

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

"□&□"□□ \$"
(THIOCETAM FORTE)

!,:04:

4VNGV @5G>28=8: 1 B01;5B:0 28=C - 400 <3, <>@D>;V=VT2>W A>;V BV07>B=>W :8A;>B8, C
?5@5@0EC20==V =0 100 % @5G>28=C - 100 <3, I> 5:2V20;5=B=> 66,5 <3 BV07>B=>W :8A;>B8.
4>?>28=8: :@>E<0;L :0@B>;O=89;<0=VB; FC:>@-?C4@0; <03=VN AB50@0B; ?>2V4>; AC
?>:@8BBO «Opadry II Yellow» 33G22623 (3V?@><5;>70; ;0:B>70, <=>3V4@0B; B8B0=C 4V>:A84
(171); ?>;V5B8;5=3;V>;L (<0:@>3>;) 3000; B@80F5B8=; EV=>;V=>289 6>2B89 (104); 6>2B89 70EV4 FCF
(E 110); 70;V70 >:A84 6>2B89 (172); V=483>:0@

V:0@AL:0 D>@<0. "01;5B:8, 2:@8BV ?;V2:>2>N >1>;>=>N.

A=>2=V DV78:>-EVABV: B01;5B:8, 2:@8BV ?;V2:>2>N >1>;>=>N 6>2B>3> :>;L>@C, >20;L=>W D>@
<8, 7 @8A:>N 7 >4=>3> 1>:C B01;5B:8. 0 @>7;0 O4@> 1V;>3> :>;L>@C.

\$0@<0:>B5@0?52B8G=0 3@C?0. A8E>AB8>B@>?>V 70A>18. >4 "% N06B X.

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

\$0@<0:>48=0

@5?0@0B =0;568BL 4> 3@C?8 F5@51@>0:B82=8E 70A>1V2, <0T ?@>B8VH5:A840=B=V,<5
<1@0=>AB01V;V7CNGV B0 =>>B@>?>V 2;0AB82>ABV.

@5?0@0B ?>:@0ICT V=B53@0B82=C B0 :>3=VB82=C 4VO;L=VABL<>7:C, ?V428ICT 5D5:B82=VABL
?@>F5AC =02G0==O, c?@8OT CAC=5==N A8

\$0@<0:>;>3VG=89 5D5:B ?@5?0@0BC 7C<>2;5=89 270T<>?>B5= FVNNG>N 4VTN BV07>B=>W :8A;>B8
B0 ?V@0F5B0

@5?0@0B 740B=89 ?@8A:>@N20B8 >:8A;5==O 3;N:>78 2 @50:FVOE 05@>1=>3> B0 0=05@>1=>3>
>:8A;5==O, =>@<0;V7C20B8 1V>5=5@35B8G=V ?@>F5A8, ?V428IC20B8 @V25=L "\$, AB01V;V7C20B8
<5B01>;V7< C B:0=8=0E <>7:C.

@5?0@0B 30;L@5==O 0:B82=8E D>@< :8A=N, @50:B82CT 0=B8>:A840=B=C A8AB5@048:0;L=V
?@>F5A8 C B:0=8=0E <>7:C ?@8 VH5:@0ICT @5>;>3VG=V 2;0AB82>ABV :@>2V 70 @0EC=>:
0:B820FVW DV1@8=>;VB8G=>W A8AB5<8, AB01V;V7CT B0 7<5=HCT 2V4?>2V4=> 7>=8 =5:@>7C B0
VH5

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

>1@5 2A<>:BCTBLAO ?@8 70AB>AC20==V 2=CB@VH=L>, ?@>=8:0T 2 @V7=V >@30=8 V B:0=8=8, 2
B>;>2=>3> <>7:C. @5?0@0B ?@>=8:0T G5@57 ?;0F5=B0@>89 10@T@. >65= :>=5=B ?@5?0@0BC
<5B01>;V7CTBLAO >:@5<. V@0F5B0< ?@0:B8G=> =5 <5B01>;V7CTBLAO 2 >@30=V748BLAO V7
A5G5N. 5@V>4 =0?V2282545==O 4-8 3>48=8. "V07>B=0 :8A;>B0 <5B01>;V7CTBLAO C ?5GV=FV V
282>48BLAO V7 A5G5N.

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

>:070==O.

"@0=78B>@>V V E@>=VG=V ?>@CH5==O <>7:>2>3> :@>2>>1V3C, 7C<>2;5=V 0B5@>A;;5@>7<<
AC48= 3>;>2=>3> <>7:C B0 ?>@CH5==O<8 <>7:>2>3> :@>2>>1V3C C <8=C;>6 ?>:070=89 ?@8
?>@CH5==OE <>7:>2>3> :@>2>>1V3C, ?>@CH5==OE >1F5AV2<>7:C, 7C<>2;5=8E G5@5?=>-<>7:>28
<8 B@02<0<8, V=B>:A8:0FVO<8, 4V015B8G=>N 5=F5D0;>?0BVTN, 0 B0:>6 C @501V;VB0FV9=89
?5@V>4 VH53> B0 35<>@03VG=>3> V=AC;LBV2.

@>B8?>:070==O.

V428I5=0 GCB;82VABL 4> ?V@0F5B0?>EV4=8E ?V@>;V4>=C, B0/01> 4> BV07>B=>W :8A;>B8, 0
B0:>6 4> 1C4L-O:>3> V=H>3> :>=5=BC ?@5?0@0BC.

>AB@5 ?>@CH5==O <>7:>2>3> :@>2>>1V3C ?> 35<>@03VG=>

"5@2>W =54>AB0B=>ABV. %>@5O %0=BV=3B>=0.

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

"V>F5B0@B5 =5 <>6=0 ?@87=0G0B8 7 ?@5?0@0B0<8, O:V <0NBL :8A;C @.

'5@57 =0O2=VABL C A:;04V ?V@0F5B0

"8@5>W4=V 3>@<>=8.

@8 ACAC20==V 7 B8@5>W4=8<8 3>@<>=0<8 ("3+"4) <>6;820 ?V428I5=0 4@0BV2;82VABL,
457>@VT=B0FVO V ?>@CH5==O A=C.

F5=>:C<0@>;.

E2>@8E 7 BO6:8< ?5@51V3>< @5F8482CNG>3> B@><1>7C 70AB>AC20==O ?V@0F5B0:8E 4>70E
(9,6 3/4>1C) =5 ?2;820;> =0 4>7C20==O 0F5=>:C<0@>;C 4;O 4>AO3=5==O 7=0G5==O ?@>B@>
<1V=>2>3> G0AC (INR) 2,5-3,5, 0;5 ?@8 9>3> >4=>G0A=>AC20==V 2V4AL 7=0G=5 7=865==O @V2=O
03@530FVW B@><1>F8BV2, @V2=O DV1@8=>35=C, D0:B>@V2 V;;V1@0=4B0 (VIII: C; VIII: vW: Ag;
VIII: vW: Rco), 2'O7:>ABV :@>2V V ?;07<8.

\$0@<0>:V=5B8G=V 270T<>4VW.

<>2V@=VABL 71V2 =87L:0, >A:V;L:8 90 % ?@5?0@0BC 282>48BLAO 2 =57

In vitro ?V@0F5B0< =5 ?@83=VGCT F8B>E@>< 450 V7>D>@<8 CYP1A2, 26, 2!8, 2!9, 2!19, 2D6, 21 V 49
/11 C :>=F5=B@0FVW 142, 426, 1422

@8 :>=F5=B@0FVW 1422 =57=0G=5 ?@83=VG5==O CYP2A6 (21 %) V 4/5 (11 %). 4=0: @V25=L V F8E
42>E CYP-V7><5@V2 4>AB0B=V9 ?@8 ?5@528I5==V 1422

@>B85?V;5?B8G=V ;V:0@AL:V 70A>18.

0AB>AC20==O ?V@0F5B07V 20 <3/4>1C I>45==> ?@>BO3>< 4 B86=V2 V 1V;LH5 =5 7:@82C @V2=O
:>=F5=B@0FVW V <0:A8<0;L=C :>=F5=B@0FVN (!max) ?@>B85?V;5?B8G=8E ?@5?0@0BV2 C

A8@>20BFV :@>2V (:0@10<075?V=, D5=VB>W=, D5=>10@1VB0;, =0B@VN 20;L?@>0B) C E2>@8E =0
5?V;5?AVN.

4=>G0A=89 ?@89>< 7 5=0;0?@8;<, :0?B>?@8;< ?V428ICT @878: @>728B:C ?>1VG=8E @50:FV9 7
1>:C A5@F52>-AC48==>W A8AB5<8.

;:>3>;L.

!C< 7 0;:>3>;5< =5 ?2;8202 =0 @V25=L :>=F5=B@0FVW ?V@0F5B020BFV, V :>=F5=B@0FVO 0;:>3>;N 2
A8@>20BFV :@>2V =5 7AC20==V 1,6 3 ?V@0F5B0

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

>15@56=VABN =5>1EV4=> ?@89<0B8 ?@5?0@0B >A>10< ;VB=L>3> 2V:C, O:V AB@0640NBL 2V4
A5@F52>-AC48==>W ?0B>;>3VW, >A:V;L:8 >?8A0=V 28I5 ?>1VG=V @50:FVW C 40=>W 3@C?8
E2>@8E 2V47=0G0NBLAO G0ABVH5.

;5@3VG=V @50:FVW G0ABVH5 7CAB@VG0NBLAO 2 >AV1, AE8;L=8E 4> 0;5@3VW.

?;82 =0 03@530FVN B@><1>F8BV2. # 7207:C 7 B8<, I> ?V@0F5B0< 7=86CT 03@530FVN B@>

<1>F8BV2, =5>1EV4=> 7 >15@56=VABN ?@87=0G0B8 ?@5?0@0B E2>@8< 7 ?>@CH5==O< 35

<>AB07C, AB0=0<8, I> <>6CBL AC?@>2>46C20B8AL :@>2>28;820<8 (28@07:0 H;C=:>2>.:8H:>2>3>

B@0:BC), ?V4 G0A 7=0G=8E EV@C@3VG=8E >?5@0FV9 (2;:NG0NG8 AB<0B>;>3VG=V

2B@CG0==O), E2>@8< V7 A8<0<8 BO6:>W :@>2>B5GV 01> E2>@8<, O:V <0NBL 2 0=0<=57V 35

<>@03VG=89 V=AC;LB; ?0FVT=B0<, O:V 70AB>A>2CNBL 0=B8:>03C;O=B8, B@><1>F8B0@=V

0=B803@530=B8, 2;:NG0NG8 =87L:V 4>78 0F5B8;A0;VF8;>2>W :8A;>B8. @5?0@0B 282>48BLAO =8@:0

<8, B>1EV4=> >A>1;82C C203C ?@84V;OB8 E2>@8< 7 =8@:>2>N =54>AB0B=VABN.

0FVT=B8 ;VB=L>3> 2V:C. @8 4>23>B@820;V9 B5@0?VW C E2>@8E ;VB=L>3> 2V:C @5:>

<5=4CTBLAO @53C;O@=89 :>=B@>;L ?>:07=8:V2 DC=:FVW =8@>;, 70 =5>1EV4=>ABV :>@83CNBL

4>7C 70;56=> 2V4 @57C;LB0BV2 4>A;V465==O ;;V@5=AC :@50B8=V=C.

@5?0@0B 7C, O: 4>?>28=C, I> A;V4 2@0E>2C20B8 ?0FVT=B0< 7 =5?5@5=>A878, 45DVF8B>< ;0:B078

01> ?>@CH5==O< 2A<:BC20==O 3;N:>78/30;0:B>78.

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

5 A;V4 70AB>A>2C20B8.

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.

5 @5:><5=4>20=> 70AB>AC20==O ?@5?0@0BC ?@8 :5@C20==V 02B>B@0=A?>@B< B0 <5E0=V7<0
<8, I> ?>B@51CNBL ?V428I5=>W C2038, C 7207:C 7 @878:< @>728B:C <>6;828E =51060=8E @50:FV9
7 1>:C =5@2>2>W A8AB5<8.

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

>7C20==O B0 B@820;VABL ;V:C20==O 287=0G0T ;V:0@ 2 :>6=>@5<> 70;56=> 2V4 E0@0:B5@C B0
?5@51V3C 70E2>@N20==O.

@8 B@0=78B>@=8E V E@>=VG=8E ?>@CH5==OE <>7:>2>3> :@>2>>1V3C B0 2 @501V;VB0FV9=89
?5@V>4 ?VA;O VH53> 01> 35<>@03VG=>3> V=AC;LBC ?> 1 B01;5BFV 3 @078 =0 4>1C ?@>BO3>< 25-
30 4=V2.

"01;5B:8 "V>F5B0<□ \$>@B5 ?@87=0G0NBL 70 30 E28;8= 4> W48.

C@A ;V:C20==O AB0=>28BL 2V4 2-3 B86=V24> 3-4

;O ;V:C20==O 4V015B8G=>W 5=F5D0;>?0BVW ?@87=0G0NBL ?> 1 B01;5BFV 3 @078 =0 45=L
?@>BO3><

45 4=V2.

VB8.

5 70AB>A>2CNBL.

5@54>7C20==O.

@8 2V4E8;5==V 2V4 =07=0G5=8E ;V:0@5< 4>7 <>6;825 28=8:=5==O B0 ?>A8;5==O ?>1VG=8E 5D5:BV2
?@5?0@0BC (71C465==O, ?>@CH5==O A=C, 48A?5?A8G=V O28I0). # F8E 28?04:0E 7<5=HCNBL 4>7C
?@5?0@0BC B0 ?@87=0G0NBL A8<0B8G=5 ;V:C20==O (28;;8:0==O 1;N20==O, ?@<>820==O H;C=:C).

>1VG=V @50:FVW.

@8 ::V=VG=>AC20==V ?@5?0@0BC "V>F5B0@B5, <>6CBL A?>AB5@V30B8AO 28?04:8 ?>1VG=8E
@50:FV9:

7 I>:C F5=B@0;L=>W B0 ?5@8D5@8G=>W =5@2>2>W A8AB5<8: 3>;>2=89 1V;L, 7030;L=0
A;01:VABL;

7 I>:C H;C=:>2>-:8H:>2>3> B@0:BC: =C4>B0, 1;N20==O, 4V0@50;

7 I>:C VW A8AB5<8: 0;5@3VG=V @50:FVW, 2;;NG0NG8 28A8?0==O, A25@1V6, :@>?82O=:C;

7 I>:C 25AB81C;O@=>W A8AB5<8: 70?0<>@>G5==O.

E2>@8E <>6;8289 @>728B>: ?>1VG=8E @50:FV9, 7C<>2;5=8E >:@5<8<8 :>=5=B0<8 ?@5?0@0BC:
?V@0F5B0<>

7 I>:C :@>2V B0 ;V 35<>@03VG=V @>7;048;

7 I>:C VW A8AB5<8: 3V?5@GCB;82VABL, 0=0DV;0:B>W4=V @50:FVW;

?A8EVG=V @>7;048: 7=5@2>20=VABL, 45?@5AVO, ?V428I5=0 71C46C20=VABL, B@82>6=VABL,
715=B565==O, 30;NF8=0FVW;

7 I>:C =5@2>2>W A8AB5<8: 3V?5@:V=57VO, A>;82VABL, 0B0:AVO, ?>@CH5==O @V2=>2038,

?V428I5==O G0AB>B8 =0?04V2 5?V;5?AVW, 3>;>2=89 1V;L, 157A>==O, B@5

7 I>:C >@30=V2 A:CEC B0 ;01V@8=BC: 70?0<>@>G5==O;

7 I>:C B@02=>W A8AB5<8: 014>B0, 4V0@50, =C4>B0, 1;N20==O;

7 I>:C H:V@8 B0 ?V4H:V@=8E B:0=8=: 0=3V>=52@>B8G=89 =01@O:, 45@<0B8B8, 28A8?0==O,
:@>?82O=:0, A25@1V6;

7 I>:C @5?@>4C:B82=>W A8AB5<8 B0 3>4C20==O 3@C44N: ?V428I5==O A5:AC0;L=>W 0:B82=>ABV;
7030;L=V @>7;048: 0AB5=VO, 71V;LH5==O <0A8 BV;0.

- BV07>B=>N :8A;>B>N:

7 I>:C H:V@8 B0 ?V4H:V@=>W ;:VB:>28=8: A25@1V6, 3V?5@5?82O=:0, 0=3V>=52@>B8G=89 =01@O;;

7 I>:C VW A8AB5<8: 0=0DV;0:B8G=89 H>;;

7 I>:C F5=B@0;L=>W B0 ?5@8D5@8G=>W =5@2>2>W A8AB5<8: 70?0<>@>G5==O, HC< C 2CE0E;

7 I>:C A5@F52>-AC48==>W A8AB5<8: B0EV:0@4VO, ?V428I5==O 0@B5@V0;L=>3> B8A:C;

7 I>:C H;C=:>2>-:8H:>2>3> B@0:BC: 48A?5?AVO, 2;;NG0NG8 ACEVABL C @>BV, 74CBBO 682>B0,
=C4>BC, 1;N20==O;

7 I>:C 48E0;L=>W A8AB5<8: 7048H:0, O4CE0;

7030;L=V @>7;048: 30@OG:0, 7030;L=0 A;01:VABL;

@5?0@0B 2B89 70EV4 FCF (E 110), I> <>65 28;;8:0B8 0;5@3VG=V @50:FVW.

"5@ABV.3 @>:8.

#<>28 715@V30==O.

>@83V=0;L=V9 C?0:>2FV ?@8 B525 °C.

15@V30B8 2 =54>ABC?=>

#?0:>2:0.

> 10 B01;5B>: C 1;VAB5@V, 3 01> 6 1;VAB5@V2 C ?0GFV.

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

0 @5F5?B>

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.

#: @0W=0, 01032, <. 8W2, 2C;. !0:A030=AL:>3>, 139.