

Telaprevit 750 mg three times daily	Telapresir: AUC: 4 54% C_: 4 53% C_: 4 52%	Kaletra and telapresis	Antivital activity of reduced in with	Kaleto in Suscepti	patients to sky to lop	aling proteuse insuit has bee	n earnine	erapy: the d d by assess	inical releva
Nerbal products	C_+52% Lopinado: ==		SS patients pread of against the SI against wild type means transcript	ous telling baseline HIV. After less inhibit	y, with ne therapy or stral isolate 45 weeks ons, plasm	th multiple p is ranged fro of treatment is HEV RIVA of	one virsi g rotease in m 0.5 to 5 with Kaleb 400 copie	shotype and slotters. The 6-fold highers, efaulters a, efaulters ahmi was of	EG _v of lop if than the I and nucleo pairwed in S
St John's wort (Hypericum perfo- rature)	Lopinsvir: Concentrations may be reduced due to induction of CHP3A by the herbs preparation St John	Heibal preparations containing St. John's worf must not be combined with lipiteair and stomaks. If a patient is already being St. John's wort, stop St. John's worf and if possible check visal levels. Lipiteair and stomak levels may	of reduction of the composition is to price to be to see executed by sensing the vising many time in particular to the composition of the composi						
	preparation St John Wort.	John's sort must not be combined with logitant and florasis. If a passer is already logitant and florasis if a passer is already logitant and florasis if a passer is already logitant and if possible check visit is levels. Logitant and if stream's levels may because on stopping 2. John's wort. The does of Kaletin may penial the at levels and a stream of the declaring effect may penial the at least 2 weeks after cassistant of their							
		The inducing elect may persist for at least 2 vession after consistion of treat- ment with 52 John's wort jace section 4.3; Threatine, Kaletta can safely 2 weeks after consistion of 52 John's wort.	patents: The pa 10 rebound last Phase II and one median told IC, 63-bbt, respects	sence of o less that he Phase III of of lopinsult elss, comp				thibitors is dance to lo r-experience and rebount rebound in	ess analyse provir durir of patients. If was 6.9- slates either
Immunosuppressant Cyclosporin, Sirol- mus (repartycin), and Tacolimus	Oydosporin, Sirol- mus (opamycin), Tacrolimus:	More frequent therapeutic concentration monitoring is recommended until plasma levels of these products have been	tained if one-n sequinair and at dan increase of i locates retained rebound includes	statunt of t scarsoit. It C _a from 3 susceptible of 1.3- an	baselne) o Abdest de 7- to 8-to By to tips of 1,8-toto	18 incident a id type virus, ir developed a preases than d in the basel rasit with a n, respectively luct Characte predictors of	ignificant of premark ac- ine and reb reden incr compare	cos resists dutywers no cound isolate same of ICs of to wild the	nce to indin oted with a ss, respects in baseline se virus, Ple
Lipid knowing www.t	Concentrations may be increased due to CYPSA inhibition by Kaletra.		near to the Aptic use of Spranait, sisters HS-1 into Clinical results The effects of Ka	u surera including p dian. etra (in cor	y of Prod genotypic ribination	ur characte predictors of eth other and	escs for a response, retrovisi a	usecral into in treatment perto) on bio	onation on of lopinavi
Lovastatin and Simustatin	Lovadatin, Simuse- tatic: Markedly increased plasms concentra- tions due to CHPSA inhibition by Kaletts.	Since increased concentrations of HMG- CoA reductase inhibitors may cause myopathy, including habitomyoljess, the combination of these agents with Kyleins	plasma HV RN studes of Kaleto Adult Une Datents without Study Mod-Stud	of 48 to 2 of 48 to 2 of 5 to 2	CONTRACTOR	-os counts) duration. DUSe-blind to	value bee	- mestigale entretrovinsi	w in contro
Atonsetatin	fone due to CYPSA Inhibition by Kaletra. Atonositatio: AUC: # 59-fold Cuc: # 4.7-fold Due to CYPSA Inhibi- tion by Kaletra.	Is contraindicated (see section 4.3). The combination of Kaletra with attornation is not recommended. If the	patients investig time times daily 259 cells/mm* (is log-copies/mi (is	ting Kaleb plus star ngs: 2 to 5 ings: 2.51	rs (400/10 udine and HS calb/n o 6.5 kg.	D mg twice I amisudine. It nem') and mea copies/mil.	dally) comp Mean base in baseline	sand to rel line CD4+ 7 plasma HW	frasir (750 -osli count i -1 RNA vasi
	Due to CYPSA inhibition by Kaletra.	the of solvalization is considered sincey recessary, the lowest possible does of recessary the lowest possible does of should be administrated with careful safety monitoring (see section 4.4).		Out	comes at	Week 40: St Kaletra (No.	tudy MSG- 126)	063 Nelfinavi	r (Ni-227)
Rosussitatin, 20 mg QD	Rosuvastatin: AUC: † 2-fold Ciu: † 5-fold While rosuvastatin is:	Caution should be exercised and reduced doses should be considered when Kaletra is co-administered with rosuvestatin (see section 4.4).	HEV FRAN < 400 Men increase	copies/n/ opies/n/1	nuin .	75% 67% 907		52% 52%	
Fluverhalin or Pravasthalin	poorly metabolised by CYP3A4, an increase of its placer concentrations was observed. The mechanism of this interaction may result from inhibition of		CD4+ Tost ox "Intent to heat a fallows †p < 0.001	nt paluh siyat wh	m) repatent	s with missing	volves an	considered	l virologic
	interaction may result from inhibition of transport proteins.	I Section to the Collector	One-hundred this haid on 16V FRW 95. Of these, led patients could be presence of the fants. Resistance force in professes	teen neith above 40 ales from amplified	aut-treate D copies h 95 nelfina for resista	d patients are ni while on to in-treated pat mos testing. I	d 74 lopins satment for lents and 3 Resistance	ut/ttonaut-ton m Week 24 to nelfinaut/	treated pate through W stonaut-trea defined as
	tatin: No dinical relevant Interaction expected Pravastatin is not	If treatment with an HMG-CoA reduc- tase inhibitor is indicated, fluveriatin or presentatin is recommended.	presence of the fants. Resistance force in professes lopinals was con	100% or L to lopins lase above smed by	20M muto it, defined ij, war ob phenotypi	analysis.			
	Interaction expected Pravastatin is not metabolised by CHP450. Fluxestatin is par- tally metabolised by CHP200.		Study MOS-730 i Kaleba 8000000 i factor daily plus facts. Given the 4.5), the results o mens are used in	ese a randi gionos da landouir D pharmaco i filis studi	lomised, o ily plus ten if and en kinetic into i might no Patients vi	pen-label, mu abuir DF and e trictabline in maction between t be strictly ex-	floette til imbligtablin 664 antire sen Kalets frapolable	al comparing a versus Kale troviral treat a and tenoto when other	j trustment i dru-400/100 ment-nalve vir (see sec backbone n
Opioids Buprenorphine, 16 mg QD	Duprenorphine:	No dose adjustment necessary.	800200 mg on stratification with identification the	a daily in neach gro tablet or th		ere randomis Kaletra 400° 1 (tablet versi sule formulati ifon once da	ed in a 1:1 100 mg tu a set cap on for 8 we 8r or twice	ratio to receil ton daily (n. sule). Patier seks, after w i daily for th	ve either Kal = 331). Fur fis were ach hich all pate e remainde
Methadone Oral Contraceptives	Methadone: #	Monitoring plasms concentrations of methodone is recommended.	ident offer the vers adminished to study. Paties 200 mg cross de tolore delly dooley the difference in 1-12% at Wask 40 Caucasian, and bangs: 20 to 775 (angs: 1,7 to 7,5 tangs: 1,7 tangs: 1,7 to 7,5 tangs: 1,7 tangs:	ts were as ly. Protoc was dem reporter	dministens of defined onetrated of subjects	d emtricitable non-inferiority if the lower bo responding i	of once of and of the once daily	of companing eversus fails is and tenotic when other ratio to receil los daily in sale, Patier eld, after with crose daily as faily dowing the contider minus twice (ange: 19 to proget 19 to proget pr	nd tenotoxis compared snos interva dally) socku
Ethinyl Osstradiol	Ethinyl Osstradiol: 4	In case of co-administration of Kaletra with contraceptives containing ethiny! cestradid (whatever the contraceptive formulation e.g. oral or patch), additional methods of contraception must be	Caucasian, and tange: 20 to 775 tange: 1.7 to 7.0 Table 2	The ware calculated big-cops	main. Me and mean su/mij.	an baseline C baseline plan	DH- Tosi ma:HV-11	trange: 19 to I count was RNA was 5.0	216 celsh log=copie
Smoking association a Bupropion	ids Buproprion and its	If the co-administration of lopinals/	Wroky	ic Respo	nee of St Week	udy Subjects	at Week	45 and We Week I	nk 96 96
	Buproprion and its active metabolite, hydroxybupropion: AUC and Cr. # -50%	If the co-administration of lightwain' storaus' with bupropion is judged unaccidable, this should be done under dose circial monitoring for bupropion efficacy, without exceeding the recom- mended dosage, despite the chairmed.	NC-Palan	2100	251001	13% (51,74)	216233	229/531 #50 750	195% C 43% (115,2)
	This effect may be due to induction of bupropion metab- olism.	Induction.	Observed data	251095 (67.1%)	250 GSI (SL2%)	-225 [7A.21]	216047 (E7.4%)	229,045 (82,2%)	-42% [-10.2, 0.
Dosentan	Lopinavir - ritoravir: Lopinavir litoravir plasma concentra-	Caution should be exercised in adminis- tering Kaleins with bosentan. When Kaleins is administered concomi-	Maninosas ton basine in CD4+1- of cost	100	198		238	254	
	plasma concertra- tions may decrease due to C1PSA4 in- duction by bosentan Bosentan:	seing Kaleira with bosentan. When Kaleira is administered concom- trantly with bosentan, the efficacy of the Parties should be monitored and patients should be chastly observed for bosentan toxicity, especially during the finit week of co-administration.	(plater) Trough Week 2 the CD group an the CD group an	L genotyp 120 paties paties	ic resister to in the S	ce testing no ID group who ed lopinavir n bitor resistant	ults were a had incor-	usibible for splete virolo and in the	25 patien sic respons D group, 1
	Bosentan: AUC: † 5-fold C.,; † 6-fold Initially, bosentan C.,; † by approxi-		Sustained virology Sustained virology	reficent po se on stud (cal expo- p (state)	F-		e at basel ination with ad in a		
	Initially, bosentan C _m : † by approxi- mately 48-fold. Due to CVPSA4 inhibition by lopinsals stonaak.		Sustained virolog verse transcripts were transcript and Kaletra in the st feets at either 20 to copied the adverse completed the a drea throughout.	eks of tre dy indud 0100 mg lets at f	atment. C ing 51 pat helos dall 400/10*	mad observe the hundred tents receiving yor 400/200 mg twice rh	patients of patients of 400/100 mg twice of ity does in	_ naselis vere original mg twice d tally). All pat thesen were	by treated ally and 49 lents conve k 46 and *
Other medicinal prod Based on known me between Kaletra av-1	Licts tabolic profiles, clinics depants, trimethors	Ay significant interactions are not expected in faultemethologicie, arithromycin or	72. Thirty-ritings due to adverse completed the a dose throughout	earts (001 sents, on tudy (05 p the study)	n/ discorti e of which attents re	nued the stud t was associ- saled the re-	y, including stad with a commenda	15 (1019) o death. Sa id 400100	scontinual ty-one pate mg twice o
fuconarols.			Table 3 Outcomes at 1	Verk 262	Study M	97-720			
s a general rule, whe ion in pregnant wome to the newborn, the a should be taken into a	n dedding to use anti n and consequently to snimal data as well a count in order to do	retrovinal agants for the treatment of HW infection reducing the risk of HW vertical transmission is the clinical expensions to program women vaccionise the safety for the foeture.	HIV FRA < 400	copies/mi		57% 50%	rs (N: 100		
were are no adequa cost-marketing survei ince January 1989, a seen reported among if birth cleave-	 and well-controlle fance through the A on increased risk of I over 500 women exp by time-fer 	d studies of Kaletra in pregnant women. In infentious if Pegnancy Registry, established birth delects exposures with Naletra has not osed during the first trimeter. The prevalence	Man howas I in CDH+ Toalio Through 360 w	om basel ourt joels eks of tre	ne Immi) alment, g	son motypic anal	ysis of vira NA sbow scids at po- resistance	i inclutes w	ne mucosse
bserved in the gener foliogy was seen. Sta lased on the limited of treastfeeding	of population. No pat idea in animals have late mentioned, the m	Ito lopinair is comparable to the presilence tem of birth defects suggestive of a common shown reproductive toxicity (see section 5.3), siformative risk is unlikely in humans.	primary or action 50, 82, 64 and 9 Datents with one MOS-802 was a	ue pate de rubil l) or prole artisatio randone	us with or one in prof see inhibit and thereo and open	mae jamino a or phenotypic abel study o	ven libbout solds at po resistance omparing	I isolates w 400 copies stons 8, 30, the safety.	
Describeding Nucleis in rate reveals nedicinal product is e nothers infected by H o avoid transmission	o that lopinavir is exc screted in human mi N/ do not breaeffeed of HNL	reted in the milk. It is not known whether this fix. As a general rule, it is recommended that their babies under any circumstances in order	subjects with del had not been on to mostive either 400/100 mp two	ophairit e dalvit i	ly and twi all loads vi havit Mon tonavir 80 200, Pat	hile receiving sair therapy. 0/200 mg on lents were 2*	g or oper their curse They were on daily in ministers."	the safety, auto thomasis of smilety and continued or sandomises = 300) or its at least two gates. The electron having rights having rights though the same than the same	maters in sempy. Pati d in a 1:1 pinavichtor nucleosid
entity virtual studies have st borself on fertity are Directs on ability ***	rown no effects on fer available. drive and use ma**	rilly. No human data on the effect of lopinals:	decide mierse to war modern prior PI and arc. to some and arc. to some and 60% were set of 60%	ranscripts bly Pt-exp and 80% of patients rais, Mean	se inhibito erienced s if patients entolled s basel**	s selected by ith more than presenting a as 41 years (CD4+ 3-w	the invest half of par strail strain ange: 21 to out it were	gator. The elects having with less file 773; 51% v 254 called	nrolled pop never rece han 3 Pl m were Cauca nr (parw
so studies on the effet takents should be into see section 4.8. Andesirable effects	drive and use much cts on the ability to d owned that nauses ha sty-crofile	eve and use machines have been performed, is been reported during treatment with Kaleba	SCC calcimity as to 6.6 log., capie Table 4	dment shij. An	meline pla and 80% o		NA was 4.3 d a vital los	llog_copie d of < 100,0	ulmi (tange 100 copiesi
he salety of Kaletra risks, of which over 7 mos daily. Along with	has been investigate 00 have received a d nucleoside revense to	d in over 2000 patients in Phase 6-W clinical lose of 800/200 mg (5 capsules or 4 tablets) areoriptase inhibitors (NATIs), in some studies,	Virsi	gic Resp	onse of S	hudy Subjec	ts at Wee	k 46 Study	802 Ofference 95% Cit
aetra was used in co he most common ac Sanhosa, nausea, vo Sanhosa may be grea	ombination with etavir twense reactions relate miting, hypertriglyceni der with once daily do	error neitrapine. Id to Kaletra therapy during chrical trials were daemia and hypercholesterdemia. The risk of eing of Kaletra. Diamhoes, rauses and vomit-	NC» Falter Observed do		171(000 (57%) 171(005 (75,0%)	\mp	161(299 (53.8%) 161(223 (72.2%)	[46	
ig may occur at the b sterolemia may occu- facontinuation for 7% is important to an	promaton with essentially have a mactions relate militing, hyperhighyosis dar with once daily do aginning of the treatm ir later. Treatment are of subjects from Pha Phat cases of pances who developed hypo on reported during No erms mactions.	ent while hyperhylicaridaemia and hypercho- ergent advense events led to premature study as I-M studies. attis have been reported in netlents and in-	Man house basine is Co	iom 6+	125	+	122	[4	z%, 11.9%
dverse reactions for	Cinca that and por	etrigljoerdaemis. Purthermose, rase increases letra therapy (see section 4.4). If marketing experience in adulf and psecilatric	mel	L genetys	ic resistan	on heating real	ults were a	valsbis for plets vi-1	n 75 patien jc neso
metric The following events it includes all reported e aussity assessment, such frequency over	tave been identified a words of moderate to The adverse reaction ing, undestrable effect in (p. 1/10), common (j. (cannot be estimate)	e adverse reactions. The frequency category assures intensity, regardless of the individual is are displayed by system organ class. Within its are presented in order of Americans	the CE group, 6 instant 20, 22, hedden Lite MSS-940 was a	I. gendys 175 patien 75 (8%) pa 8, 50, 62, open-lab	dents den SA, SO, s el study o	sondrated no e did 12/77 () (a liquid form	w primary (10%) patier sulation of	protesse info to in the DD Kaletra in 1	bitor mutal group. 00 antireto
subsery assessment, such frequency group aument: very commo 1/100) and not known twents noted as have reliance.	ing, undertable effect (\$ 1/10, common) (carnot be estimated ing frequency Not kn	s 1/100 to < 1/100, uncommon ly 1/1000 to < I from the available data; own" were identified via post-marketing su-	nave (HHL) and means transcrip vir57.5 mg filor also movied nu mestaphy risk	uperience sale inhibit suir per m decelde m p to ten	or piché p or pales. I or 300 m werse fran udeos	woath's patie fatients were ing biphavis? scripture into reverse?	ets. All pr randomise 5 mg ritors bitors. Dig oriptase	rotasse in the BE Kaletra in 1 derts were all per my setienced pa shore. Safe son the 20 or 12 years) eline CD4+ 7 log, copies	on-rudeo 230 mg lop Nalve pasi idents rece by, effic
ellance. Undesirable effects System organ class		and post-marketing in adult patients	pharmacokhelic apy in each calle	profiles of rs. Subse	the two di quently, al	cos regimens regimens	were acces to continue	ersed after 3 d on the 30 o 12 years) v	weeks of to 175 mg pe with 14 pate
	Frequency		doss. Patients h less than 2 years	ad a mean old and E p	age or 5	ears (range 0 e year or less.	Meanbas	sine CD4+ 1	Fosil counts
infections and infes- tations	Very common Common	Adverse reaction Upper respiratory tract infection Lower respiratory tract infection, skin	doss. Patierish less than 2 years 838 calls herr' ar Table 5 Outcomes at 1	sd a mean sid and 6 p d mean b	atients on saline pla	e year or less erra HU-1 Fb	Mean bas 6A was 4.2	sine CD4+1	Foell counts shall.
infections and infes- tations	Very common Common	Advene reaction Upper respiratory tract infection Lover respiratory tract infection, siles reflections including callulitis, foliculitis and faruncia: Ansemia, isucoperia, reultroperia, lym-	dose. Patients in less than 2 years at 2 dose in less than 2 years at 2 dose in less than 5 dose in less t	as a mean did and 6; d mean b	Study MS Antini Nation	piani (ranga 6 e year or kea. ema HSV-1 FB 6-940 diroviral Nali	Mean bas 6A was 4.7 se Anti- (Nut		Foil count int.
Infections and infec- tations Diood and lymphatic system disorders Immune system disorders	Vey common Common Common Common Uncommon	Adverse reaction Upper registrally tract infection Loser registrally tract infection, sile- trickins including callulate, tolkcultes and strundle Ansamis, Insucperais, multiparais, lym- phaderogaths, phobuling unificate and angloaderas.	doss. Patients in less there? years 858 calls/her? at Table 5 Outcomes at 1 HIV FRM < 400 Man increase baseline in CO court justs her	so a mean sid and 6; d mean to livek 40; 1 copies/hil ton - Tosii	Study MS Study MS Study MS Study MS Strict	plant (range 1 in year or leas, area HS-1 Pb 8-940 strovinal Nati			periences
Infections and infec- tations Blood and lymphatic system disorders Immune system disorders Endocrine disorders Endocrine disorders and rutit for disorders	Very common Common Common Common Uncommon Uncommon Uncommon Uncommon Common	Advance reaction Upper registrative feet indicts Claser equality feet indicts Claser equality feet indicts Feet feet feet feet feet feet feet feet	dos. Polarita III in a Table 5 Outcomes at 1 Hel 7894 < 400 Mare Increase at 1 baseline in Color of the C	c propert	404		m Anti- (Nud 75% 284	etrovirsi E	speriences
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Infections and infes- tations Blood and lymphatic system disorders Immune system disorders Endoories disorders Metabolism and nutrition disorders Psychiatric disorders Nersous system disorders	Very common Common Common Common Uncommon	Advanta rectain Salam especially part designed Love especially selected rectain Love especially selected rectain Love especially rectain designs Love especially rectain Love especially rectain Love especially rectain Love especially rectain Representation Repr	diss. Patients diss. Patients diss. Patients di years solici distributi ar Table 5 Outcomes all'1 Hell 1994 - 400 Hell 1994 - 400 Pharmacokinet The plan her benedit publicati The plan her benedit publication of the plan her benedit publication o	c propert	Ses fee of lop fees of lop fees and two gra- ts the met under, arb r plasma loss of 60 w than the	insir co-adm in 190/intach ps. Lephasis shokem of lo ninistration of concentration plasma levels ing twice do it of ritonavit."	P Anti- plud 70% 254 254 254 254 25 except 25 except 26 except 26 except 26 except 27 except 28 except 28 except 29 except 29 except 20	ethorizal E Ej eth dionavir i ally compliate any increase D-1030 mg is D-103d higher are less this the artistal a	sperienced trave been e ritial differently metaboling the pla slock daily significant than the state of the plant than the state of the plant than the state of the plant than the ECu of belief of the plant than the state of the plant than the plant the plant than the plant than the plant the plant than the plant the plant than the plant the pla
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Interiors and infla- tables Blood and funphistic Brobbothe disorders Brobbothe disord	в Рекумесу Wey сигнол Солтол Солтол Солтол Окаленол Окалено	Advantance (Land Advantance) Sour empirity in pict Products Court empirity in Pacific Products Court empirity in Pacific Products And Court empirity in Pacific Products And Court empirity in Pacific Products Angered Sangered (Land Court empirity) Angered (Land Court empirity) Ange	doss. Polarini hi such sur June Sur June Table 5 Culturenes at 1 He VPM < 40.7	is properly incompared to proper adult volume to the top top to the top top top to the top	Ses fee of lop fees of lop fees and two gra- ts the met under, arb r plasma loss of 60 w than the	hasir co-adm in 1944-infacts pp. Lopinsus abdism of la initiatism of concentration in particle and in gradual of 100 mg Kalet 100 mg Ka	Post Post Post Post Post Post Post Post	etropiral E El et donavir i c no substa ally complete most into articles the articles ally for 2 was concertad ion. The har 'ggird' Lope e shoulder'	trave been or that different sky metabol ing the plas side dealy ye of that the second strain of the plan of the p
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