

!" #&/
4;O <548G=>3> 70AB>AC20==O ?@5?0@0BC
&!"-®
(CELESTODERM-V®)

!::04:

4VNG0 @5G>28=0: betamethasone;
1 3 <07V
4>?>28=8: ?0@0DV= 1V;89 <'O:89, >;VO

V:0@AL:0 D>@<0. 07L.

A=>2=V DV78:>-EVABV:
;045=L:0 >4=>@V4=0 <07L 1V;>3> :>;L>@C 157 AB>@>==VE 2::NG5=L.

\$0@<0:>B5@0?52B8G=0 3@C?0.

>@B8:>AB5@>W48 4;O 70AB>AC20==O C 45@<0B>;>3VW. :B82=V :>@B8:>AB5@>W48 (3@C?0).
>4 ""% D07A C01.

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

\$0@<0:>48=0
5B0<5B07>=C 20;5@0B A8=B5B8G=89 3;N:>:>@B8:>AB5@>W4 4;O 7>2=VH=L>3> 70AB>AC20==O.
5B0<5B07>= ?@>O2;OT 28A>:C 3;N:>:>@B8:>AB5@>W4=C 0:B82=VABL V BV;L:8:>@B8:>W4=89
5D5:B.

024O:8 ?@>B870?0;L=V9, ?@>B8A25@1V6=89 B0 AC48=>72C6C20;L=V9 4VW B0:V
:>@B8:>AB5@>W48, O: 15B0<5B07>=C 20;5@0B, ?5@5206=> 28:>@8AB>2CNBLAO 4;O ;V:C20==O
45@<0B>7V2, GCB;828E 4> 4VW :>@B8:>AB5@>W4V2.

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

VA;O ?@>=8:=5==O 2 H:V@C ?@>DV;L D0@<0:>:V=5B8:8 @B8:>AB5@>W4V2 ?>4V1=89 4> B0:>3>
A8AB5<=8E :>@B8:>AB5@>W4V2.

>@B8:>AB5@>W48 72'O7CNBLAO 7 1V;:0<8 ?;07<8 :@>2V 2 @V7=V9 A=>2=>=8 <5B01>;V7CNBLAO 2
>5GV=FV V 282>4OBLAO V7 A5G5N.

!8AB5<=5 2A<:>:BC20==O :>@B8:>AB5@>W4V2 3> 70AB>AC20==O >GV:CTBLAO BV;L:8 70
=5A?@8OB;828E C<>2 (B@820;5 ;V:C20==O, >;N7V9=0 ?>2'O7:0).

FV=N20;>AO G5@57H:V@=5 2A<:>:BC20==O 15B0<5B07>=C 20;5@0BC 7 540 2 >;VW» C 74>@>28E
4>1@>2>;LFV2 7 5:A?5@8<5=B0;L=> ?>H:>465=>N H:V@>N. '5@57 24 3>48=8 =0 H:V@V 28O2;O;>AO
68,1 ± 6,9 % 3H-W 4>78 200 <3. '5@57 72 3>48=8 7,34 ± 2,74% V 4,80 ± 0,76% 70AB>A>20=>W 4>78
282>48;>AO V7 A5G5N V :0;< 2V4?>2V4=>.

5O:V B>?VG=V :>@B8:>AB5@>W48 B0 WE <5B01>;VB8 282>4OBLAO 7 6>2GN.

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

>:070==O.

V:C20==O 45@<0B>7V2, GCB;828E 4> A8;L=>4VNG>W 3;N:>:>@B8:>AB5@>W4=>W B5@0?VW, B0:8E
O: ?A>@V07; ?>G0B:>25 ;V:C20==O BO6:>W 0B>?VG=>W 5:75<8.

@>B8?>:070==O.

?5AB>45@®, <07L, ?@>B8?>:070=89 ?0FVT=B0< 7 0;5@3VG=8<8 @50:FVO<8 =0 1C4L-O:89 7 :>=5=BV2
?@5?0@0BC.

?5AB>45@®, <07L, ?@>B8?>:070=89 C B0:8E 28?04:0E:

- 2V@CA=V V=D5:FVW, C B>AB20:F8=0;L=V @50:FVW B0 2VB@O=0 2VA?0;
- 2V@CA=V H:V@=V V=D5:FVW (=0?@8::04 ?@>AB89 35@?5A, >?5@V7C20;L=89 ;8H09,
2VB@O=0 2VA?0);
- @>652V 2C3@8;

- @>70F50?>4V1=89 (?5@V>@0;L=89) 45@<0B8B;
- 10:B5@V0;L=V 45@<0B>78, C B>7 V A8DV;VA H:V@8;
- 3@81:>2V 70E2>@N20==O;
- >DB0;L<>;>3VG=V 70E2>@N20==O (?5AB>45@®, <07L, =5 ?@87=0G5=89 4;O >DB0;L
<>;>3VG=>3> 70AB>AC20==O).
5 @5:><5=4CTBLAO 70AB>AC20==O <07V ?5AB>45@® ?V4 >;:N7V9=8<8 ?>2'O7:0<8 (3V?A B>I>).
!;V4 4>B@8A>1;82>W >15@56=>ABV ?@8 =0=5A5==V ?5AB>45@®, <07L, =0 H:V@C >1;8GGO. 5
4>?CA:0B8 ?>B@0?;O==O ?@5?0@0BC 2 >GV 01> =0 A;87>2V >1>;>=:8. !;V4 C=8:0B8 B@820;>3>
>V:C20==O B0/01> 70AB>AC20==O =0 25;8:V9 ?>25@E=V H:V@8, >A:V;L:8<>6;825 2A<>:BC20==O
0:B82=>W @5G>28=8.
5 A;V4 70AB>A>2C20B8 <07L ?5AB>45@® C ?5@H>

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

72'O7:C 7 ?@8ACB=VABN ?0@0DV=C 1V;>3> <'O:>3> V >;VW W O: 4>?>28= ;V:C20==O <077N
?5AB>45@® 2 0=>35=VB0;L=V9 4V;O=FV <>65 ?>H:>48B8 AB@C:BC@C ;0B5:A=8E ?@575@20B82V2
V 7=878B8 WE 157?5:C ?@8 28:>@8AB0==V ?V4 G0A ;V:C20==O.

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

?5AB>45@® =5 ?@87=0G5=89 4;O 70AB>AC20==O 2 >DB0;L<>;>3VW.
!8AB5<=5 2A<>:BC20==O @B8:>AB5@>W4V2, O: ?@028;>, 71V;LHCTBLAO 7V 71V;LH5==O<
4>7C20==O :>@B8:>AB5@>W4C, 71V;LH5==O< B@820;>ABV ;V:C20==O V 25;8G8=8 >1@>1;N20=>W
?>25@E=V BV;0.
">@B8:>AB5@>W48 7 28A>:>N 0:B82=VABN =0 25;8:V 4V;O=:8 H:V@8 A;V4 70AB>A>2C20B8 ?V4
@5B5;L=8< @53C;O@=8< :=B@>;5<, >A:V;L:8 2>=8 <>6CBL A?@8G8=8B8 ?@83=VG5==O 3V?>B0;0
<>-3V?>DV70@=>=-04=8@:>2>70;>7=>W A8AB5<8 ().
@07V @>728B:C ?@83=VG5==O ;V:0@AL:89 ?@5?0@0B A;V4 2V4BC =0=5A5==O 7=878B8 01>
?5@525AB8 ?0FVT=B0 =0 :>@B8:>AB5@>W4=89 ?@5?0@0B A;01H>W 4VW.
\$C=:FVO , O: ?@028;>, 2V4=>2;NTBLAO ?VA;O 2V4
>:@5<8E 28?04:0E <>6CBL @>72820B8AO A8<8 2V4
?5AB>45@® <07L ?5@5=>A8BLAO 2 >A=>2=>1@5. @>B5 ;V:C20==O A;V4 ?@8?8=8B8 ?@8 28=8:=5==V
?>4@07=5==O 01> ?V428I5=>W GCB;82>ABV.
@8 28=8:=5==V ?>4@07=5==O H:V@8 01> ?>02V >7=0: ?V428I5=>W GCB;82>ABV C 7207:C V7
70AB>AC20==O< ?5AB>45@® ;V:C20==O A;V4 ?@8?8=8B8 V ?V4V1@0B8 E2>@>ABV V=D5:FVW
A;V4 ?@87=0G8B8 2V4?>2V4=V ?@>B83@81:>2V 01> 0=B810:B5@V0;L=V 70A>18. /:I> ?@8 FL>,
70AB>AC20==O :>@B8:>AB5@>W4V2 =5>1EV4=> ?@8?8=8B8 4> ;V:2V40FVW >7=0: V=D5:FVW.

0AB>AC20==O 2 ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

'5@57 B5 I> 157?5:0 70AB>AC20==O @B8:>AB5@>W4V2 4;O 203VB=8E =5 2AB0=>2;5=0, =5 A;V4
70AB>A>2C20B8 <07L ?5AB>45@® 2 ?5@H> @87=0G5==O B0:8E ?@5?0@0BV2 <>6;825 BV;L:8 2
?V7=VHV B5@ABV 70 C<>28, I> >GV:C20=0 :>@8ABL 4;O <091CB=L>W <0B5@V O2=> ?5@528ICT
?>B5=FV9=C 703@>7C 4;O ?;>40. @5?0@0B8 40=>W 3@C?8 =5 A;V4 70AB>A>2C20B8 203VB=8< =0
25;8:V 4V;O=:8, C 25;8:8E :V;L:>ABOE, ?@>B03< B@820;8E ?5@V>4V2 01> ?V4 >;:N7V9=8<8 ?>2'O7:0
<8.
>B5?5@ =5 70A>20=>, G8 <>6CBL :>@B8:>AB5@>W48 2=0A;V4>: A8AB5<=>W 01A>@1FVW ?@8
AC20==V ?@>=8:0B8 2 3@C4=5 <>;>:, B>4> ?@8?8=5==O 3@C4=>3> 283>4>2C20==O 01>
?@8?8=5==O 70AB>AC20==O ?@5?0@0BC =5>1EV4=> 2@0E>2C20B8 206;82VABL ;V:C20==O, O:5
?@>2>4OBL, 4;O <0B5@V.

**40B=VABL 2?;820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> @>1>BV 7
V=H8<8 <5E0=V7<0<8.**

0728G09 ?@5?0@0B =5 2?;820T =0 H284:VABL @50:FVW ?0FVT=B0 ?@8 :5@C20==V
02B>B@0=A?>@B< 01> @>1>BV 7 V=H8<8 <5E0=V7<0<8.

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

?5AB>45@®, <07L, A;V4 =0=>A8B8 B>=:8< H0@<=0 C@065=V 4V;O=:8 H:V@8 45:V;L:0 @07V2 =0 4>1C.

!>AV1 70AB>AC20==O

0=5AB8 4>AB0B=N :V;L:VABL<07V ?5AB>45@® B>=:8< H0@<, I>1 ?>2=VABN ?>:@8B8 C@065=V 4V;O=:8 H:V@8, V >15@56=> 2B5@B8 2 H:V@C. @8 ?>;V?H5==V AB0=C G0AB>BC =0=5A5=L<>6=0 7=878B8.

!;V4 C=8:0B8 B@820;>3> 70AB>A>2C20==O ?5AB>45@® (1V;LH5 3 =0=5A5==O <07V =0 25;8:8V 4V;O=:8 (?>=04 20 % ?>25@E=V BV;0). &5 AB>ACTBLAO V ;V:C20==O 1V;LH =V6 10 % ?>25@E=V BV;0 ?@>BO3< 1V;LH5 1 B86=O.

VA;O ?>;V?H5==O ;V=VG=>W :0@B8=8 G0AB> @5:<5=4CTBLAO 70AB>AC20==O A;01H>3> 3;N:>:@B8:>AB5@>W4C.

'0AB> @5:<5=4CTBLAO B0: 720=89 ?V4EV4 B0=45<=>W B5@0?VW, O:89 ?>;O30T 2 70AB>AC20==V <07V ?5AB>45@® >48= @07 =0 4>1C, ?>BV< G5@57 12 3>48= - 2V4?>2V4=>3> 3> ?@5?0@0BC, I> =5 3> :=5=B0.

>65 1CB8 4>FV;L=>N 9 V=B5@20;L=0 B5@0?VO, O:0 ?>;O30T 2 70AB>AC20==V <07V ?5AB>45@® B0 3> ?@5?0@0BC, I> =5 3> :=5=BC, ?> G5@7V ?@>BO3< B86=O.

5:<5=4CTBLAO @5B5;L=5 A?>AB5@565==O 70 @>728B:<>7=0: V A8

!>AV1 70AB>AC20==O A;V4 040?BC20B8 4> B8?C H:V@8 V AB04VW 70E2>@N20==O.

?5AB>45@®, <07L, T ?5@5206=>N ;V:0@AL:>N D>@<N 4;O ACE>W, ;CA:0B>W B0 3@C1>W H:V@8 ?@8 E@>=VG=V9 B0 ?V43>AB@V9 D>@N20==O.

!;V4 70AB>A>2C20B8 04@5A=C 0=B810:B5@V0;L=C B5@0?VN ?@8 45@<0B>70E, ?>2'O70=8E 7 10:B5@V9=>N V=D5:FVTN.

0FVT=B8 7 45@<0B>70<8 3@81:>2>3> ?>E>465==O ?>B@51CNBL A?5FV0;L=>3> ;V:C20==O.

5 70AB>A>2C20B8 ?V4 >;N7V9=8<8 ?>2 O7:0<8, >A:V;L:8 <>65 ?>A8;N20B8AO ?>1VG=0 4VO ?@5?0@0BC.

VB8.

5<0T ;V=VG=8E 40=8E I>4> 70AB>AC20==O ?@5?0@0BC C 4VB59, B> 70AB>A>2C20B8 9>3> ?0FVT=B0< FVTW 2V:>2>W :0B53>@VW.

A:V;L:8 C 4VB59 25;8G8=0 A?V22V4=>H5==O ?>;IV ?>25@E=V B0<0A8 BV;0 1V;LH0, =V6 C 4>@>A;8E, V, >B65, ?>3;8=0==O ?@5?0@0BC 1V;LH 0:B82=5, 4VB8 1V;LH AE8;L=V 4> @878:C ?@83=VG5==O DC=:FVW 3V?>B0;0<-3V?>DV70@=>=-04=8@:>2>70;>7=>W A8AB5<8 () 7 1>:C :>@B8:>AB5@>W4V2 V @>728B:C 5:7>35==8E 5D5:BV2 :>@B8:>AB5@>W4V2.

5@54>7C20==O.

04 4>23>B@820;5 28:>@8AB0==O :>@B8:>AB5@>W4V2 4;O 3> 70AB>AC20==O <>65 A?@8G8=8B8 ?@83=VG5==O 3V?>DV70@=>-04@5=0;>2>W DC=:FVW, I> ?@872>48BL 4> 2B>@8==>W

=54>AB0B=>ABV =04=8@=8:>28E 70;>7 B0 ?>O28 A8?B>@B8F87< F5=:0-CH8=30. >AB@V A8<8 3V?5@:>@B8F871>@>B=V.

@8 ?5@54>7C20==V ?>:070=> 2V4?>2V4=5 A8<0B8G=5 ;V:C20==O. 0 =5>1EV4=>ABV ?@>2>4OBL :>@5:FVN 5;5:B@>;VB=>3> 10;0=AC. # @07V E@>=VG=>W B>:A8G=>W 4VW @5:<5=4CTBLAO ?>ABC?>20 2V4@B8:>AB5@>W4C.

>1VG=V @50:FVW.

'0AB>B0 ?>1VG=8E 5D5:BV2:

4C65 G0AB> (≥1/10);

G0AB> (≥ 1/100 - < 1/10);

=5G0AB> (≥ 1/1 000 - < 1/100);

@V4:> (≥ 1/10 000 - < 1/1 000);

4C65 @V4:> (< 1/10 000);

52V4><> (G0AB>BC =5<>6;82> 2AB0=>28B8 =0 ?V4AB02V =0O2=8E 40=8E).

>1VG=V 5D5:B8, ?>2'O70=V 7 ;V:C20==O<

<p>>@CH5==O 7 1>:C H:V@8 V ?V4H:V@=>W :;VB:>28=8 '0AB>:</p> <p>5G0AB>:</p>	<p>5GV==O, A25@1V6, ?>4@07=5==O, ACEVABL H:V@8, D>;V:C;VB, 3V?5@B@8E>7, 2C3@>?>4V1=89 28A8?, 3V?>?V3<5=B0FVO, 0:=5 =0 B;V 70AB>AC20==O AB5@>W4V2, @>70F50?>4V1=89 (?5@V>@0;L=89) 45@<0B8B, 0;5@3VG=89 :>=B0:B=89 45@<0B8B</p> <p><0F5@0FVO H:V@8, 0B@>DVO H:V@8, AB@8W, ?VB=8FO, >A>1;82> ?V4 >;N7V92=>N ?>2'O7:>N</p>
<p>=D5:FVW B0 V=207VW 5G0AB>:</p>	<p>2B>@8==0 V=D5:FVO, >A>1;82> ?V4 >;N7V92=>N ?>2'O7:>N</p>

>:>;N20==O H:V@8, CIV;L=5==O H:V@8, @>7B@VA:C20==O H:V@8, 2V4GCBBO B5?;0, ?;0AB8=G0B5
;CI5==O H:V@8, 2>3=8I525 ;CI5==O H:V@8, D>;V:C;O@=89 28A8?, 5@8B5<0, B5;50=3V5:B07VW.

@8 70AB>AC20==V ?@5?0@0BC =0 25;8:V ?>25@E=V 01> ?V4 >;N7V9=>N ?>2'O7:>N, >A>1;82>
?@>BO3<< B@820;>3> ?5@V>4C, =5>1EV4=> <0B8 =0 C207V <>6;82VABL @>728B:C A8AB5<=>W
4VW ?@5?0@0BC.

?0FVT=BV2 7 V=482V4C0;L=>N =5?5@5=>A8 1C4L-O:>3> :>=5=B0 ?@5?0@0BC <>6;82V @50:FVW
3V?5@GCB;82>ABV.

C4L-O:V ?>1VG=V O28I0, I> A?>AB5@V30NBLAO ?@8 A8AB5<=>AC20==V 3;N:>:>@B8:>W4V2,
2;;NG0NG8 AC?@5AVN :>@8 =04=8@:>28E 70;>7, <>6CBL 28=8:0B8 V ?@8 AC20==V
3;N:>:>@B8:>AB5@>W4V2.

"5@ABV.
3 @>:8.

#<>28 715@V30==O.
15@V30B8 2 =54>ABC?=>

#?0:>2:0.
> 15 3 01> 30 3 2 0;N 1 BC1V 2 :0@B>==V9 :>@>1FV.

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

8@>1=8:.
(5@V=3-;0C 01> ..., 5;L3VO/
Schering-Plough Labo N.V., Belgium.

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A0 20465==O 4VO;L=>ABV.
=4CAB@VT?0@: 30, %59AB->?-45=-5@3, =B25@?5=, -2220, 5;L3VO/
Industriepark 30, Heist-op-den-Berg, Antwerpen, B-2220, Belgium.