LAMOTRIGINE - lamonigiae tablet A-5 Medication Solutions

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FULL PRESCRIBING INFORMATION: CONTENTS* WARNING: SERIOUS SKIN RASHES INDECATIONS AND USAGE

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12.2 Pharmacolimeter 12.3 Pharmacolimeter IS NONCLINICAL TOXICOLOGY 12.1 Cartinogenesis, Mangenesis, Impairment of Fertility 12.1 Cartinogenesis, Mangenesis, Impairment of Fertility 14.1 CLINICAL STUDIES

14.2 Bipolar Disorder 16 HOW SUPPLIED STORAGE AND HANDLING 17 PATIENT COUNSELING INFORMATION Sections conductions entited from to fail

ULL PRESCRIBING INFORMATION NULTRESERVENCE NYOUNTED iearly all cases of life-threatening raches caused by lanstrigine have accurred within 2 to creaks af treatment inklution. However, isolated cases have occurred after prolonged reatment (e.g., 6 months). Accordingly, duration of therapy cannot be relied upon as sams to predict the potential risk heralided by the first appearance of a rach. Although benign raches are also caused by lamorrigine, it is not possible to predictiveliably which raches will prove to be verince or life threatwing. Accordingly, lamorrigine should ordinarily be discontinued at the first sign of rach, unless the rath is (barly not drug related. Discontinuation of transment may not prevent a rach from becoming life threatening life threatening.

I ROBEATIONS AND ESAGE LI Epilopy Adjourds: Thompy Lamaciging is indicated as adjunctive througy for the following seizure types in patients aged 2 years Lamorigine is indicated as adjunctive therapy for the following seizur and older: • partial-seases testizares. • primary generalized unic-closic seizures (PCTC) seizures. • generalized seizures of Lemon-Gamma syndrome. Monotherapy

tre, Discontinuation of treatment may not prevent a rash from termanently disabling or disfiguring [see WARNINGS AND P

Manatherapy Lamorigies is indicated for convection to memoherapy in addres (aged 16 years and older) with partial-coust incates who are receiving measurement with cardinataspine, phenytain, phenohashital, printidoos, or valprocate as the imple anticipited circle (AUS). dispute the range interplete data (MA) in the second strategies of the second strategies of the second strategies and the second strategies are also strategies of the second strategies of the sec

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sponyov For patient receiving lamostigine in combination with other AEDs, a re-evaluation of all AEDs in the regime should be considered if a change in seizure control or an appearance or wresening of adverse reactions in shourset.

To decision is made to discontinue therapy with lanorrigine, a step-wise reduction of dose over at least 2 versits (approximately 20% per week) is recommended takes safety concerns require a more rapid withdrawil (see WARNINGS AND PRECAUTIONS (5.8)).

Discretining carbamappine, phenytoin, phenotechian (1997). Discretining carbamappine, phenytoin, phenotechian (1997), phenotechian (199

An example of the first the second end of the se

Table 1 Escalation Regimen for Lamontgine in Patients Older than 12 Years with Epilepsy					
	In Patients TAKING Valoreate	In Patients NOT TAKING Carbamatenine, Phenytnin, Phenebarbital, Primidone ^k , or Valoreate [®]	in Patients TAKING Carbamateeine, Phenotoin, Phenotharbital, or Primidene ⁶⁴ and NOT TAKING Values are		
Hirels 1 and 2	25 me every other day	Zime every day	50 meidar		
Heeks 3 and 4	25 mg every day	50 mg/day	100 mg/day		
			En 2 divided down)		
week 5 centred to maintenance	Increase by 25 to 50 mg/day every 1 to 2 weeks.	Increase by 50 mgiday every 1 m 2 weeks.	Increase by 100 mg/day every 1 to 2 weeks.		
lead maintenance dose	100 to 200 mg/day with valpreate alone	225 to 375 mg/day	300 to 500 mgiday		
		(in 2 divided doses)	(in 2 divided down)		
	100 to 480 mg/day with valpreate and other drugs that induce glucuronidation				
	(in 1 or 2 divided doses)				

	Table 2 Excatation Regiment for Lamontigine in Patients Appel 2 to 12 Years with Epilepsy					
	In Patients TAKING Valproats*	In Patients NOT TAKING Carbamazepine, Phenytnin, Phenobarhital, er Primidone ^b , er Valpraate ^a	In Patients TAKING Carbamazepine, Phenytnin, Phenobarbital, or Primidone ¹⁶ and NOT TAKING Valproate ¹⁶			
Heeks 1 and 2	0.15 mg/kg/kgy in 1 or 2 di vide dones, rounded down to the macrost	0.1 ac_2 divided down, rounded down to the matters whole tablet	6.6 mg/kg/day in 2 divided does, readed downow the nearest whole tablet			
	in 1 or 2 or under doese, y consider doese, y co	is 1 or 2 divided doces, rounded down to the nearest whole tablet	in 2 divided does, subject do within the instruct whose tablet			
Hirela: 3 and 4	0.3 mg/kg/day	0.5 mg/kgitay	1.2 mg/kg/day			
	in 1 or 2 divided dozen, rounded down to the nearest	in 2 divided doses, rounded down to the nearest whole table t	in 2 divided doses, rounded downto the nearest whole tablet			
	whole ublet (see Table 3 for weight based doxing guide)					
wieek 5 coward to maintenance		The door should be increased every 1 to 2 weeks as follows: calculate 0.6 meAnitist: round this amount down to the nearest whole tablet, and add this amount to the revelously administered daily door.	The doso should be increased every 1 to 2 seeks as follow: calculate 1.2 markedays, cound this amount down to the nearest whole tables, and add this amount to the previously administered daily dose.			
Jaud maintenance dose	1 to 5 mg/kg/day (maximum 200 mg/day in 1 or 2 divided doses)	4.5 to 7.5 mg/kg/day	5 to 15 mg/kg/day (maximum 400 mg/day in 2 divided doses)			
	I to 3 mg/kg ktay with valprouse alone	(maximum 300 mg/day in 2 divided down)				
chaintenance dose in patients less than 30 kg	May need to be increased by as much as 50%,	May need to be increased by as much as 50%,	May need to be increased by as much as 50%,			
	based on clinical response.	based on clinical response.	hased on clinical response.			
None: Only whole table to should be used for						
*Valproate has been shown to inhibit glucur	onidation and decrease the apparent clearance of lamonigine [see DRUG INTERACTIONS (7), Pharmacokinetics (12.3)].					

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Conversion from Adjunctive Therapy with AEDs other than Cathamanpiles, Phenymin, Phensharthing, Phulidana, ar Valproate za Monachanagy with Lamonplate No specific during guidelines can be provided for convension to montherapy with lamorigize with AEDs other than chammerplate, phenymin, phensharthical, printidens, st valproate.

ALTS: other than characepies, phonehastics, providence, evolutions, 2.2. **Unput: Discost:** The goal of missionscore are some with harmorigins is on day part does no occurrence of mode phondes unput the source of mode phondes. The source of the source of mode phondes with mainted theory (so executions) and a source of the source of the source of the mode of a continuous control. The source of the Patients need for Adults

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If other drags are subsequently introduced, the dose of lamonigine may need to be adjusted. In particular, the introduction of valgeouse requires reduction in the dose of lamonigine [see BRUG INTERACTIONS (7), CLINICAL PHARMACOLOGY (12.3)].

To avoid an increased risk of rash, the recommended initial doss and subsequent dose escalations of lamonigine should not be exceeded [see **BOXED WARNING**].

 Table 1 Standber ligt part of standberge have been standberge have bee h Palem ne, Phenymin, Phenoharbini, or Primidoad 50 mg dulty. 100 mg dulty, individed disses 200 mg dulty, individed disses 300 mg dulty. Individed disses up to 400 mg dulty, in divided disses a viapicone tais test indoven in intensi gine gineericentaneon and circuise the apporter Contracts off-b Drugs that lades harming ing gineericedation and circuise chearace, dete than the comming crail contract patient, it imply, and the pressure inhibitors in logismitritionswir and Patients contribution and the prosessor inhibitor logismitritionsmir should follow the same di PAREMACOLIGY (12.21)-(d): rogen-ons for oral o r can be found in General Dosing Considerations [see DOSAGE AND ADMINISTRATION (2.1) # [see DOSAGE AND ADMINISTRATION (2.1), DRUG INTERACTIONS (7), and CLINICAL Table 3 Decoge Adjacements Lanneijen is kalas vili lipide Biorde Fallweig Bioreninaska el Psychemyd Modizaken
Decostinaska el Psychemyd Nego Specificat
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ade enzogen-mentations for coral commaceptives and the promose inhibitor azarametricitonaris cashe found in General Dosing Considerations [see DOSAGE AND ADMINIST RATION (2.1)] used with antisplippic drugs that indice ginc monidation and increase clearance [see DOSAGE AND ADMINIST RATION (2.1)] DRUG INTERACTIONS (7), and CLINICAL

PROBABLISHEST (22):19-39-20 Antibiothesis and association and the second seco

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4 CONTRAINDECATIONS Laravigine is commandizated in pairon: who have demonstrated hypervensitivity (e.g., rath, angiotedema, acute utricatio, somethic particular, acute data (e.g., rath, and binning, binning, starbing, end Proceeding (E.J.), (2.2).

and compared with a spectra of the spectra of the

Among the rather leading to hospitalization were Sowen-Johnson synthesize, angloedena, and a nuch associated with a variable number of the following systemic maintenzion: fever, lymphadenopathy, facial overling, and hemanlogic and hepanologic abnormaliae.

There is evidence that the inclusion of valproate in a milddrug regimen increases the risk of serious, powerally iffe-threamening rath in adults. Specifically, of 564 parkens administered lamorigine with valproate in epilepsy clinical strink, 6 (Vs) were hespitalized inaxoscitation with melt; in contrast, 4 (51/S)(of 2,200 clinical trial parkens and volumese administered lamorigine in the absence of (n. 15-6) del 2.2010 Chércá de na functiona de volumente à distitutione d'internet que servedifiel de disposante serve hospitatione. **Parisante del Baser y d'Allerge es Bach na Other ALEN**The risk of numericano milta mpi hiererand schende forezonne durade dissa andire due rato est disease calation for lamoritgine is exceeded and in patients with a history of allergy or rath no other ALED.

AEDs. 23 Midiogra Hypersensiblely Reactions and Organ Fahrer Middiogra Hypersensible (International Content on the second and the second and the second production of the second and the second and the second and the second and the production of the second and the second and

This encoder is variable in the appression, and other cogan system not noted new may be inverse Families associated with non-medicogan failures and variations despines of the panic failures have bee reported in 2 of 3,796 adult patients and 4 of 2,425 pediantic patients who received lamontigine in

Adverse reactions that occurred in at least 2% of particus toward with homotique and at a greater incidence that place 7 holeses in these adjustices traik wave receiving 1 is 3 of the concontant antisplaying design cathemateping, phengin phenological, in positions in additions to lanoning ine or place. Receives reached multiple adverse reaction during the tables at documination; thus, partents may be included in more than 1 category.

Fever	6	4
Abdominal pain	5	4
Neckpain	2	1
Reaction aggravated	2	1
(seizure exacerbation)		
Digestive		
Naurea	19	10
Vomiting	9	4
Diarrhea	6	4
Dyspepsia	5	2
Constipution	4	3
America	2	
Mux culo skele til		
Arthrolgia	2	0
Nervoux		
Dizziness	38	13
Atoxia	22	6
Somableace	14	7
accordination	6	2
ine cuia	6	2
Tremor	4	1
Depression	4	3
Amiety	4	3
Consulsion	3	1
mishiliny	3	2
Speech disorder	3	0
Concernation disturbance	2	1
Respiratory		
Rhinida	14	9
Pharymeids	10	9
Cough increased	1	6
Skin and apprendances		
Rath	20	5
Pracine	3	2
Special senses		
Diologia	21	7
Harred vision	16	6
Vision absormation	1	i.
Licogenical		
Female patients only	(#-365)	62-207)
Dysmemorrhea	7	6
Variotis		ī
Amenorrhea	2	

Approximately 11.2% of the 1,011 pediatic patients aged 2 to 16 years who received laworigine as adjuscrive therapy in premariseing clinical train discontinued treatment because of analysers reaction. The adverse reactions must commody associated with discontinuation were rash (4.4%), species aggreented (17.%) and assia (3.6%). agground (1, 7%), and anzia (0, 6%). Controlled Adjunctive Cheice Trickin Audits with Epilopy Table I line adverse moders of the control and patients with epilopy travand with latteringiae in placebic-controlled table. In these study, either latteringians ar placebic was added to the patients current ALD therapy. AD energy.
Table Makerse Roscience in Parish, Paraba Constanti, Carlo Bardin, Constanti, Carlo Makerse Roscience in Parish, Paraba Constanti, Table Makerse Roscience in Parish, Paraba Constanti, Parish, Carlo Martin, Carlo Mar

protine, and intensive. Association (3): the GD2 and in pattern who received functinging as a monitoring to generative classic at the discussion of semantic means of an adverse received. The discussion of the d now na, tototenus, tra syntrome, and diplopia. In 200 patients aged 2 to 16 years with particle const orienters or generalized orientered or Lennos-Gamma synthesis, 42% of patient on alarcenteringian and 29% orienters on placents on placets reactions. The most commonly reported adverse reaction that led to discontinued due to adverse reactions.

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The relative risk for waiched thoughts or behavior was higher in clinical trials for epilopay than in clinical trials for psychiatric or other conditions, but the absolute risk differences were similar for the epilopay and psychiatric indications. The second second

ratery, aptaetic merias and pure red c 54 Suicidal Behavior and Ideation

symptone cannot be examined. Peter in induction of rearments with lanearizinging, the pasient should be instructed that a rach or other signs are symptoms of hypercensibility (e.g., frees, hyperbalencepathy) may breach a verieum medical event and that the patient chould report any such occurrence to a healthcare provider insmediately. 5.3 Blood Dyscraelas Three have been reports of blood dyscraelas that may or may not be associated with the hypervensitivity syndrome. These have included neuropenia, headspecia, anemia, threehocytopenia, pancytopenia, and, results unducts sources not neuro real students.

nd liver failure without tash or involvement of other organs has also been reported with terms. namengone. It is importent to note that early matifestations of hypersonicisticy (e.g., fever, lymphadenopathy) may be present eventhough a rath is not evident. If such signs or rymptoms are present, the pulsent should be evaluated immediately. Lamonicipies chould be decontinued if an interactive ecidoxy for the signs or

In a randomized, parallel trial comparing placebo with 300 and 500 mg/day of lamonigine more common drug-related adverse reactions were done related (see Table 9). e Reactions from a Randomized, P Trial in Adults with Epilepsy - ----

	Percent of Patients Experiencing Adverse Reactions			
Adverse Reaction	Placebo (a = 73)	Lametrigine 300 mg (n = 71)	Lamotrigine 500 mg (a = 72)	
Annia	10	10	28',1	
Blarred vision	10	11	25*7	
Diplopia		24*	49*.7	
Oluziness	27	31	5457	
Nausea	11	18	25'	
Vomiting		11	18"	
independent of age. Because exposed to lamortigize inpla regarding the distribution of	cebo-comolied trials, t adverse reaction report	here are insufficient data by race. Generally, fem	to support a statement	
The only adverse reaction for females that males (without a (difference = 16.5%). There	er which the reports on 1 corresponding different was little difference be	monigine were greater ce by gender on placebo were femiles and miles	se reactions than males than 10% more frequer) was dispiness	
The only adverse reaction for females than males (without i (difference = 36.5%). There discontinuation of lamorigin Controlled Monotheropy Tria	er which the reports on 1 a corresponding differen- was little difference be a for individual advecce	mortigian were greater ce by gender on placebo ween femiles and males reactions.	se reactions than males than 10% more frequer) was dispiness	

Table 10Adverse Reactions in a Controlled Monotherapy Trial in Adult Patients with Partial-Onset Seinares ^{5,1}				
llody System/ Adverse Reaction	Percent of Patients Receiving Laurotrigine ² as MonotherapyPercent of Patients Receiving Low-Dase Valpeaau ³ (n = 43) (n = 44)			
fiedy as a whale				
Paia	5	0		
infection	6	2		
Chest pain	6	2		
Digestive				
Vomiting	9	0		
Dyspepsia	7	2		
Naurea	7	2		
Metabolic and mutitional				
Weight decrease	5	2		
Nervous				
Coordination absormality	7	0		
Dizziness	7	0		
Amiety	5	0		
levoraia	6	2		
Respiratory				
Rhinida	7	2		

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Table 11Adverse Reactions in Pueled, Placebo-G

	onPercent of Patients Receiving Lamotrigine (n=168)	Percent of Patients Receiving Placebo (n=171
liedy as whole		
nlection	20	17
Fever	15	14
Accidental iniury	14	12
Abdominal pain	10	5
Asthenia		4
Fluxsadrome	7	6
Pala	5	4
Facial edema	2	1
Photosepsitivity	2	
Cardiovascular		
Hemorrhage	2	1
Digestive		
Vomiting	20	16
Diarrhea	11	9
Nausea	10	2
Constipution	4	2
Dysproxia	2	1
Hemic and lymphatic		
Lymphadenopathy	2	1
Metabolic and matricional		
Edena	2	0
Nervous system		
Sompleace	17	15
Dizziness	14	4
Atoxia	11	1
Tremor	10	1
Emotional lability	4	2
Gait aboveradity	4	2
Thinking absormality	3	2
Convulsions	2	1
Nervossaess	2	1
Vertigo	2	1
Respiratory		
Pharyneids	14	11
Bronchitis	7	5
increased cough	7	6
Sinusidis	2	1
Brenchospasm	2	1
Skin		
Rath	14	12
Ecze ma	2	1
Pracine	2	i
Special seases		
Diologia	5	1
Harred vision	4	i
Visual abnormality	2	0
Unevenital		
Male and female patients	1	1
Urinary tract infection	1	
	a at least 2% of patients proped with how trighter and at a press	

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iody System/ idverse Reaction	Percent of Patients Receiving Lamotrigine (a=227)	Percent of Patients Receiving Placel (n+150)
inerest		
lack pain		6
adgue		5
determinal pain	6	2
ligestive		
Sausea.	14	11
contipation .	5	2
omiting	5	2
iervous Syxtem		
wo maia	20	6
omnience	9	7
ecostomia (dry mosth)	6	4
des picabary		
žánisk	7	4
saceshadon of cough	5	3
haryngisis	5	4
kin		
tash (nonorrigan) ²	1	5

(picela.) Proteom in these task were concerned to knowing two (100 to 400 mg/thg) or picerio meanthrapy from add-on therapy with other psychotropic medication. Parience may have reported multiple adveces reactions during the task, func, patients may be tackled in more.

5.3 Postmarketing Experience The following adverse reactions have been identified during postpproval use of lamotigine. Because

Note one structure and structure of a structure of the st

Concombase Deng Dano po-comanding end come optive preparations consisting 20 mcg ethinple-studied and 150 mcg levecoreg Enhancerplas and epo tale use in levenorgented component by 29%. contgets angine opoxido levels. ned lamorigine concentration approximately 50% ned lamorigine AUC approximately 32%. warmstriptee concernsist approvinged v 40%, and tametigite concernsist approximately 40%, and tametigite AUC approximately 40%, addimension : lanotigine

Rfarges Edgesate 1 = Decreased (infaces Lanorfigine glucarosidation). 1 = Lacrassed (inhibin Lanorfigine glucarosidation). 2 = Costlicting data.

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Mitch down of Lamortigine should be load on partnet." ADD registress, reduced animenance down may be reflective for parloadine with digital care and impairment. For parlom, with an even mult impairment the parloadine should be used on the careful in the section. The BOOKGELAND ADMENTITION (21).
HOYSEBOOKEE
Hall Bases Observations Experiments Overdoses involving quantizes up to 15 g have been reported for lamorigize, some of which have been find. Overdose has resulted in anxis, systems, evisures (including unic-clock seizures), decreased level of conscionsness, com, and introventically conduction have.

The test constraints, using, manufactures as inducation to a support of sensitive to the sensitive test of the

Const. Centre chaids be connected to introduce an one angular and the connected to introduce and the connected to internation and the connected to internation

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One proposed mechanisms of accises of lancentiples, the relevance of which remains to be established in human, involves another as solidan channels. Is viron pharmacological studen suggest that lancenspine shiftshiron theorem and the student students and the students and consequently methoding prospective students are students and so acids (e.g., planame and approxim).

Effect of Lamorigins on N-Methyl & Aspanan-Receptor Mediand Activity Lanorigine (ili no inhibi N-mehg) d-separate (MIDA)-induced depolarization in rat cortical siles to ex MIDA-induced cyclic GMP formation in immuter rat corebeilum, nor dd-lanorigine diplace compounds that are when competitive or necomprised to rights at this dynamic messare complex (FNR), CCS, TCEBP, The Ac₀ for lanorigine affects on NMDA-induced current (in the presence of 3 pM of phytical) inclusived bioperating aurons rescared 100 pM.

The mechanisms by which lanserigine evens in thempeutic action in bipolar disorder have nor be-emblished.

Contraction
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An example of the exa

The placeneoskinetics of lamontigine have been stadied in subjects with spillepsy, healthy young and elderly volumeers, and volumeers with thronic second failure. Lamontigine placeneoskinetic parameters for addit and positivity subjects and healthy surrary volumeers are assummizing all at Tables 14 and 16.

Table 14 Mean Pharmacekinetic Pr Adult Study Population in Healthy rol Sobiar Healthy volumeers taking no other medications 179 36 2.2 (0.25 to 12)

hidspie-dose Lamonigine Healthy volumeers taking valpreate: Gwale-dose Lamonigine

48.3 (31.5 to 88.6) 70.3 (41.9 to 113.5) 58.8 (30.5 to 88.8) 27.2 (11.2 to 51.6) 14.4 6 18 1.8 (1 m 4) 1 9 0.30 (0.14 to 0.42) 0.18 (0.12 to 0.33) inhjects with epilepsy taking valpreate only: ingle-door Lamoriaine 1.9 (0.5 to 2.0) 0.28 (0.16 to 0.44) 0.53 (0.27 to 1.04) 1.10 (0.51 to 2.22) 1.23 (0.66 to 1.82) fair user wegland enge een van een oper Simboleen 1 amerikaan op taking carbamazepine, phenynein, Pheneharbitat, or primidene¹ phe valproats: Simboleen 1 amerikaan z subjects with epilepsy taking carbamaxepine, phenytoin, Phenobarbital, or primidone[†]: 24 le-dose Lanotrigire

porty of generation means determined in each study had corefficients of stratents hereaves 20% and 40%. For harder of volumeses hadron and the strategies and the strategies and the strategies hadron and persons the hadron and the strategies hadron and the strategies hadron and persons the hadron and the strategies hadron and tha

Altergraphic in equilible and complexity distributed after and administration with explorable fine-space manderine (photome biosenicializity is (2015)). The biosenicalizity is not discoved by (since 2 hold parameter expresentions accuracy syntheme frame (and a data bases following data parameters) and the submediage address (biosenicalis, discoved biosenicalistic syntheme administration and the biosenic parameter data anginess. In discoved biosenic parameters data in teams of any construct data anginess.

4.8 (1.8 ± 4.4) (1 ± 0.10) 2.3 (0.5 ± 5.5) 14.4 (5.4 to 30.4) 12.6 (7.5 to 22.1)

CL/F: rent Plasma Clearance (mL/s

0.44 (0.12 to 1.00) 0.58 (0.24 to 1.15)

In healthy volumeers not receiving any other medications and given single closes, the plasma concentrations of lammatigue increment is direct properties to desse administered ever the range of 50 ± 600 mg. Statimit insides (or 2 ± 2 md [16] plasma with where maintained on other ADDs, there also was a line are indicated by the seven does and lammatigue plasma concentrations at mady uses following disses of 20 mg. 200 mg. provide diff.

Distribution Entranses of the mean apparent volume of distribution (VdF) of Lamontigine following scal administration ranged from 0.3 to 1.3 Ldg. VdF is independent of does and is similar following single and multiple doese is both patients with epilepsy and in healthy volumeers.

Prom's Blading Data from is vitro condicts indicate that lamoningine is approximately 55% bound to human plasma protein at plasma lamoningine concentrations from 1 to 10 mcg/ml, (10 mcg/ml, is 4 to 6 times the recogin plasma

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The other alterating and the depicted optimizing faith of the depicted optimizing and the depicted optimizing and

Aripiprazole	Not assessed	
Anonavietinouvie		1
Reprepion	Not assessed	
Carbanazepine	-	
Carbanazepine eposide#	7	
Felhamate	Not assessed	-
Cahapemin	Not assessed	-
avetracetan	-	-
ithium	-	Not assaysted
opiawirtizoawir		
Tancopine	-	
hsc arbazepine	-	-
0-Monohydroxy oxrarbazepine metabolite ^b		
Tereobarbital primidone	-	
Terrysola	-	
tegahalis	-	-
lifampin	Not assessed	
Experidore	-	Not assaysted
-hydroxynispecidoae ¹	-	
Copiraman		-
/alproate		
Valposate + phenymin and/or carbamazepine	Not assessed	-

Manufactorial Control Con

Gradual transient increases in identifying plasma lowers (page-tonic mar.) - Fold increases) sociaries during increases during the classical sector of latering plan (classical sector) - plan (classic

In the same such, conductorstation of largest give (260 mpdig) in 14 fermits volume en data near first the plannessistance of the estipole-studie composer of the and concerptive programmer. They are manufactures in the ACCs of the same planness of the same planness of the same track of the same planness of the same plannessistance of a same planness of the conductors in any of the 16 volumeses, abrong measurement of the same plannessistance in three was noted of samponessing of the syndrometers was and a same plannessistance of the three was noted as deservolves and the syndrometers was and and and and three was noted as deservolves and the syndrometers was and a same plannessistance of the syndrometers and the sy

The effects of doses of lancerigine other than 300 mg/kg have not been systematically evaluated in committed clinical stults.

The cluical significance of the observed hormonal charges on evaluately activity is unknown. However, the possibility of dicrossed common price efficacy in some patients cannot be excluded. Therefore, patients should be instructed to promply report charges in their meansuil pattern (e.g., brand-through the effug).

Dosage adjustments may be necessary for women receiving entrogen-commising oral contraceptive preparations [see DOSAGE AND ADMINISTRATION (2.1)].

The Market Des Mark Market Transform, S. 1999.
Contrasting Contrast

Concentrational nature gate in the restore and matters are particular stateworks in the networks to canterparts. **Bapepian** The pharmacolinetics of a 100 mg single dose of lamontigins in healthy volumeers (n= 12) were not changed by coadminimized or huperpion statistic-toriesse formulation (150 mg twice daily) starting 11 days before lamontigian.

The approximation of the appro

namene we parameterizete to manageme. **Jahaan** The pharmacolaretics of linkians were not alreved inhealthy subjects (n = 20) by coadministration of Izamating (100 mg/mg) for 6 days. Laplander/Blumene/e

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Phenyman Lamorigine has no appreciable effect on sendy-state phenymin plasma concentrations in parl-sm with epile pays. The addition of phenymolodic ranses framenigine study-state concentration by approximatly diffe.

Progabalia Smoly-state trough plasma concernations of lamentigine were not affected by conconstant progabalia (200 mg / 3 mms daily) administration. There are no plasmacoliteric interactions between lamontigine and progabalia.

and inpution. **Hexpe** The start of the second sec

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subjects with mild, moderate, servero without accirs, and servero with accirs hepatic impairment were 46 ± 20 , 72 ± 64 , 47 ± 11 , and 100 ± 44 hours, respectively, as compared with 33 ± 7 hours in headby comole (see DOSAGE AND ADMINISTRATION (2.1)).

f lamontigine following a single 2 mg/kg dose were evaluated in 2 studies in 6 for subjects aged 20 months to 50 yoars and n = 26 for subjects aged 5 to 11 cms neovied concentant theory with other ALDS and 12 subjects received apy. Lamontigine pharmacolonetic parameters for pediastic patients are

sensitive methods that the sensitive sensitiv

es 10 months to 5.3 year phenymin, phenoharbital, or primidone 1 7.7 3.62 (1 ± 5.3) (5.7 ± 11.4) (2.44 ± 5.21 5.2 ± 19 1.2 (2.9 ± 6.1) (12.9 ± 27.1) (0.75 ± 2.4 en taking aniepileptic drags with no known effect on the apparent clearance of lamorti (1 % 6) (25 Ages 5 to 11 years Solary ulius cubernaulus theremis thereducting or window
 1.6
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 (1 m 3)
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 (1 m 6.4)
 (7 m 31.2)
 0.20 m 1.50

 4.5
 65.8
 0.24

 (1 m 6.6)
 50.7 m 73.7(0.21 m 0.26
 Ages 13 to 28 years s taking carbamanopine, phenymin, phenobarbital, or primidone* plus sulproate . 0.5 0.3

The pharmicolinetics of lancetigine following a single 150 mg does of lancetigine were evaluated in 12 elderly volumesce between the ages of 65 and 76 pears (mun cruatine clearance = 61 mLinin, range 32 in 161 mLinin); The manufal-161 of a flamositigine in these subjects was 31.2 hower (range: 24.5 m 43.4 hours); and the mean clearance was 0.40 mLining (range: 0.26 to 0.48 mLining);

Genter The character of humorigane is an entropy by gender. However, character, data was moulational of humorigane concentrations maniputed for variable wave 20% to 40% highlar (0.3 to 1.5 mcg)mcl.) is formise thanks mark. Raw The approve and clearance of humorigane was 20% lower in same Casculane than Casculane.

The opported of learning of even stars locations are detected and the data with a **UNCLENENT CONCOUNT USACINATION CONCOUNT USACINATION CONTROL (SEE A)** Name of the stars of the stars

14 CLINICAL STUDIES

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One trial (n = 216) was a double-blied, placebo-controlled, parallel trial consisting of a 24-week meaning period. Patients could not be on more than 2 other anticonvolume and subpose was not allowed. Patient were mathematical to receive placebo, a surger door of 200 mg/kp of lamerigine, or a

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The primary officacy endpoint was percentage change from baseline in PGTC solutions. For the inter-to-over population, the median percent reduction in PGTC solutions was 60% in patients reased with lammatuke and 10% to mixely be a difference the was statistically significant to =0.00%).

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particular for each subjects to Tail and the Tail particular to Tail particular

episode could be depression, marks, hypogenetic, ex atted spinole. In First 11, primer resolution dashe birdi memory with intentigion of myltry ($n \leq 50$), transmission of the metric of the start of

Figure 2: Kapla (Trial 2) 12 May-20

10 29 38 48 10 40 70 58 Texts

16 HOW SUPPLIED/STORAGE AND HANDLING Product 50999-3814 NDC: 50990-3814-0 1 TABLET in a BLISTER PACK / 32 in a BOX, UNIT-DOS

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Lanuxigiare should not be used for a case warment of marke or mixed mod spinodes. **We should not be lanuxigiar** (you have had an allergic reaction to learninging or any of the lanuxigiar).

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5 mg, white to off-white One side of the bioset is debessed with "2" and char side is debessed with "1."

Lamottigine Tablets (Chrscable, Dispersible)

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dree loped meting its while taking lancering its. **Lancetigins can cause other eventses tide effects.** For more information ask year healthcase provides or plannamicit. Tell year healthcare provider if you have any side effect has bathers you. Its same to much the active healthcare effect. Where not the normalia while effect that bathers? mode the rescalability under "White and the product side inferred latencipate". P. Popoly percending single have assessible to be subsective beneficiant. The second size of the second

Meningitis has many causes other than lat

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acting aggressive, being aggry, or violent
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 acoutorem increase in activity and talking (musia)
 other unusual changes in behavior or mood

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pregnant during the rapy and if they immed to breastfeed or are breast-feeding an infam. Encourage parients to enroll in the NAAED Pregnancy Registry if they become pregnant. This registry is collecting informationabout the safety of antiopilopic drugs during pregnancy. To encoll, parients can call the soli-free number 1-1400-2203 (new USE IN SPECIFIC POPULATIONS [0.1]).

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