

!" #&/

4;O <548G=>3> 70AB>AC20==O ?@5?0@0BC

"_ /

!;:04 ;V:0@AL:>3> 70A>1C:

4VNG0 @5G>28=0: pancreatin;

1 B01;5B:0 ;VB8G=8E M(Ph. Eur. U.), 7000 ;V?>;VB8G=8E M, 400 ?@>B5>;VB8G=8E M;

4>?>28=8: ;0:B>70, <=>3V4@0B; F5;N;>70 :@8AB0;VG=0, =0B@VN :@>A:0@<5;>70, :@>A?>2V4>=, ?>2V4>=, :@5<=VN 4V>:A84 :>;>W4=89 1572>4=89, <03=VN AB50@0B, ?>;V5B8;5=3;V:>;L, 07>@C1V= (122); ACE0 ACAcryl-eze white», I> B0;L:, B8B0=C 4V>:A84 (171), <5B0:@8;0B=89 A>?>;V<5@, =0B@VN ;0C@8;AC;LD0B, =0B@VN 3V4@>:0@1>=0B, :@5<=VN 4V>:A84.

V:0@AL:0 D>@<0. "01;5B:8, 2:@8BV >1>;>=:>N, :8H:>2>@>7G8==V.

"01;5B:8, 2:@8BV >1>;>=:>N, :@C3;>W D>@<8 7 42>>?C;>;N ?>25@E=5N, A2VB;>-@>652>3> :>;L>@C, 7V A;01:8< A?5F8DVG=8< 70?0E>?5@5G=>7@V7V 284=> 420 H0@8.

0720 V 465==O 28@>1=8:0. "«\$0@<0F52B8G=0 :>@>2 □O».

#:0W=0, 61013,

\$0@<0:>B5@0?52B8G=0 3@C?0. 0A>18, I> ?>;V?HCNBL B@02;5==O, 2;:NG0NG8 D5@<5=B8. >;VD5@ <5=B=V ?@5?0@0B8. >4 "!" 0902.

>;VD5@<5=B=89 ?@5?0@0B, I> A?@8OT B@02;5==N. > A;:04C ?@5?0@0BC 2E>4OBL >A=>2=V ?0=:@50B8G=V B@02=V D5@<5=B8 ;V?070, α-0B5078 (B@8?A8= V EV<B@8?A8=), O:V G8=OBL ;V?>;VB8G=C, 0;VB8G=C V ?@>B5>;VB8G=C 4VN, ?V4A8;NNBL @>7I5?;5==O 1V;:V2, 2C3;52>4V2 V 68@V2 C 420=04FOB8?0;V9 :8HFV, ?@>:A8<0;L=V9 G0AB8=V B>=:>W :8H:8, I> A?@8OT WE 1V;LH ?>2=> 2A<:BC20==N. >:@0ICT DC=:FV>=0;L=89 AB0= B@02=>3> B@0:BC V =>@<0;V7CT ?@>F5A8 B@02;5==O.

"01;5B:8 <0NBL 70E8A=C >1>;>=:C, =5@>7G8==C C :8A;>460T @C9=C20==N ?0=:@50B8G=8E D5@ <5=BV2 ?V4 4VTN H;C=:>2>3> A>:C. 0=:@50B8G=V D5@<5=B8 0:B82=V BV;L:8 C ;C6=>28IV V 282V;L=ONBLAO 7 ;V:0@AL:>W D>@<8 C ;C6=>28IV B>=:>3> :8H5G=8:C, 4VNG8 C ?@>A2VBV :8H5G=8:C.

\$5@<5=B8, I> 2E>4OBL 4> A;:04C ?@5?0@0BC, C B@02=>2>B>FV =5 28O2;ONBLAO; V=0:B82 CNBLAO C ?@>F5AV 3V4@>;V7C V ?5@5B@02;NNBLAO. 525;8:0 G0AB8=0D5@<5=BV2, I> =5 ?V440;8AO 3V4@>;V7C, 284V;OTBLAO C =57 7 :0;>

>:070==O 4;O 70AB>AC20==O.

□ □02=VH=L>A5:@5B>@=V9 =54>AB0B=>ABV ?V4H;C=:>2>W 70;>78: E@>=VG=89 ?0=:@50B8B, AB0=8 ?VA;O ?0=:@50B5:B>, @0: ?V4H;C=:>2>W 70;>78, 48A?5?AVO, 2VAF84>7 (:VAB>7=89 DV1@>7).

□ 5B5>@87<, 4V0@5O =5V=D5:FV9=>3> '5=57C.

□ >@CH5==O 70A2>T==O W6V (AB0=8 ?VA;O@575:FVW H;C=:0 V B>=:>W :8H:8).

□ <5B>N ?>;V?H5==O ?5@5B@02;N20==O W6V 2 >AV1 7 =>@<0;L=>N DC=:FVTN B@02=>3> B@0:BC ?@8 ?>@CH5==OE 6C20;L=>W DC=:FVW, ?@8 26820==V 206:>?5@5B@02;N20=>W @>A;8=>W, 68@=>W 01> =5728G=>W W6V; A?>6820==O =04W :V;L:>ABV W6V.

□ V43>B>2:0 4> @5=B35=>;>3VG=>3> 4>A;V465==O V C;LB@072C:>28E 4V03=>AB8G=8E 4>A;V465=L >@30=V2 G5@52=>W ?>@>6=8=8 (453070FVO :8H5G=8:C).

@>B8?>:070==O. V428I5=0 GCB;82VABL 4> ?0=:@50B8=C A28=OG>3> ?>E>465==OV=H8E :>=5=BV2 ?@5?0@0BC,3>AB@89 ?0=:@50B8B, 703>AB@5==O E@>=VG=>3> ?0=:@50B8BC, :8H:>20 =5?@>EV4=VABL.

0;56=V 70E>48 157?5:8 ?@8 70AB>AC20==V.# E2>@8E =0 2VAF84>7, O:V ?@89<0;8 28A>:V 4>78 ?@5?0@0BV2 ?0=:@50B8=C, >?8A0=V 28?04:8 72C65==O V;5>F5:0;L=>3> 2V44V;C :8H5G=8:C V B>2AB>W :8H:8 (DV1@>7CNG0 :>;>=>?0BVO), 0 B0:>6 :>;VB, 0;5 4>:07V2 72O7:C <<< ?@5?0@0BC V 28=8:=5==O< DV1@>7CNG>W :>;>=>?0BVW =5 28O2;5=>. # O:>ABV 70?>1V6=>3> 70E>4C 7 <5B>N 28;:NG5==O <>6;82>ABV C@065==O B>2AB>W :8H:8 @5:<5=4CTBLAO :>=B@>;N20B8 CAV =5728G=V A8<8 01> 7@>6=8=V, >A>1;82> ?@8 ?@89>1C.

VBO<, O:V >45@6CNBL B@820;5 ;V:C20==O ?@5?0@0B< ?@8 2VAF84>7V, A;V4 ?5@51C20B8?V4 ?>ABV9=8< =03;04>< ;V:0@O.

@8 B@820;>AC20==V @5:><5=4CTBLAO >4=>G0A=5 ?@87=0G5==O ?@5?0@0BV2 70;V70.

A>1;82V 70AB5@565==O.

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N. 57?5:0 70AB>AC20==O ?0=:@50B8=C C ?5@V>4 203VB=>ABV 282G5=0 =54>AB0B=L>.

?5@V>4 203VB=>ABV B0 3>4C20==O 3@C44N ?@5?0@0B ?@89<0NBL 70 ?@87=0G5==O< ;V:0@O, O:l> >GV:C20=0 :>@8ABL 4;O<0B5@V ?5@52060T ?>B5=FV9=89 @878: 4;O ?;>40/48B8=8.

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

VB8. @5?0@0B @5:><5=4CTBLAO 4;O 70AB>AC20==O 4VBO< 2V:>< 2V4 3 @>:V2.

!>AV1 70AB>AC20==O V 4>78. @89<0B8 2=CB@VH=L> ?V4 G0A 01> >4@07C ?VA;OW48, B01;5B:8 A;V4 :>2B0B8 FV;8<8, =5 @>76>2CNG8, 70?820NG8 25;8:>N :V;L:VABN @V48=8 (2>40, D@C:B>2V A>:8). >7C20==O ?@5?0@0BC 107CTBLAO =0 V=482V4C0;L=8E ?>B@510E ?0FVT=B0 V 70;568BL 2V4 2V:C, ABC?5=O ?>@CH5==O B@02;5==O B0 A;:04C W6V.

>7C20==O ?@8 2VAF84>7V.>G0B:>20 4>70 4;O 4VB59 2V:>< 4> 4 @>:V2 AB0=>28BL 1000 M ;V?078/:3 <0A8 BV;0 (1 B01;5B:0/7 :3)?V4 G0A :>6=>3> ?@89< 2V4 4 @>:V2 500 M ;V?078/:3 <0A8 BV;0 (1 B01;5B:0/14 :3)?V4 G0A :>6=>3> ?@89>/:I> 25;8G8=0 <0A8 BV;0 48B8=8 7=0E>48BLAO 2 V=B5@20;V 3> V=B5@20;C (=0?@8::04 ?@8 <0AV BV;0 48B8=8 20 :3 =0 ?>G0B:C ;V:C20==O @5:><5=4CTBLAO 4>70, I> ?@87=0G0TBLAO ?@8 <0AV BV;0 14 :3).

>7C A;V4 ?V418@0B8 V=482V4C0;L=>, 70;56=> 2V4 B06:>ABV 70E2>@N20==O, :=B@>;N AB50B>@5W V ?V4B@83> =CB@8B82=>3> AB0BCAC.

0728G09 4>70 AB0=>28BL ?> 2 B01;5B:8 (14000 M;V?078) 4 @078 =0 4>1C.

V4B@870 4;O 1V;LH>ABV ?0FVT=V2 =5 <0T ?5@528IC20B8 10000 M;V?078/:3 <0A8 BV;0/4>1C.

>7C20==O ?@8 V=H8E 2840E 5:7>:@8==>W =54>AB0B=>ABV ?V4H;C=:>2>W 70;>78. 28G09=0 ?>G0B:>20 4>70 AB0=>28BL 1-4 B01;5B:8 (7000-28000 M ;V?078) ?V4 G0A :>6=>3> ?@89>, I> 45O:8< E2>@8< <>65 7=04>18B8AO ?V428I5==O 4>78 C 1,5-2 @078 01> =02VBL 1V;LH5 4;O CAC=5==O AB50B>@5W V ?V4B@8<0==O =0;56=>3> =CB@8B82=>3> AB0BCAC. 5 @5:><5=4CTBLAO ?5@528IC20B8 4>7C 15000-20000 M;V?078/:3 <0A8 BV;0/4>1C.

"@820;VABL ;V:C20==O<>65 20@VN20B8 2V4 :V;L:>E 4=V2 (?@8 ?>@CH5==V B@02;5==O G5@57 A?>6820==O =04W :V;L:>ABV W6V) 4> :V;L:>E =02VBL @>:V2 (?@8 =5>1EV4=>ABV ?>ABV9=>W 70 W B5@0?VW).

5@54>7C20==O. !8<8: 3V?5@C@8:>7C@VO, 3V?5@C@8:5 4VB59 70?>@8.

V:C20==O: 2V4AB0B=O 3V4@0B0FVO, A8<0B8G=0 B5@0?VO.

>1VG=V 5D5:B8.

I>:C A8AB5<8 B@02;5==O: 4C65 @V4:> =C4>B0, 1;N20==O, <5B5>@87<, 4V0@50, 48A:>@B 2 5?V30AB@0;L=V9 4V;O=FV, 7@>6=5=L; ?@8 70AB>AC20==V 28A>:8E 4>7 C E2>@8E =0 2VAF84>7 AB@8:BC@8 2 V;5>F5:0;L=>1>4>2V9 :8HFV, :8H:>20=5?@>EV4=VABL, 70?>@.

>6;82V @50:FVW 3V?5@GCB;82>ABV (C B. G. 28A8?0==O, A25@1V6, GE0==O, A;L>7>B5G0, 1@>=E>A?07<, :@>?820=:0, 0=0DV;0:B8G=V @50:FVW), ?5@V0=0;L=5 ?>4@07=5==O.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9. @8 70AB>AC20==V ?@5?0@0BC <>6;825 7=865==O 2A<:BC20==O 70;V70, D>;VT2>W :8A;>B8, 7<5=H5==O 3V?>3;V:53> 5D5:BC 0:0@1>78. @8 >4=>G0A=>AC20==V 7 0=B0F840<8, I> :0;L:FN :0@1>=0B V/01> <03=VN 3V4@>:A84, 7 B0=V=><, A?8@B>2 70A>10<8 7=86CTBLAO 5D5:B82=VABL ?0=:@50B8=C.

"5@ABV.3 @>:8.

#<>28 715@V30==O. 15@V30B8 2 >@83V=0;L=V9 C?0:>2FV ?@8 B55 □!. 15@V30B8 C =54>ABC?=>

#?0:>2:0. "01;5B:8, 2:@8BV >1>;>=:>N, :8H:>2>@>7G8==V 10, 10□2, 10□5, 20 C 1;VAB5@V C :>@>1FV.

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