, D&C yellow no. 10 lake (600 mg only), lactose monohydrate, magnesium stearate, microcrystalline cellulose and pregelatinized maize starch.	monohydrate, magnesium stearate, microcrystalline cellulose and pregelatinized maize starch.	Vision Abnormal	5.3	2.3	MLEK 4	Table 6 Dosage Table (adults)	WEEK 3	PHYSICIAN STATEMENT:
onydrato, magnosiam otoarato, miorooryotainno oonalooo ana progolaamizoa maizo otalom	I	mononyurato, magnociam otoarato, microoryotamino contributo ana progotatimizoa maizo caron.	Children Incidence in a Controlled Add-On Trial in Chil			Dosage reduction of concomitant REDUCE original dose			I have fully explained to the patient,, the nature and purpose of the treatment with felbamate and the potential risks associated with that
Medication Guide has been approved by the U.S. Food and Drug Administration.	This Medication Guide has been approved by the U.S. Food and Drug Administration.	This Medication Guide has been approved by the U.S. Food and Drug Administration.		more than once among 31 pediatric patients who received felbamate up t sified using standard WHO-based dictionary terminology.	ρ to 45 mg/kg/day or a maximum of	Felbamate Dosage 1,200 mg/day Initial of	dose	3,600 mg/day	treatment. I have asked the patient if he/she has any questions regarding this treatment or the risks
by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761	Mfd by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761	Mfd by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761	Table 5 Children Treatment	-Emergent Adverse Event Incidence in Controlled Add-On Lennox-G	ux-Gastaut Trials	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		Therapeutic dosage range	and have answered those questions to the best of my ability. I also acknowledge that I have read and understand the prescribing information.
	Dist. by: Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532	Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532	Samuran maanifilt	Felbamate Felbamate	Placebo	*See Adjunctive and Conversion to Monotherapy sections.			
ed: June 2023	Revised: June 2023	Revised: June 2023		(N=31)	(N=27)	While the above felbamate conversion guidelines may result in a felbamate dose has been achieved in as little as 3 days with appr		atients titration to a 3,600 mg/day	
523-0623-02	5201523-0623-02	5201523-0623-02	Body System/Event	%	%	Children with Lennox-Gastaut Syndrome (Ages 2 to 14 yea	ears)		Physician Date
			Body as a Whole			Adjunctive Therapy: Felbamate should be added at 15 mg/kg/ control plasma levels of concurrent phenytoin, valproic acid, pher	g/day in divided doses three or four times daily while reducing penobarbital, and carbamazepine and its metabolites. Further red	eductions of the concomitant AEDs	Revised: June 2023
		' .	Fever	22.6	11.1	dosage may be necessary to minimize side effects due to drug int 45 mg/kg/day. Most side effects seen during felbamate adjunctiv			
		' .	Fatigue	9.7	3.7	HOW SUPPLIED Falhamata Tahlats LISP 400 mg ara white canlet channel function	tionally corred on one side energyed #FFF# # 1.0. ("	core line and #400" 45	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.
		! !	Weight Decrease	6.5	0	Felbamate Tablets USP, 400 mg are white, caplet shaped, function Engraved "Taro" on the other side; available in bottles of 30 (NDC Felbamate Tablets USP, 600 mg are yellowish, caplet shaped, function	C 51672-4185-6), 90 (51672-4185-5) and 100 (NDC 51672-4	2-4185-1).	
		!	Pain	6.5	0	Feibamate lablets USP, 600 mg are yellowish, caplet snaped, fun Engraved "Taro" on the other side; available in bottles of 30 (NDC			SUPPLY OF PATIENT/PHYSICIAN ACKNOWLEDGMENT FORMS: A supply of "Patient/Physician Acknowledgement" Forms as printed above is available, free of
		l '	Central Nervous System			Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Dispense in a tight container.	Temperature].		charge, from your local Taro Pharmaceuticals U.S.A., Inc.'s representative, or may be obtained
			Somnolence	48.4	11.1	To report SUSPECTED ADVERSE REACTIONS, contact Tai	aro Pharmaceuticals U.S.A., Inc. at 1-866-923-4914	or FDA at 1-800-FDA-1088 or	by calling customer service at 1-800-544-1449 or via download from Taro's website at www.
	! !	l		16.1	14.8	www.fda.gov/medwatch.	,		tarousa.com. Permission to use the above Patient/Physician Acknowledgment Form by photocopy reproduction is also hereby granted by Taro Pharmaceuticals U.S.A., Inc.
	 	 	Insomnia		18.5	Mfd by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 262 Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10			
	 	 	Nervousness	16.1			9532		
			Nervousness Gait Abnormal	9.7	0	Revised: June 2023 5201523-0623-02	U532		Mfd by: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 2624761
			Nervousness Gait Abnormal Headache	9.7 6.5	0 18.5	Revised: June 2023			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023
			Nervousness Gait Abnormal	16.1 9.7 6.5 6.5	3.7	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532
			Nervousness Gait Abnormal Headache Thinking Abnormal Ataxia	16.1 9.7 6.5 6.5 6.5	16.6	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023
			Nervousness Gait Abnormal Headache	16.1 9.7 6.5 6.5 6.5 6.5 6.5	3.7	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023
			Nervousness Gait Abnormal Headache Thinking Abnormal Ataxia Urinary Incontinence	16.1 9.7 6.5 6.5 6.5 6.5 6.5 6.5 6.5	3.7	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023
			Nervousness Gait Abnormal Headache Thinking Abnormal Ataxia Urinary Incontinence	16.1 9.7 6.5 6.5 6.5 6.5 6.5 6.5 6.5	3.7	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023
			Nervousness Gait Abnormal Headache Thinking Abnormal Ataxia Urinary Incontinence	16.1 9.7 6.5 6.5 6.5 6.5 6.5 6.5 6.5 9.7	3.7	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023
			Nervousness Gait Abnormal Headache Thinking Abnormal Ataxia Urinary Incontinence	16.1 9.7 6.5 6.5 6.5 6.5 6.5 6.5 9.7	3.7 3.7 7.4 0	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023
			Nervousness Gait Abnormal Headache Thinking Abnormal Ataxia Urinary Incontinence	16.1 9.7 6.5 6.5 6.5 6.5 6.5 6.5 6.5 9.7	3.7 3.7 7.4 0	Revised: June 2023 5201523-0623-02			Dist. by: Taro Pharmaceuticals U.S.A., Inc. , Hawthorne, NY 10532 Revised: June 2023