$! ®
(FLOXAL®)

!:;04:

4VNG0 @5G>28=0: >D;>:A0F8=;

1 <; @>7G8=C D;>:A0F8=C 3 <3; 1 :@0?;;O

4>?>28=8: 15=70;;:>=VN E;>@@@84, :8A;>B0 E;>@@8AB>2>4=520, =0B@VN 3V4@0@>:A84, =0B@VN E;>@@84, 2>40 4;O V='T:FV9.

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

@0?;;V >G=V, @>7G8=.

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

0A>18, I> 70AB>A>2CNBLAO 2 >DB0;;L<>;>3VW. @>B8l=V 70A>18. D>:A0F8=.

>4 "% S01A E01.

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

>:070==O.

=D5:FVW ?5@54=L>3> A53<5=B0 >:0, A?@8G8=5=V GCB;828<8 4> >D;>:A0F8=C ?0B>35==8<8
>@30=V7<0<8, B0:V O: 70?0;5==O :>='N=:B828, @>3V2:8 >:0, :@0W2 ?>2V: A;V7>=>3> 3V2:8.

@>B8?>:070==O.

V428I5=0 GCB;82VABL 4> 1C4L-O:>3> 7 :><?>=5=BV2 ?@5?0@0BC, V=H8E EV2>;>=V2.

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

>7C ?@5?0@0BC B0 B@820;VABL ;V:C20==O 702648 287=0G0T ;V:0@ 70;56=> 2V4 BO6:>>ABV
70E2>@N20==O B0 2V:C ?0FVT=B0.

/:I> =5 ?@87=0G5=> V=H5, 4>@>A;8<, 4VBO<, C B2>@=0@>465=8<, A;V4 22>48B8 2 :>='N=:B820;L=89 :
C@065=>3> >:0 ?> 1 :@0?;;V 4 @078 =0 4>1C. "@820;VABL ;V:C20==O $;>:A0;×®, :@0?;;O<8 >G=8<8, =5
?>28==0 ?5@528IC20B8 2 B86=V2.

:07V2:8 I>4> 70AB>AC20==O

15@56=> 2V4BO3=CB8 =86=N ?>2V:C 2=87 V, 7;53:0 =0B8A=C2H8 =0 D;0:>= 7 :@0?;;=8F5N,225AB8 1
:@0?;;N 2 :>='N=:B820;L=89 :C@065=>3> >:0.

>1VG=V @50:FVW.

V4@07C ?VA;O 22545==O ?@5?0@0BC<>65 28=8:=CB8 =5GVB:VABL 7>@C 2?@>4>26 45:V;L:>E
E28;8=.

030;L=V ?@>O28.

!5@9>7=V @50:FVW ?@8 70AB>AC20==V A8AB5<=>3> 70AB>AC20==O >D;>:A0F8=C @V4:VABL A8
1>@>B=V.572060NG8 =0 B5, I> =57=0G=0 :V;L:VABL >D;>:A0F8=C 01A>@1CTBLAO C
A8AB5<=<89 :@>2>BV: ?@8 AC20==V, =5 <>6=0 28:;NG0B8 28=8:=5==O ?>1VG=8E
5D5:BV2, ?@> O:V ?>2V4><;O;>AL.

1>:C VW A8AB5<=<8.

=:>;8: ?>>G5@2==O :>='N=:B828 B0/01> ;53;5 2V4GCBB>O ?5GV==O 2 >FV. # 1V;LH>ABV 28?04:V2
FV A8<?B>=8 =5>B820=V.

4C65 @V4:VMA=8E 28?04:0E (<1/10 000): 3V?5@GCB;82VABL, C B.G. 0=3V>=52@>B8G=89 =01@O:,
7048H0, 0=0DV;0:B8G=V @50:FVW/H>:, =01@O: >@>B>3;>B:0, A25@16V6 >G59 B0 ?>2V:.

1>:C =5@2>2>W A8AB5<8: C ?>>48=>:8E 28?04:0E - 70?0<>@>G5==O.

1>:C >@30=V2 7>@C.

'0AB>: 48A;>@B 2 >G0E, ?>4@07=5==O >:0;

=:>;8: :5@0B8B, :>=N=:B82VB, 70BC<0=5==O 7>@C, D>B>D>1VO, =01@O: >G59, ?>G5@2>=V==O >:0,
2V4GCBBO AB>@>==L>3> BV;0, ?>A8;5=0 A;L>7>B5G0, ACEVABL >G59, 1V;L 2 >G0E, A25@1V6,
=01@O: ?>2V:.

@V4:VA=8E 28?04:0E (2V4 1/10 000 4> 1/1 000) <>6CBL 28=8:0B8 2V4:;045==O =0 @>3V2FV, >A>1;82>
?@8 =0O2===>ABV 2 0=0<=5=V 70E2>@N20=L @>3V2:8.

?>2V4><;;5==O ?@@> B5, I> ?@8 28=8:0;8 B0:V @50:FVW, O: B>:A8G=89 5?V45@@<0;L=89 =5:@>7,
A8=4@@><< !BV25=A0 6>=A>=0. @8G8==>-=0A;V4:>289 72O7>>: 7 $;>:A0;><;®, :@0?;O<8 >G=8<8 >G=8<8,
AB>A>A>2=><@> B0:8E ?@@>O2V2 =5 2AB0=><2;5=0>.

1>:C >@30=V2 B@@02==>3> B@@0:B: C ?>>48=:><:8E 28?04:0E - =C4>B0.
1>:C H:V@@8 B0 ?V4H:V@@=>W :;VB:B:>28=8: C ?>>48=:><:8E 28?04:0E - =01@O: >1;8GGO,
?5@V>@@V4V1B>;L=89 =01@O:.

!5@@9>7=V, V=>4V ;5BB0;L=V, @50:FVW 3V?5@@G:8;82>>ABV, 45>:8 ?VA;O 22545==O ?5@H>W 4>78,
A?>>AB5@V30;8AO ?@8 A8AB5<=<>A=><<C20==V EV=>;>=>=V2.

5@54>7C20==O.
@>> 28?04:8 ?5@54>7C20==O ?>2V4><;;5=V 4> FL>3> G0AC =5 1C;;>.
V:C20==O A8<0B>G=5, =5>1EV4=>> 2V4@@07C ?@@>><8B8 >:> (>GV) 2>4>N.

0AB>AC20==O C ?5@@>4V4 203VB=><ABV 01> 3>4C20==O 3@C44N.
572060NG8 =0 2V4ACB=VABL ?V4B25@@465=L 1C4L-O:8E 5<1@V>B>:@A8G=< 2?;82V2, $;>:A0;®,
:@0>0?;V >G=V, ?><<6;82> =5 A;V4 70AB>>A>2C20B8 C ?5@@>4V4 203VB=><ABV 01> 3>4C20==O
3@C44N.

VB8.
$;>:A0;®, :@0?;V >G=V,<>6=0 ?@87=0G0B8 4VBO< 2 1V:>< =0@>465=8

A@>4V4 203VB=><ABV 70>4C20==O.
/:I> @@>728=:;8;8 0;5@>3V=V @50:FVW ?@87=0G0B8, =5>1EV4=>> ?@@8?8=8B8 70AB>>A>2C20==O.
5@@54 ?5@H8< C25545==O< ?@87>4V4@@028 1060=> ?@@>25AB8 1V;>;>3V=5 4>A;V465==O <07:V2, 27@@028E
7 :>=N=:B820@;L=>W 4;O 287>7G5==O GCB;82>ABV HB>0 ?@87>4@@0V2C.
@8 B@@020@;>A20==V <>6;825 D>@W @578AB5=>>ABV B0 CB2@@465==O =5GCB;82><;V 4>
=5>1EV4=>> ?@@8?8=8B8 ;V:C20==O B0 70ABAC20B8B8 0;LB5@@=08B82C B5;@0?VN.
V4 G0A ;V:C20==O =5 A;V4 :>@@8AB2@20B8AO B25@@45<8 :>=B0:B=<8 :;V=7=<8. "><5=4CBL:L0>> 7=>OB8
B25@@4V ;V=7=8 ?5@54 70AB>>A>2C20==O< :V0@@0V2 V >4>3>8 WE 7>>2 =5 @0=V=V =V6
G5@54 57 20 E28;8= ?VA;O 22545==O :@0?5;L.
@5@@>4V4@@08 =05@20=V 15=70:L:>=N E;>@0V84, I> <>6 A?@87=8B8 ?>4@07>5==O :@0=N:B828.
@8 70AB>>A>2C20==V $;>:A0;C®, :@0?5;L >G=8E, @07>< 7 V=H8< :@0?8< :@0:<8 :>4>8 >G=8< <07:<8
<548G=V ?@87>4@@0V2C20==O A;V4 70AB>>A>2C20B8 >AB0==L<8.
@8 A8AB5<=<>A=><<C20==V DB>@>@EV@@07><;V2 7 >15@56=8<8 A;V4 70AB>>A>2C20B8 ?@@54>4@@028 E2>@@8<
< V7 @0>BV8 ?@@>4>2265==O V=B5=7B2=>;CBL QT, 0 A0>:5: V7 2>@465=8< A8A=@@><<< ?@@>4>2265==O
V=B5=7B2=>;CBL QT, ?@8 >4>=@@>8A20==V ;V:<>A=<<AL8E 70>4@@028, O:V ?@@>4>26CNBL V=B5=7B2=>;CBL QT
(=0?@@8:;048, 0-B;0>0@><8B3<03=<VT:08@40, 1@048:08@40VO).

40B=VABL 2@@0>20B8 =0 H284:VABL @0>4V4@@024 ?@@8 :5@C20==V 02B>@B>@8=<0A@@0B>@ 01> @>1>BV 7
V=H8<8 <5E0=V7<0<8
0AB>>A>2C20==O $;>:A0;®, :@0?5;L >G=8E, =5 2?;82>0T =0 74>0B=VABL >?@@0V2C20B8 ?0FVT=B B0.
VA;O 70>0:@0B=<C20==O ?5@@>4V4>0@;LVT0> C @0>25AV >0 <>6 A?@@8B8 :>@>B:0?0A=0B8B8 7@@0
2?@@0>@26 :;V=7>W E28;8=. >A8 7V@ =5 2@@028B8 ?5@@>4V4@@02V2C20B8 :V0@@0V2 B0 @V7 <5E0=V7<0<8 7
V=H8<8 <5E0=V7<0<8.

7@>BV<>0@>426 7 V=H8<8 <5E0=V7<0<0 B0 2@>@4V4@@04 25 2?@@>4@>1V2.
>B5?5@@> =0 52V4>0@><0. >0;L6V@7465==O ;V:<>A=<<AL@0W 27@@0B=VABL :V0@@0V2C20B8
7@>BV<>0@>426 V >0;>4V4>0AV4, ?@@>><0V8?@@0V2C20B8 A8A>@=@@><< A8A<@@> 2>@465=<8 A8A<@@> =57=0>G=<
N 70>A8568BL 2V4 >0:@0B=<C20==O.

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

$0@<0:>48=0D;>:A0F8=, ?>EV4=0 EV=>;>=>2>W :8A;>B8, T DB>@EV=>;>;>==><× (V=3V1VB>@ 3V@078), 0=B81V>B8:, I> G8=8BL 10:B5@8F84=C 4VN.

>@@>3>2V 7=0G5==O

8?@@>1C20==O 35=B02=48;8AL V7 28:>@8@8@5@@@V4 V0;5>2C @@>72545=L. C;8 287=0G5=V B0:V

>@@>3>2V 7=0G5==O EUCAST (2@@>?59AL:>3> :>ABV 4> 0=B81=8E ?@5?@0@0BV2)

0B>35=	'CB;8289	578AB5=B=89
Enterobacteriaceae	≤2 <3/;	>4 <3/;
Pseudomonas spp.	≤4 <3/;	>4 <3/;
Acinetobacter spp.	≤4 <3/;	>4 <3/;
Staphylococcus spp.	≤1 <3/;	>1 <3/;
>@@>3>2V 7=0G5==O, I> =5 AB>ACNBLAO :>=:@5B=><V 284C*	≤2 <3/;	>4 <3/;

*V;LH>N N 287=0G5=V =0 >A=>2V D0@<0:>:V=5B8:8 A8@>20B8:V :@>2V

=B810:B5@V0;L=89 A?5:B@@:
A?5:B@@ 4VW >D;@:A0F8=C 2:;NG0T >:05@>18, D0:C;LB0B82=V 0=05@>18, 05@>18 B0 V=HV >@@30=V7<8, B0:V O: *Chlamydia.*
>H8@5=VABL =01CB>W @578AB5=B=>ABV I>4> :@>>5@V8F284 284V2 <>65 20@VN20B8 70;56=> 2V4 < G0AC. ">;>2>=8=8< 4;O ?@87=0G5==O 045;20B>3> ;V:C20==O BO6:89 V=D5:F9 T >B@8<0==O ;>:0;L=>W V=D>@@<0F9 I>4> @578AB5=B=>ABV.
V:@>1V>;>3V3VG=5 287=0G5==O 284C ?>B@V1=V2 B0 WE GCB;820ABV 4> >D;@:A0F8=C 284C ?>B@V12048B8AL C 28?04:0E BO6:89 V=D5:F9 01> O:I> ;V:C20==O =5 40;> B@52>3G=>3> 5D5:BC. 5@5@5A0=0 @578AB5=B=VABL >D;@:A0F8=C 4> V=H8E DB>@EV=>;>=V2 T <>6;82>N.
=D>@@<0FVO, =02545=0 =86G5, 27@B5 4>A0;V7=4===O @578AB5=B=>ABV, ?@>2545=>3> 7 28:>@8AB0==O< 1391 V7;>;BOC 4>A;V46C20=8E >G59 (2 >A=>2>2V0@VH=V 7<828) 7 31 F5=B@@C V <5GG8=8.
&5 4>A;V465==O 40T @5?@575=B0B82=V 40=V I>4> 05@>18, O:V A?@8O>ONBL >G59 @>72V8BC. >6=> ?@@8?CAB8B8, I> :@0B>18 @578AB5=B=V 10:B5@V9, 740B=V 28:;8:0B8 >HB0B:V2 >DB0;L<>;>3V8V=D5:F9 70;5605B8 @V7=>< < 0=05@>18 :;0W=0W :;0=5 =5 >5 1C45 V4:V 2 @V7=828 @V7=8E AE>6VN, ?@>B5 1C45 B0:8< >6>N, 0 B8?>2>
0=V I>4> @578AB5=B=>ABV 4> >D;@:A0F8=C AB>ACNBLAO A8AB5<=>3> 70AB>ACN20==O. @8 70AB>ACN20==V 2 >:> 4>AO30NBLAO 7=0G=> 28IV :>=F5=B@@0F9, =V6 <>6;82V 70 A8AB5<=>3> 284V7=0G5==O, B>4V O: :@0AB5@@5@5AB5@@5F284, O:V @>72V8BC ABVA=VABL. ">:89 5D5:B A?@8O>ONBL A8AB5<=><C @>72V8BC, =0?@@8:;04, 7 *Enterococcus species*

0728G09 GCB;82V 2848

 @078B82=V 05@>18: *Bacillus spp., Staphylococcus aureus*GCB;82V 4> <5B8F8;V=C,
 @0<=53530B82=V 05@>18: *Acinetobacter baumannii, Acinetobacter lwoffi, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Moraxella catarrhalis, Proteus mirabilis, Serratia marcescens.*

848, I> 2=0A;V4: =01CB>W @578AB5=B=>ABV <>6CBL 1CB8 =5GCB;82V 284V2 70AB>ACN20==V ?@5?@0@0BC

 @078B82=V 05@>18: *Corynebacterium spp., Enterococcus faecalis, Staphylococcus aureus* @578AB5=B=V 4> <5B8F8;V=C[1], *Staphylococcus epidermidis, Streptococcus pneumoniae*, !B@5?B>:>:8 (>:@V< *Streptococcus pneumoniae*)[2].
 @0<=53530B82=V 05@>18: *Pseudomonas aeruginosa, Stenotrophomonas maltophilia.*

848, I> <0NBL ?@8@>4=C @578AB5=B=VABL 4> ?@5?@0@0BC

@078B82=V 05@>18: *Enterococcus spp.*

[1] V25=L @578AB5=B=>ABV ?5@528GN>T 50 % 28?04:V2 2 4>>=5>V.

[2] @8@>4=0 GCB;82V1V;LH>ABV 284V2;LH>=0;L=V 284V2 :>?>@0B82=> ;>5@V8 A5@@548=5<5 A5@548=5<5. 4>=: C A;V7=V9 @V48=V, ?@8AB;O@G@0 >4=0:>2><V =5 >B@8<C20;>AO 4>AB0B=L>W :V;L:>ABV 4;O 28A=>2:C. @8 ?@82'O7:V, I> ?@848< V>1@0BL, I>1 C18B8 100 % >@30=V7

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

D5:B82=VABL 1030B> 2 G>H5==O <0:A8<0;L=>W :>=F5=B@0FVW 2 B:0=8=V (Cmax) B0 :A?5@8<5=B8 =0 B20@8=0E ?>:070;8, I> ?VA;O3> 70AB>AC20==O >D;>:A0F8= <>65 1CB8 28O2;5=89 C @>3>2V9 >1>;>=FV, :>=N=:B82V, >G=>AC20==V ?@5?0@0B =0:>>?8GCTBLAO C B5@0?52B8G=8E :>=F5=B@0FV>E C A:;>284==>

$;>:A0; " , :@0?;:V >G=V, 22545=89 ?OBL @07V2 =0 45=L 7 V=B5@20;>< 5 E28;8=, G5@57 60-120 E28;8= 28O2;>OTBLAO C 2=CB@VH=L>=>G=V9 @V48=V ;=48=8 2 :>=F5=B@0FVW >D;>:A0F8= C 1,2 - 1,7 0 0=0;>3VTN 4> @57C;LB0BV2 4>A;V465=L =0 B20@8=0E <>6=0 ?@8?CAB8B8, I> V=HV >G=V B:0=8=8 :V :>=F5=B@0FVW ;V:0@>=>G=V 70A1C =V6 2=CB@VH=L>>G=0 @V48=0. A:V;:8 >D;>:A0F8= <>65 72O7C20B8AO 7 B:0=8=0<8, I> AC20==V AB0=>28BL 2V4 3,5 4> 6,7 3>48=.

$0@<0:>4V=0<V:0 E0@0:B5@8AB8:8.
A=>2==V=>V DV78:>-EVABV:V: ?@>7@0@89, 6>2BC20B89 2>4=89 @>7G8=.

5AC
5 28O2;5=0.

"5@ABV.
"5@ABV ?@5?0@0B0 2 70:@8B8>=V - 3 @>:8.
"5@ABV ?VA;O 2V4:@8BBO D;0:>=0 - 6 B86=V2.
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 2 >@83V=0;L=V9 C?0:>2FV ?@8 B5<?5@0B?=>

#?0:>2:0.
> 5 <; ?@5?0@0B0 C D;0:>=V 7 :@0?5;L=8F5N B0 :@8H:>N, I> =0328=GCTBLAO. > >4=>=C 2 :0@B>==V9 :>@>1FV.

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

8@>1=8:.
@. 5@0@4 0== 0== %5
Dr. Gerhard Mann !hem.-pharm. FabriA GmbH, Germany.

VAF57=0E>465==O.
@C=A1NBB5;5@ 0<< 165-173 13581 5@;V=, V<5GG8=0/
Brunsbu5tteler Damm 165-173 13581 Berlin, Germany.