

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

"\$!®
(THERAFLEX®)

!::04:
4VNGV @5G>28=8: D-3;N:>70E;>@84 B0 =0B@VN E>=4@>WB8=C AC;LD0B;
1 :0?AC;0 E;>@84C, 400 <3 =0B@VN E>=4@>WB8=C AC;LD0BC;
4>?>28=8: 65;0B8=, :8A;>B0 AB50@8=>20, <03=VN AB50@0B, <0@30=FN AC;LD0B <=>3V4@0B.

V:0@AL:0 D>@<0. □0?AC;8.
A=>2=V DV78:>-EVABV: B25@4V, ?@>7>@V 65;0B8=>2V :0?AC;8, I>@>H>: 2V4 1V;C20B>3> 4>
A2VB;>-15652>3> :>;L>@C 7 :@8AB0;VG=8<8 G0AB8=:0<8.

\$0@<0:>B5@0?52B8G=0 3@C?0. 0A>18, I> 70AB>A>2CNBLAO ?@8 ?0B>;>3VW >?>@=>-@CE>2>3>
0?0@0BC. >4 ""% 09%.

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

\$0@<0:>48=0

&59 ;V:0@AL:89 70AV1 AB&>W B:0=8=8. %>=4@>WB8= B0 3;N:>70AB5>0@B@>7V. V:0@AL:89
70AV1 G8=8BL ?@>B870?0;L=C 4VN =0 ;VB8==>35==8E ?@>B5>3;V:0=V2, B0: V 5=4>35==>W
3V0;C@=>2>W :8A;>B8, 7=86CT :0B01>;VG=C 0:B82=VABL E>=4@>F8BV2 H;OE× V=3V1C20==O
45O:8E D5@<5=BV2, I> @C9=CNBL E@OI, B0:8E O: :>;035=070, 5AB0;070, ?@>B5>3;V:V=070,
D>AD>;V?070-2, N-0F5B8;3;V:>70I>, 0 B0:>6 V=3V1CT: D>@28=, O:V <>6CBL CH:>46C20B8 E@OI>2V
B:0=8=8 (in vitro), B0:8E O: AC?5@>:A84=V @048:0;8; 0:B82=VABL ;V7>A><0;L=8E D5@<5=BV2.
%>=4@>WB8= >48= 7 3>;>2=8E 5;5<5=BV2 E@OI0. V= 7=86CT 0:B82=VABL 70?0;L=>3> ?@>F5AC =0
@0==VE AB04VOE V, B0:8< G8=><, A?>2V;L=NT 4535=5@0FVN E@OI>2>W B:0=8=8. !?@8OT 7
<5=H5==N 1>;N, ?>;V?HCT DC=:FVN AC3;>1V2 B0 7<5=HCT ?>B@51C C =5AB5@>W4=8E
?@>B870?0;L=8E 70A>10E ?@8 >AB5>0@B@>7V :>;V==8E B0 :C;LH>28E AC3;>1V2.
;N:>70;>3VG=> ?@8ACB=V9 C ;N4AL:>@30=V7in vitro B0 in vivo ?>:070;8, I> 3;N:>70E;>@84 AB8
>3VG=8E 3;V:>703;V:0=V2 B0 ?@>B5>3;V:0=V2 E>=4@>F8B0<8 B0 A8=B57 3V0;C@=>2>W :8A;>B8
A8=>2V>F8B0<8.

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

VA;O >4=>@07>2>3> ?5@>@0;L=>3> ?@89>W 4>78 <0:A8<0;L=89 @V25=L E>=4@>WB8=C AC;LD0BC
2 ?;07AO30TBLAO G5@57 3-4 3>48=8. V>4>ABC?=VABL 4>78, I> 1C;0 70AB>A>20=0 ?5@>@0;L=>,
AB0=>28BL 12 %.

:@>2V 85 % E>=4@>WB8=C B0 9>3> 45?>;V<5@87>20=8E ?>EV4=8E 72O7CNBLAO 7 45:V;L:<0
?@>B5W=0<8 ?;07<8.

)>=09<5=H5 90 % 70AB>A>20=>W 4>78 E>=4@>WB8=C A?>G0B:C <5B01>;V7CNBLAO ;V7>A><0;L=8
<8 D>AD0B070<8, ?VA;O G>3> 45?>;V<5@87CNBLAO 3V0;C@>=V407>N, β-3;N:C@>=V407>N B0 β-N-
0F5B8;35:A>70N C ?5GV=FV, =8@:0E B0 V=H8E >@30=0E.

%>=4@>WB8= B0 9>3> 45?>;V<5@87>20=V ?>EV4=V 282>4OBLAO ?5@5206=> H;OE× =8@:>2>W
5:A:@5FVW. 5@V>4 =0?V2282545==O AB0=>28BL 2V4 5 4> 15 3>48=.

VA;O ?5@>@0;L=>3> 70AB>AC20==O 3;N:>70E;>@84 H284:> B0 <0965 ?>2=VABN 2A<>:BCTBLAO C
:8H5G=8:C. \$0@<0:>:V=5B8:0 3;N:>70 AB0=40@B=>W 4>78 1500 <3 >48= @07 =0 45=L, 0 28IV 4>78 =5
?@87254CBL 4> ?@>?>@FV9=> 28I>3> 71V;LH5==O <0:A8<0;L=>W :>=F5=B@0FVW 3;N:>70

V;LH5 25 % ?@89=OB>W 4>78 3;N:>704OBL 7 ?;07<8 :@>2V 4> E@OI>2>W B:0=8=8 B0 A8=>2V0;L=>W
AC3;>1>2>W <5<1@0=8.

3V4=> 7 5D5:B<< ?5@H>3> ?@>E>465==O C ?5GV=FV 1V;LH5 =V6 70 % 3;N:>70

:A:@5BCTBLAO C =57 =8@:0<8 V7 A5G5N B0 G0AB:>2> 7 :0;>4 =0?V2282545==O AB0=>28BL 68
3>48=.

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

>:070==O.

5@28==V B0 2B>@8==V >AB5>0@B@>78; >AB5>E>=4@>78; ?;5G>;>?0B:>289 ?5@V0@B@8B; ?5@5;>
<8 (4;O ?@8A:>@5==O CB2>@5==O :VAB:>2>W <>7>;V).

@>B8?>:070==O.

V428I5=0 GCB;82VABL 4> 1C4L-O:>3> 7 :>5=BV2 ?@5?0@0BC (0;5@3VG=V @50:FVW).

A>1;82V 70E>48 157?5:8.

- 5 ?5@528IC20B8 @5:><5=4>20=C 4>1>2C 4>7C.
- >15@56=VABN 70AB>A>2C20B8 ?0FVT=B0< 7 ?V428I5=>N GCB;82VABN (0;5@3VTN) 4>
<>@5?@>4C:BV2.
- 0FVT=B0< 7 FC:@>28< 4V015B<< 4>FV;L=> G0ABVH5 ?@>2>48B8 :>=B@>;L @V2=O FC:@C 2
:@>2V, >A>1;82> =0 ?>G0B:C ;V:C20==O.
- C;> >?8A0=> 703>AB@5==O A8<, B>
- # @V4:VA=8E 28?04:0E C ?0FVT=BV2 7 A5@F52>N B0/01> =8@:>2>N =54>AB0B=VABN
A?>AB5@V30;8AO =01@O:8 B0/01> 70B@848 2 >@30=V7

70T<>4V0 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.

>4=8E A?5FV0;L=8E 4>A;V465=L ;V:0@AL:>W 270T<>4VW =5 1C;> ?@>2545=>, >4=0: DV78:>-EV
=4@>VB8=C A2V4G0BL ?@> =87L:C V<>2V@=VABL 270T<>4VW.
V:0@AL:89 70AV1 ACW4=8<8 ?@>B870?0;L=8<8 70A>10<8 B0 :>@B8:>AB5@>W40<8.
450:8E 465@5;0E 2:07CTBLAO, I> ?@8 >4=>G0A=>AC20==V 3;N:>704=>3> =>@<>20=>3>
A?V22V4=>H5==O (INR) B0 @>728B>: :@>2>B5GV. ">4=>G0A=>AC20==V =5>1EV4=> :>=B@>;N20B8
?0@0<5B@8 73>@B0==O :@>2V.

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

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.
7207:C 7 B8<, I> ;V=VG=V 40=V I>4> 5D5:B82=>ABV B0 157?5G=>ABV 70AB>AC20==O
?@5?0@0BC C ?5@V>4 203VB=>ABV 2V4ACB=V, ?@5?0@0B C F59 ?5@V>4 A;V4 70AB>A>2C20B8
;8H5 ?VA;O :>=AC;LB0FVW 7 ;V:0@5

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 1C;> ?@>2545=> 4>A;V465=L I>4> 2?;82C =0 740B=VABL :5@C20B8 02B>B@0=A?>@B< 01> V=H8
<8 <5E0=V7<0<8. 4=0.; ?0FVT=B <0T A;V4:C20B8 70 7

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

@89<0B8 2=CB@VH=L>, 70?820NG8 =525;8:>N :V;L:VABN 2>48. >@>A;8< 70AB>A>2C20B8 ?> 1
:0?AC;V 3 @078 =0 4>1C. V=V<0;L=0 B@820;VABL ;V:C20==O 22B>@N20B8 7 V=B5@20;>< 2V4 3 4> 6
. /:I> =5>1EV4=>, :C@A ;V:C20==O <>6=0 ?>2B>@8B8 7 V=B5@20;>< C 3
&59 ;V:0@AL:89 70AV1 =5 ?@87=0G5=89 4;O ;V:C20==O 3>AB@8E 1>;L>28E 2V4GCBBV2. >;53H5==O
A8A>1;82> ?>;53H5==O 1>;N) <>65 =5 A?>AB5@V30B8AO =02VBL ?VA;O 45:V;L:>E B86=V2
;V:C20==O, 0 2 450:8E 28?04:0E V 4>2H5. /:I> ?VA;O 2-3;53H5==O =5 A?>AB5@V30TBLAO, A;V4
725@=CB8AO 4> ;V:0@O.
0FVT=B8 <0NBL 725@=CB8AO 4> ;V:0@O, O:I> A8<8 ?>A8;NNBLAO ?VA;O ?>G0B:C 70AB>AC20==O
FL>3> ;V:0@AL:>3> 70A>1C.

VB8. # 7207:C 7 B8<, I> 4>A2V4C 70AB>AC20==O 4VBO< =54>AB0B=L>, =5 @5:><5=4CTBLAO
70AB>A>2C20B8 4VBO

5@54>7C20==O.

5 1C;> >?8A0=> 6>4=8E 28?04:V2 ?5@54>7C20==O. 0 @57C;LB0B0<8 4>A;V465=L 3>AB@>W B0
E@>=VG=>W B>:A8G=>ABV, 6>4=8E B>:A8G=8E A8GV:CTBLAO, =02VBL 70 C<>2 70AB>AC20==O
28A>:8E 4>7. 4=0: O:I> 28=8:0T ?5@54>7C20==O, 9>3> ;V:C20==O <0T 1CB8 A8<0B8G=8AC20B8
AB0=40@B=V ?V4B@848.

>1VG=V @50:FVW.

>ABC?=V 40=V 2:07CNBL =0 B5, I> 3;N:>70=4@>WB8=C AC;LD0B 4>70E, I> 70728G09
?@87=0G0NBLAO (1500 <3/45=L B0 1200 <3/45=L 2V4?>2V4=>), =5 B>:A8G=V B0 =5 A?@8G8=ONBL
2V4><8E <>45;59 =5A?@8OB;828E @50:FV9.
86G5>?8A0=V ?>1VG=V 4VW 1C;> 2V4 C ?>AB@5TAB@0FV9=89 ?5@V>4 70AB>AC20==O
;V:0@AL:>3> 70A>1C. A:V;L:8 V=D>@<0FVN =04020;8 4>1@>2V;L=> V7 ?>?C;OFVW
=52AB0=>2;5=>W G8A5;L=>ABV, G0AB>BC F8E @50:FV9 2AB0=>28B8 =5 702648 <>6;82>.
I>:C H;C=:>2>-.8H:>2>3> B@0:BC.
V;L 2 5?V30AB@0;L=V9 4V;O=FV, 48A?5?AVO, 4V0@5O, =C4>B0 B0 1;N20==O.
I>:C VW A8AB5<8.

;5@3VG=V @50:FVW. /:I> 28=8:0NBL 0;5@3VG=V @50:FVW, ;V:C20==O<OT 1CB8 ?@8?8=5=5,
=5>1EV4=0 :=AC;LB0FVO A?5FV0;VAB0.

I>:C =5@2>2>W A8AB5<8.

0?0<>@>G5==O, 3>;>2=89 1V;L, A>=;82VABL.

=HV ?>1VG=V @50:FVW, I> 7304CNBLAO C ;VB5@0BC@=8E 465@5;0E.

>2V4><;O;>AO ?@> 5:AB@0A8AB>;8 B0 0;>?5FVN ?@8 ?@89>

"5@ABV.3 @>:8.

#<>28 715@V30==O.

15@V30B8 2 >@83V=0;L=V9 C?0:>2FV ?@8 B5>C. 15@V30B8 C =54>ABC?=>

#?0:>2:0. ;0AB8:>289 D;0:>= ?> 30, 01> 60, 01> 120 :0?AC; C :0@B>==V9 :=@>1FV.

0B53>@VO 2V4?CA:C. 57 @5F5?B0.

8@>1=8:.

>=B@0:B \$0@<0:0; >@?>@59H=, !(/
Contract Pharmacal Corporation, USA.

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

135 40?>3, LN->@: 11788, !(/

135 Adams Avenue, Hauppauge, New York 11788, USA.

VAF5 ?@>20465==O 4VO;L=>ABV:

160 ><<5@A @092, %>?>3, LN->@: 11788, !(/

160 Commerce Drive, Hauppauge, NY 11788, USA.

002=8:.

09T@ >=ALN<5@ 5@ , (259F0@VO/

Bayer Consumer Care AG, Switzerland.

VAF57=0E>465==O 7002=8:0.

5B5@ 5@V0=-(B@0AA5 84, 4052 075;L, (259F0@VO/

Peter Merian-Strasse 84, 4052 Basel, Switzerland.