

!" #&/  
4;O <548G=>3> 70AB>AC20==O ;V:0@AL:>3> 70A>1C

□  
(LORIZAN)

!;:04:  
4VNG0 @5G>28=0: loratadine;  
1 B01;5B:0 @0B048=C 10 <3;  
4>?> @5G>28=8: ;0:B>70, <=>3V4@0B; ;@>E<0;L :0@B>?;O=89; :0;LFVN AB50@0B.

V:0@AL:0 D>@<0. "01;5B:8.  
A=>2=V DV78:>-EVABV: B01;5B:8 1V;>3> :>;L>@C 7 ?;>A:>N ?>25@E=5N, 7 D0A:>N.

\$0@<0:>B5@0?52B8G=0 3@C?0. □=B83VAB018 4;O A8AB5<=>3> 70AB>AC20==O.  
>4 "% R06A X13.

\$0@<0:>;>3VG=V 2;0AB82>ABV.

\$0@<0:>48=0

>@0B048= B@8F8;;VG=89 A5;5:B82=89 1;>:0B>@ ?5@8D5@8G=8E 1-3VAB028E @5F5?B>@V2. @8  
70AB>AC20==V C @5:><5=4>20=V9 4>7V =5 G8=8BL ;;V=VG=> 7=0GCI>W A540B82=>W B0  
0=B8E>;V=5@3VG=>W 4VW. @>BO3× B@820;>3> ;V:C20==O =5 28O2;5=> 6>4=8E ;;V=VG=>  
7=0GCI8E 7:07=8:0E 68BBT2> 206;828E DC=:FV9, ;01>@0B>@=8E 4>A;V465==OE, 40=8E DV78:0;L=>3>  
>1AB565==O E2>@>3> 01> 2 5;5:B@>:0@4V>3@0@0B048= =5 <0T 7=0GCI>3> 2?;82C =0 0:B82=VABL  
2-3VAB028E @5F5?B>@V2. 5 1;>:CT 70E>?;5==O =>@5?V=5D@8=C B0 D0:B8G=> =5 <0T 2?;82C =0  
A5@F52>-AC48==C A8AB5 =0 0:B82=VABL 2>4VO @8B  
A=CNBL 40=V,I> ?@8 ?@>2545==V H:V@=8E ?@>1 =0 3VAB0AC20==O @07>2>W 4>78 10 <3,  
0=B83VAB048=8, 4>AO30T ?V:C G5@57 8-12 3>48= V B@820T 1V;LH5 24 3>48=. 5 2V47=0G0;>AO  
@>728B:C ABV9:>ABV 4> 4VW ?@5?0@0BC ?VA;O 28 4=V2 70AB>AC20==O ;>@0B048=C.  
;V=VG=0 5D5:B82=VABL V 157?5:0.

V4><>, I> >@0B048= (B01;5B:8) 2 4>7V 10 <3 1 @07 =0 4>1C 1C2 5D5:B82=VH8<, =V6 ?;0F51>, V B0:8<  
65 5D5:B82=8<, O: ;5<0AB8=, 2V4=>A=> ?>:@0I5==O AB0=C ?@8 A8<0E (=070;L=8E V =5 =070;L=8E)  
0;5@3VG=>3> @8=VBC. @8 70AB>AC20==V ;>@0B048=C, A>;82VABL 28=8:0T 7<5=H>N  
G0AB>B>N, =V6 ?@8 70AB>AC20==V ;5<0AB8=C, V ?@0:B8G=> 7 B0:>N 6 G0AB>B>N, O: V ?@8  
70AB>AC20==V B5@D5=048=C B0 ?;0F51>.

V4B25@645=>, I> >@0B048= C 4>7V 10 <3 1 @07 =0 4>1C 5D5:B82=VH89 70 ?;0F51> C ;V:C20==V  
E@>=VG=>W V4V>?0B8G=>W :@>?82O=:8 (?>A;01;5==O A25@156C, 5@8B5<8 V 0;5@3VG=>3>  
28A8?0==O).

VB8. D5:B82=VABL C 4VB59 1C;0 ?>4V1=>N 5D5:B82=>ABV C 4>@>A;8E.

\$0@<0:>:V=5B8:0.

A<>:BC20==O. >@0B048= H284:> V 4>1@5 2A<>:BCTBLAO. 0AB>AC20==O ?@5?0@0BC ?V4 G0A  
W6V <>65 45I> 70B@8

>7?>4V; >@0B048= 72O7CTBLAO 0:B82=> (2V4 97 % 4> 99 %) 7 1V;:0<8 ?;07<8 :@>2V, 0 9>3> 0:B82=89  
<5B01>;VB 7 ?>N 0:B82=VABN (2V4 73 % 4> 76 %).

# 74>@>28E 4>1@>2>;LFV2 ?5@V>4 =0?V2@>7?>4V;C ;>@0B048=C B0 9>3> 0:B82=>3> <5B01>;VB0 2  
?;072V A:;040T ?@81;87=> 1 B0 2 3>48=8 2V4?>2V4=>.

V>B@0=AD>@<0FVO. VA;O ?5@>@0;L=>3> 70AB>AC20==O ;>@0B048= H284:> V 4>1@5  
01A>@1CTBLAO, 0 B0:>6 5:AB5=A82=> <5B01>;V7CTBLAO ?@8 ?5@H>E>465==V G5@57 ?5GV=:C,  
3>;>2=8< G8=><, 70 4>?><>3>N CYP3A4 V CYP2D6. A=>2=89 <5B01>;VB 457;>@0B048= T D0@  
<0:>;>3VG=> 0:B82=8< V 1V;LH>NN 2V4?>2V40T 70 ;;V=VG=89 5D5:B. >@0B048= V 457;>@0B048=  
4>AO30NBL <0:A8<0;L=>W :=F5=B@0FVW C ?;072V (Tmax) G5@57 1-1,5 3>48=8 V 1,5-3,7 3>48=  
2V4?>2V4=>, ?VA;O 70AB>AC20==O ?@5?0@0BC.

82545==O. @81;87=> 40 % 4>78 282>48BLAO V7 A5G5N V 42 % 7 :0;× C?@>4>26 10 4=V2, 2 >A=>2=>  
@=N3>20=8E <5B01>;VBV2. @81;87=> 27 % 4>78 282>48BLAO V7 A5G5N C?@>4>26 ?5@H8E 24  
3>48=. 5=H5 1 % 4VNG>W @5G>28=8 282>48BLAO C =57@>@0B048= 01> 457;>@0B048=.

# 4>@>A;8E 74>@>28E 4>1@>2>;LFV2 A5@54=V9 ?5@V>4 =0?V2282545==O ;>@0B048=C  
AB0=>282  
8,4 3>48=8 (4V0?07>= 2V4 3 4> 20 3>48=), 0 >A=>2=>3> 0:B82=>3> <5B01>;VB0 28 3>48= (4V0?07>= 2V4 8,8 4> 92 3>48=).  
>@CH5==O DC=:FVW =8@>:. # ?0FVT=BV2 V7 E@>=VG=8< ?>@CH5==O< DC=:FVW =8@>:  
>V428IC20;8AO ?>:07=8:8 AUC V <0:A8<0;L=>W :>=F5=B@0FVW C ?;072V (!max) ;>@0B048=C V 9>3>  
0:B82=>3> <5B01>;VB0 ?>@V2=O=> 7 B0:8<8 ?>:07=8:0<8 2 ?0FVT=BV2 V7 =>@<0;L=>N DC=:FVTN  
=8@>:. !5@54=V9 ?5@V>4 =0?V2282545==O ;>@0B048=C V 9>3> 0:B82=>3> <5B01>;VB0 =5  
2V4@V7=O2AO 7=0G=>N N 2V4 ?>:07=8:V2 C 74>@>28E ;N459. # ?0FVT=BV2 V7 E@>=VG=8<  
>@CH5==O< DC=:FVW ?5GV=:8 35<>4V0;V7 =5 2?;820T =0 D0@<0:>:V=5B8:C ;>@0B048=C V 9>3>  
0:B82=>3> <5B01>;VB0.  
>@CH5==O DC=:FVW ?5GV=:8. # ?0FVT=BV2 V7 E@>=VG=8< 0;:>3>;L=8< C@065==O< ?5GV=:8  
>:07=8:8 AUC V !max ;>@0B048=C 1C;8 2 420 @078 28I8<8, 0 WE 0:B82=>3> <5B01>;VBC =5 7B=> ?@8  
>@V2=O==V 7 B0:8<8 ?>:07=8:0<8 2 ?0FVT=BV2 V7 =>@<0;L=>N DC=:FVTN ?5GV=:8. 5@V>4  
=0?V2282545==O ;>@0B048=C V 9>3> 0:B82=>3> <5B01>;VB0 AB0=>28BL 24 V 37 3>48= 2V4?>2V4=>  
V 71V;LHCTBLAO 70;56=> 2V4 BO6:>ABV 70E2>@N20==O ?5GV=:8.  
0FVT=B8 ;VB=L>3> 2V:C. >:07=8:8 D0@<0:>:V=5B8:8 ;>@0B048=C V 9>3> 0:B82=>3> <5B01>;VBC  
1C;8 0=0;>3VG=8<8 2 74>@>28E 4>@>A;8E 4>1@>2>;LFV2 V 74>@>28E 4>1@>2>;LFV2 ;VB=L>3>  
2V:C.

**;V=VG=V E0@0:B5@8AB8:8.**

**>:070==O.**

18<0B8G=5 ;V:C20==O 0;5@3VG=>3> @8=VBC B0 E@>=VG=>W V4V>?0B8G=>W :@>?82O=:8.

**@>B8?>:070==O.**

>@870=® ?@>B8?>:070=89 ?0FVT=B0< V7 ?V428I5=>N GCB;82VABN 4> 0:B82=>W @5G>28=8 01> 4>  
1C4L-O:>3> V=H>3> :=5=B0 ?@5?0@0BC.

**70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.**

@8 70AB>AC20==V >4=>G0A=> 7 0;:>3>;5< 5D5:B8 ?@5?0@0BC =5 ?>A8;NNBLAO, I> ?V4B25@465=>  
4>A;V465==O<8 ?A8E><>B>@=>W DC=:FVW.

>B5=FV9=0 270T<>4VO <>65 <0B8 AC20==V 2AVE 2V4<8E V=3V1VB>@V2 CYP3A4 01> CYP2D6, I>  
?@872>48BL 4> ?V428I5==O @V2=V2 ;>@0B048=C, 0 F5 2 A2>N G5@3C <>65 1CB8 ?@8G8=>N  
?V428I5==O G0AB>B8 28=8:=5==O ?>1VG=8E @50:FV9.

V4><> ?@> ?V428I5==O :=F5=B@0FV9 ;>@0B048=C 2 ?;072V ?VA;O >4=>G0A=>3> 70AB>AC20==O 7  
:5B>:=07>;<, 5@8B@>< V F8<5B848=><, I> =5 AC?@>2>46C20;>AO ;;V=VG=> 7=0GCI8<8 7  
VB8. >A;V465==O 270T<>4V9 7 V=H8<8 ?@5?0@0B0<8 ?@>2>48;8AO BV;L:8 7 CG0ABN 4>@>A;8E  
?0FVT=BV2.

**A>1;82>ABV 70AB>AC20==O.**

>@870=® A;V4 7 >15@56=VABN 70AB>A>2C20B8 C ?0FVT=BV2 V7 BO6:>N D>@<>N ?>@CH5==O  
DC=:FVW ?5GV=:8.

> A;:04C ?@5?0@0BC 2E>48BL ;0:B>70. FVTW ?@8G8=8 ?0FVT=B8 7 B0:8<8 @V4:8<8 A?04:>28<8  
70E2>@N20==O<8 O: =5?5@5=>A878, 45DVF8B ;0:B078 0?0 V <0;L01A>@1FVO 3;N:>78-30;0:B>78 =5  
?>28==V 70AB>A>2C20B8 40=89 ?@5?0@0B.

0AB>AC20==O ?@5?0@0BC >@870=® =5>1EV4=> ?@8?8=8B8, O: 18 <>6CBL =59B@0;V7C20B8 01>  
V=H8< G8=>< ?>A;01;OB8 ?>78B82=C @50:FVN ?@8 287=0G5==V V=45:AC @50:B82=>ABV H:V@8.

**0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.**

03VB=VABL 0=8E ?@> 70AB>AC20==O ;>@0B048=C 203VB=8<8 6V=:0<8 4C65 <0;>. >A;V465==O =0  
B20@8=0E =5 28O28;8 ?@O<8E 01> =5?@O<8E =530B82=8E 5D5:BV2, I> AB>ACNBLAO

@5?@>4C:B82=>W B>:A8G=>ABV. 060=>, O: 70EV4 157?5:8, C=8:0B8 70AB>AC20==O ?@5?0@0BC  
>@870=® C ?5@V>4 203VB=>ABV.

>4C20==O 3@C44N. 40=V I> A2V4G0BL ?@> 282545==O ;>@0B048=C/<5B01>;VBV2 V7 3@C4=8<  
<>;>:® =5 A;V4 70AB>A>2C20B8 2 ?5@V>4 3>4C20==O 3@C44N.

**\$5@B8;L=VABL 0=V I>4> 2?;82C ?@5?0@0BC =0 6V=>GC 01> G>;>2VGC D5@B8;L=VABL 2V4ACB=V.**

40B=VABL 2?;820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> V=H8<8 <5E0=V7<0<8.

>@870=® =5 2?;820T 01> 2?;820T =57=0G=8< G8=>< =0 740B=VABL :5@C20B8 02B>B@0=A?>@B< 01> V=H8<8 <5E0=V7<0<8. @>B5 ?0FVT=B>2V =5>1EV4=> ?>2V4><8B8, I> 4C65 @V4:> ?>2V4><;O;>AO ?@> A>=;82VABL, I><>65 2?;820B8 =0 740B=VABL :5@C20B8 02B>B@0=A?>@B< 01> <5E0=V7<0<8.

!>AV1 70AB>AC20==O B0 4>78.

!>AV1 70AB>AC20==O.

5@>@0;L=>. "01;5B:8 <6=0 70AB>A>2C20B8 =570;56=> 2V4 ?@89> >7C20==O.

>@>A;V B0 4VB8 2V:< 2V4 12 @>:V2 A;V4 ?@89<0B8 ?> 1 B01;5BFV (10 <3 ;>@0B048=C) 1 @07 =0 4>1C.

;O 4VB59 C 2VfV 2V4 2 4> 12 @>:V2 4>7C20==O 70;568BL 2V4 <0A8 BV;0. @8 <0AV BV;0 1V;LH5 30 :3:

10 <3 (1 B01;5B:0) 1 @07 =0 4>1C. VBO< 7 <0A>N BV;0 <5=H5 30 :3 70AB>A>2C20B8 ?@5?0@0B C 283;04V A8@>?C.

0FVT=B8 ;VB=L>3> 2V:C. 5 28<030TBLAO :>@5:FVW 4>7C20==O ;N4O< ;VB=L>3> 2V:C.

0FVT=B8 7 ?>@CH5==O< DC=:FVW ?5GV=:8. 0FVT=B0< 7 ?>@CH5==O<8 DC=:FV9 ?5GV=:8 BO6:>3> ABC?5=N A;V4 ?@87=0G0B8 ?@5?0@0B C =86GV9 ?>G0B:>2V9 4>7V, >A:V;L:8 2 =8E<>6;825 7=865==O ;;V@5=AC ;>@0B048=C. ;O 4>@>A;8E V 4VB59 V7 <0A>N BV;0 1V;LH5 30 :3 @5:> <5=4>20=0 ?>G0B:>20 4>70 A;:040T 10<3 G5@57 45=L.

0FVT=B8 7 ?>@CH5==O< DC=:FVW =8@>:. 5<0T =5>1EV4=>ABV 2 :>@5:FVW 4>78 4;O ?0FVT=BV2 7 ?>@CH5==O< DC=:FVW =8@>:.

**VB8.**

D5:B82=VABL B0 157?5:0 70AB>AC20==O ;>@0B048=C 4VBO< 2V:< 4> 2 @>:V2 =5 2AB0=>2;5=V. @5?0@0B C 283;04V B01;5B>: ?@87=0G0B8 4VBO< 7 <0A>N BV;0 1V;LH5 30 :3.

5@54>7C20==O.

5@54>7C20==O ;>@0B048=C ?V428ICT G0AB>BC 28=8:=5==O 0=B8E>;V=5@3VG=8E A87C20==V ?>2V4><;O;>AO ?@> A>=;82VABL, B0EV:0@4VN V 3>;>2=89 1V;L. # @07V ?5@54>7C20==O @5:> <5=4>20=> A8<0B8G=5 B0 ?V4B@84>26 =5>1EV4=>3> ?5@V>4C G0AC. >6;825 70AB>AC20==O 0:B82>20=>3> 2C3V;;O C 283;04V 2>4=>W ACA?5=7VW. "0:>6<>6=0 ?@>25AB8 ?@><820==O H;C=:0. >@0B048= =5 282>48BLAO V7 >@30=V72545==V 35<>4V0;V7C; 5D5:B82=VABL ?5@8B>=50;L=>3> 4V0;V7C C 282545==V ?@5?0@0BC =52V4><0. VA;O =52V4;:04=>W 4>?<>38 ?0FVT=B <0T 70;8H8B8AO ?V4 <548G=8< =03;O4>

>1VG=V @50:FVW.

@8 70AB>AC20==V ;>@0B048=C 2 @5:><5=4>20=V9 4>7V 10 <3 =0 4>1C ?@8 ?>:070==OE, I> 2;:NG0NBL 0;5@3VG=89 @8=VB V E@>=VG=C V4V>?0B8G=C :@>?820=:C, C 4>@>A;8E V ?V4;VB:V2 G0ABVH8<8 ?>1VG=8<8 @50:FVO<8, ?@> O:V ?>2V4><;O;>AO, 1C;8: A>=;82VABL, 3>;>2=89 1V;L, ?>A8;5==O 0?5B8BC V 157A>==O. # 4VB59 2V:< 2V4 2 4> 12 @>:V2 2V47=0G0;8AO B0:V =51060=V O28I0 O: 3>;>2=89 1V;L, =5@2>7=VABL 01> 2B<0. >1VG=V @50:FVW, O:V <>6CBL A?>AB5@V30B8AO ?@8 70AB>AC20==V ?@5?0@0BC, 2:070=V =86G5 70 ;:0A0<8 A8AB5< >@30=V2. '0AB>B0 287=0G5=0 O:: 4C65 G0AB> (>=1/10), G0AB> (2V4 >=1/100 4> <1/10), =5G0AB> (2V4 >=1/1 000 4> <1/100), @V4:> (2V4 >=1/10 000 4> <1/1 000), 4C65 @V4:> (<1/10 000) V =52V4><> (=5<>6;82> 2AB0=>28B8 70 =0O2=8<8 40=8<8).

# :>6=V9 3@C?V G0AB>B8 ?>1VG=V @50:FVW 2:070=V 2 ?>@O4:C 7=865==O A5@9>7=>ABV.

I>:C VW A8AB5<8: 4C65 @V4:> 0=0DV;0:AVO.

I>:C =5@2>2>W A8AB5<8: 4C65 @V4:> 70?0<>@>G5==O, AC4<<8.

I>:C A5@F52>-AC48==>W A8AB5<8: 4C65 @V4:> B0EV:0@4VO, ?0;L?VB0FVO.

I>:C (": 4C65 @V4:> =C4>B0, ACEVABL C @>BV, 30AB@8B.

I>:C 35?0B>1V;V0@=>W A8AB5<8: 4C65 @V4:> ?0B>;>3VG=V 7

I>:C H:V@8 V ?V4H:V@=>W ;:VB:>28=8: 4C65 @V4:> 28A8?0==O, 0;>?5FVO.

>@CH5==O 7030;L=>3> AB0=C V ?>2O70=V 7V A?>A>1<< 70AB>AC20==O ?@5?0@0BC: 4C65  
@V4:> 2B><0.

"5@ABV.

3 @>:8.

#<>28 715@V30==O.

15@V30B8 2 >@83V=0;L=V9 C?0:>2FV ?@8 B5ABC?=> 4;O 4VB59

#?0:>2:0.

> 10 B01;5B>: C 1;VAB5@V, 1 1;VAB5@ C ?0GFV.

0B53>@VO 2V4?CA:C.

57 @5F5?B0.

8@>1=8:.

" «8W2<54?@5?0@0B».

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A020465==O 4VO;L=>ABV.

01032, #:@0W=0, 3>, 139.