

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

\$!\$□ .□ ,
(PHOSPHALUGEL)

!,:04:

4VNG0 @5G>28=0: 0;NAD0B (aluminium phosphate);
1 ?0:5B AD0BC 20 % 35;N 12,38 3;
4>?>28=8: A>@1VBC @>7G8=, I> =5 :@8AB0;V7CTBLAO (420), 030@, ?5:B8=, :0;LFVN AC;LD0B,
:0;VN A>@10B, 0@><0B870B>@ 0?5;LA8=>289, 2>40 >G8I5=0.

V:0@AL:0 D>@<0. 5;L >@0;L=89.
A=>2=V DV78:>-EVABV: 35;L :@5<2>-1V;>3> :>;L>@C V7 70?0E< B0 A<0:< A>;>4:>3> 0?5;LA8=C.

\$0@<0:>B5@0?52B8G=0 3@C??. @5?0@0B8 4;O ;V:C20==O :8A;>B>70;56=8E 70E2>@N20=L.
=B0F848. ;NAD0B. >4 "% A02A B03.

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

\$0@<0:>48=0
@5?0@0B 02;OT A>1>N 710;0=A>20=89 35;L 0;NAD0BC. '8=8BL :8A;>B>=59B@0;V7CNGC,
>12>;V:0NGC, 04A>@1CNGC 4VN. =86CT ?@>B5>;VB8G=C 0:B82=VABL ?5?A8=C, 7207CT 6>2G=V
:8A;>B8 B0 ;V7>;5F8B8=
;NAD0B 70240:8 1CD5@=8< 2;0AB82>ABO< =59B@0;V7CT BV;L:8 =04;8H>: A>;O=>W :8A;>B8,
715@V30T DV7V>;>3VG=V C<>28 B@02;5==O B0 =5 ?@872>48BL 4> 2B>@8==>W 3V?5@A5:@5FVW
H;C=:>2>3> A>:C. =B0F84=0 4VO ?@5?0@0BC ?@>O2;OTBLAO H284:>.
VF5;8 0;NAD0BC <0NBL 1V;LHC :=B0:B=C ?>25@E=N, >12>;V:0NBL A;87>2C >1>;>=:C >4=>@V4=8<
H0@><, 70E8I0NBL WW 2V4 4VW 03@5A82=8E D0:B>@V2 B0 A?@8ONBL @535=5@0FVW.
&8B>?@>B5:B>@=0 4VO ?@5?0@0BC 7C<>2;5=0 B0:>6 740B=VABN 0:B82C20B8 A8=B57
?@>AB03;0=48=V2, O:V AB8=0BV2 C A;87>2V9 >1>;>=FV H;C=:0.
0AB>AC20==O ?@5?0@0BC =5 ?@872>48BL 4> ?>@CH5=L 5;5:B@>;VB=>3> 10;0=AC, =5 A?@8G8=OT
@>728B:C 0;0;>7C B0 CB2>@5==O :0<5=V2 A5G>282V4=8E H;OEV2.
\$0@<0:>:V=5B8:0.
;NAD0B =59B@0;V7CT A>;O=C :8A;>BC 7 CB2>@5==O< 0;N@84C. V4 2?;82< ;C6=>3> A5@54>28I0
:8H5G=8:C >AB0==V9 ?5@5B2>@NTBLAO C ;C6=V A>;V 0;N30=> 2A<:BCNBLAO B0 282>4OBLAO 7
:0;>AD0;N35;L =5 7207CT E0@G>2V D>AD0B8, =5 ?@872>48BL 4> ?>@CH5=L D>AD>@=>:-
:0;LFVT2>3> >1AB5>?>@>7C B0 >AB5><0;OFVW.
0;568BL 4> 3@C?8 0=B0F84V2, I> =5 2A<:BCNBLAO.

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

>:070==O.

V:C20==O :8A;>B>70;56=8E 70E2>@N20=L.
@5?0@0B 70AB>A>2CNBL O: <=>B5@0?VN, B0: V 2 A:;04V :>W B5@0?VW ?@8:
- 28@07:>2V9 E2>@>1V H;C=:0 B0 420=04FOB8?0;>W :8H:8;
- 3>AB@>=VG=>@<0;L=>N 01> ?V428I5=>N A5:@5B>@=>N DC=:FVTN H;C=:0;
- 3@86V AB@02>EV4=>3> >B2>@C 4V0D@03<8, 30AB@>57>D0350;L=V9 @5D;N:A=V9 E2>@>1V (C
B.G. ?@8 @5D;N:A-57>D03VBV), 4C>45=>30AB@0;L=>
- DC=:FV>=0;L=V9 48A?5?AVW;
- DC=:FV>=0;L=V9 4V0@5W;
- H;C=:>2>:-8H:>28E @>7;040E, A?@8G8=5=8E V=B>:A8:0FVTN, :8H:>28<8 V=D5:FVO<8,
70AB>AC20==O< ;V:0@AL:8E ?@5?0@0BV2, ?>4@07=NNG8E @5G>28= (:8A;>B8, ;C38);
- 48A:>@BV B0 1>;N 2 5?V30AB@VW, ?5GVW, :8A;V9 2V4@86FV,<5B5>@87B@8<0==O 4VTB8, =04
3> 26820==O :028, =V:>B8=C, 0;:>3>;N.

@>B8?>:070==O.

V?5@GCB;82VABL 4> 0;NAD0BC 01> 4> V=H8E 4>?>28= ?@5?0@0BC. !8;L=89 1V;L 2 682>BV
=5CB>G=5=>3> '5=57C, 728G=89 70?>@, E@>=VG=0 4V0@5O. %2>@>10 ;LF359<5@0.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9.
=B8F848 270T<>4VNBL 7 45O:8<8 V=H8<8 ;V:0@AL:8<8 70A>10<8, I> 2A<>:BCNBLAO C H;C=:>2>-
:8H:>2>AB5@V30TBLAO 7=865==O 2A<>:BC20==O C H;C=:>2>-.8H:>2>1V2, I> >4=>G0A=>
70AB>A>2CNBLAO 7 0=B0F840<8: DC@>A5
\$>AD0;N35;L @5:<5=4>20=> 70AB>A>2C20B8 70 2 3>48=8 4> 01> ?VA;O 70AB>AC20==O V=H8E
;V:0@AL:8E 70A>1V2.

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

5 @5:<5=4>20=> 70AB>A>2C20B8 ?@8 E@>=VG=V9 =8@:>2V9 =54>AB0B=>ABV, >A:V;L:8 0;N
AD0B =5 7=86CT @V25=L D>AD>@C 2 A8@>20BFV :@>2V.
/:I> A8<8 70E2>@N20=L/AB0=V2, ?@8 O:8E ?@87=0G0TBLAO \$>AD0;N35;L, =5 7=8:0NBL ?@>BO3<<
7 4=V2, =5>1EV4=> 725@=CB8AO 4> ;V:0@O. @8 28=8:=5==V 1>;N2 682>BV, I> AC?@>2>46CTBLAO
30@OG:>N, 1;N20==O<, =5>1EV4=> =5309=> 725@=CB8AO 4> ;V:0@O.
V:0@AL:89 70AV1@1VB. 5 A;V4 70AB>A>2C20B8 ?0FVT=B0< 7 =5?5@5=>A878. /:I> C ?0FVT=B0
=5?5@5=>A8:>=AC;LBC20B8AO 7 ;V:0@5< ?5@H =V6 70AB>A>2C20B8 F59 ;V:0@AL:89 70AV1.

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

@>DV;L 157?5:8 70AB>AC20==O \$>AD0;N35;N C 6V=>: ?V4 G0A 203VB=>ABV B0 C ?5@V>4
3>4C20==O 3@C44N =5 2AB0=>2;5=89. 45@60=V 40=V 2 ;;V=VG=8E 28?@>1C20==OE I>4>
70AB>AC20==O 0;NAD0BC 6V=:0<8 C B@8<5AB@V 203VB=>ABV 4>72>;ONBL ?5@V>48G=>
(=5B@820;89 G0A) 70AB>A>2C20B8 \$>AD0;N35;L C B5@0?52B8G=8E 4>70E 70 ?>:070==O<8.

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 2?;820T =0 740B=VABL :5@C20B8 B@0=A?>@B=8<8 70A>10<8 B0 <5E0=V7<0<8.

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

5@5
@5?0@0B <>6=0 70AB>A>2C20B8 2 G8AB> @>725AB8 ?5@54 70AB>AC20==O< C ?>;>28=V A;O=:8
2>48.

>78 4;O 4>@>A;8E:

\$>AD0;N35;L 70AB>A>2C20B8 2=CB@VH=L>, 1 01> 2 ?0:5B8 2-3 @078 =0 4>1C.

/:I> 2 ?@>AC20==O< \$>AD0;N35;N 1V;L ?>=>2;NTBLAO, B> 70AB>AC20==O ?@5?0@0BC ?>B@V1=>
?>2B>@8B8.

0:A8<0;L=0 4>1>20 4>70 6 ?0:5BV2.

>78 4;O 4VB59:

- 2V:<4> 6 1 G09=0 ;>6:0 ?VA;O :>6=>3> 7 6 3>4C20=L;

- ?VA;O 6 2 G09=V ;>6:8 ?VA;O :>6=>3> 7 4 3>4C20=L.

!E5<0 70AB>AC20==O ?@5?0@0BC 70;568BL 2V4 E0@0:B5@C 70E2>@N20==O:

- 3@860 AB@02>EV4=>3> >B2>@C 4V0D@03<8, 30AB@>57>D0350;L=0 @5D;N:A=0 E2>@>10,

4C>45=>-30AB@0;L=89 @5D;N:A: ?VA;O 26820==O W6V B0 =0 =VG;

- 28@07:>20 E2>@>10 H;C=:0 B0 420=04FOB8?0;>W :8H:8: G5@57 1-2 3>48=8 ?VA;O 26820==O W6V
B0 ?@8 28=8:=5==V 1>;N;

- 30AB@8B, DC=:FV>=0;L=0 48A?5?AVO: 4> 26820==O W6V;

- DC=:FV>=0;L=0 4V0@5O: 2@0=FV, 4> 26820==O W6V B0 =0 =VG.

"5@

VB8.

\$>AD0;N35;L 70AB>A>2CNBL C ?54V0B@8G=V9 ?@0:B8FV.

5@54>7C20==O.

@8 70AB>AC20==V 28A>:8E 4>7 <>6;82V 70?>@ 06 4> :8H:>2>W =5?@>EV4=>ABV. 0A;V4:8

?5@54>7C20==O A5@9>7=VHV C ?0FVT=V2 V7 =8@:>2>N =54>AB0B=VABN.

>1VG=V @50:FVW.

=>4V 28=8:0T 70?>@, >A>1;82> C ;560G8E E2>@8E B0 >AV1 ;VB=L>3> 2V:C. # F8E 28?04:0E @5:>
<5=4CTBLAO A?>6820B8 4>AB0B=N :V;L:VABL @V48=8.\$>AD0;N35;L @1VB, O:89 <>65 A?@8G8=8B8
@>728B>: 4V0@5W.
>AV1 7 ?V428I5=>N GCB;82VABN 4> :>5=BV2 ?@5?0@0BC <>6;8289 @>728B>: 0;5@3VG=8E
@50:FV9.

"5@ABV. 3 @>:8.
5 70AB>A>2C20B8 ?@5?0@0B ?VA;O 70:V=G5==O B5@ABV, 707=0G5=>3> =0 C?0:>2FV.

#<>28 715@V30==O.
15@V30B8 ?@8 B5 =5 28I5 25 °!. 15@V30B8 2 =54>ABC?=>

#?0:>2:0. > 20 3 35;N C ?0:5B0E, ?> 20 ?0:5BV2 C :0@B>==V9 ?0GFV.

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

8@>1=8:. \$0@<0B8A, \$@0=FVO / Pharmatis, France.

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A020465==O 4VO;L=>ABV.
..AB 1, 60190 AB@5A-!0V=B-5=VA,\$@0=FVO/ Z.A Est 1, 60190 Estrees-Saint-Denis, France.

0O2=8:. AB5;;0A \$0@<0 .@>? .. / Astellas Pharma Europe B. V.

VAF57=0E>465==O 70O2=8:0.
!8;L2VCA253, 62, 2333 BE 5945=, V45@;0=48 / Sylviusweg, 62, 2333 BE Leiden, the Netherlands.
@54AB02=8FB2> 2 #: @0W=V: 04050, <. 8W2, 2C;. 8<>=5=:0, 13, :>@?. 7-, >DVA 41.

0B0 >AB0==L>3> ?5@53;O4C.

28?04:C 28=8:=5==O ?>1VG=8E 5D5:BV2 ?@>A8<> =0?@02;OB8 V=D>@<0FVN 4> ?@54AB02=8FB20
AB5;;0A \$0@<0 .@>? .. =0 04@5AC: 04050,