

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

S® H

(FARMAZOLINE N)

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

4VNG0 @5G>28=0: xylometazoline hydrochloride;

1 <; ?@5?0@0BC :A8;><5B07>;V=C 3V4@>E;:>@84C C ?5@5@0EC20=V =0 100 % @5G>28=C 1 <3;

4?>>28=8: 15=70;=>VN E;:>@84; =0B@VN E;:>@84; =0B@VN 483V4@>D>AD0B, 483V4@0B; =0B@VN 3V4@>D>AD0B, 4>45:03V4@0B; 2>40 4;O V=T:V9.

V:0@AL:0 D>@<0. !?@59 =070;L=89.

@>7>@0 15710@2=0 @V48=0.

0720 V 465=O 28@>1=8:0.

" «\$0@<0».

#:@0W=0, 04080, <. 8W2, 2C.; \$@C=75, 63.

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

@>B8=01@O:>2V B0 V=HV ?@5?0@0B8 4;O 3> 70AB>AC20=O ?@8 70E2>@N20=OE ?>@>6=8=8 =>A0. !8"! R01A A07.

A8;><5B07>;V= T A8

\$0@<07>;V=® A?@8G8=OT 72C65=O =070;L=8E :@>2>=>A=8E AC48=, 7=5=HCNG8 =01@O: B0 3V?5@52>W >1>;>=:8 =>A0, 9>3> ?@840B;>28E ?07CE V, B0;8< G8=><, ?>;V?HCNG8 =>A>25 48E0=O ?@8

70:;045=>ABV =>A0 B0 ?@840B;>28E ?07CE.

VO ?@5?0@0BC @>7?>G8=0TBLAO G5@57 :V;L:0 E28;8= ?VA;O 70AB>AC20=O B0 715@V30TBLAO 4>

12 3>48=.

@5?0@0B 4>1@5 ?5@5=>A8BLAO, C B>@8<8 7 GCB;82>N A;87>2>N >1>;>=:N. @5?0@0B =5 7=86CTF8;V0@=C DC=FN. \$0@<07>;V=® <0T 710;O=A>20=5 7=0G5=O @C <560E, 2;0AB828E =>A>2V9 ?>@>6=8=8=V.

@8 AC20=V =>F=5=B@OFVW :A8;><5B07>;V=C C ?;072V =0ABV;L:8<0;V, l> WE =5>6;82> 287=0G8B8 ACG0A=8<8 0=0;VB8G=8<8 <5B>40<8.

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

l8<0B8G=5 ;V:C20=O 70:;045=>ABV =>A0 ?@8 70ABC4V, AV=V9 30@OGFV, 0;5@3VG=8E @8=VB0E, A8=CA8B0E.

:O ?>;53H5=O 2V4B>C A5:@5BC ?@8 70E2>@N20=OE ?@840B;>28E ?07CE =>A0.

>?>3> >B8BC (4;O CAC=5=O =01@O:C A;87>2>W >1>;>=:8).

:O ?>;53H5=O ?@>2545=O @8=>A:>?VW.

@>B8?>;070=O.

V42815=0 GCB;82VABL 4> >=5=BV2 ?@5?0@0BC; 3>AB@V :>@>=0@V 70E2>@N20=O, :>@>=0@=0 0AB<0, 3V?5@B8@5>7, 70:@8B>:CB>20 D>@<0 3;0C;><8. 0B@>DVG=89 @8=VB, EV@C@3VG=V

2B@CG0=O 7 >3>;N20=O< B25@4>W <7>2>W >1>;>=:8 01> B@0=AD5=>W40;L=0 3V?>DV75;B>@0<8 B0 ?>@B03<> 2 B86=V2 ?VA;O ?@8?8=5=O WE 70AB>AC20=O.

0;56=V 70E>48 157?5:8 ?@8 70AB>AC20=V.

@5?0@0B =5 A;V4 70AB>A>2C20B8 4>2H5 10 4=V2 ?>A?V;L. "@820;VH5 ;V:C20=O ?@5?0@0B< <65 A?@8G8=8B8 72>@>B=89 5D5:B C 283;04V @8=VBC, A?@>2>=>20=>3> 4VTN ?@5?0@0BC.

5 A;V4 ?5@5281C20B8 @5:>>4=20=C 4>7C ?@5?0@0BC, >A>1;82> ?@8 ;V:C20=V 4VB59 B0>AV1 ;VB=L>3> 2V:C.

@5?0@0B A;V4 7 >15@56=VABN ?@87=0G0B8 ?0FVT=B0F 7 ?V42815=8<0@B5@V0;L=8< B8A;><, FC:@>28< 4V015B><, 3V?5@B@>DVTN ?@>AB0B8, VA=CNG=N D5>E@>F8B>>N C 7207:C 7 <6;828< A8AB5

<<8< A8 ?V42815=0 0@B5@V0;L=>3> B8A:C.

@5?0@0B=VN E;:>@84, l> <65 A?@8G8=0B8 ?>4@07=5=O H:V@8 B0 A;87>2>W >1>;>=:8, 1@>E>A?07

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

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

A;V;L:8 ?@5?0@0B<0T AC48=>72C6C20;L=C 4VN, 9>3> 70AB>AC20=O C ?5@V>4 203VB=>ABV 01> 3>4C20=O 3@C44N =5 @5;>5=4CTBLAO.

40B=VABL 2?;820B8 =0 H284;VABL @50:FFVW ?@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 70AB>A>2CNBL 4VBO< 2V;>< 2V4 12 @>:V2.

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

>@>A;8< V 4VBO< 2V;>< 2V4 12 @>:V2

@87=0G0B8 ?> 1 2?>@A:C20=N 2 :>6=C=V74@N 3 @078 =0 4>1C.

0:A8<0;L=0 4>1>20 4>70 3 2?>@A:C20=O.

"@820;VABL ;V:C20=O 70;568BL 2V4 ?5@51V3C 70E2>@N20=O V =5<0T ?5@5281C20B8 10 4=V2 ?>A?V;L.

577>A5@54=L ?5@54 70AB>AC20=O< A;V4 ?>B@8<0B8 D;0>=> 7 ?@5?0@0B<C 4>;>=V, l>1 ?V4V3@VB8 9>3> 4> B5AC20=O ?@5?0@0BC D;0>=> B@8<0B8 25@B8;0;L=>, @>?78;N20G5< 4>3>@8. 5@54

70AB>AC20=O< 7=0B8 70E8A=89 >2?0G>; D;0;>=0, ?>=5G=8: C =>A>289 EV4, :>@>B<8< @V7:8< @CE<< AB8A=CB8 D;0>=> V, 289=02H8 =0>=>5G=8: 7 =>A0. @>7B8A=CB8. V4 G0A 2?>@A:C20=O @5>

<5=4CTBLAO 7;53;0 248E=CB8 G5@57 =VA. VA;O 70AB>AC20=O ?@5?0@0BC D;0>=> 70:@8B8 70E8A=8=>?2?0G;><, 715@V30B8 73V4=> 7 @5;>>5=40FVO<8, =02545=8<8 2 V=AB@C:VFW.

5@54>7C20=O.

@8 22545=V 1V;LH=V6 0,2<3/3 ?@5?0@0BC<>6;825 28=8=5=O B0:8E A8<N20=VABL. ?@8A>@5=5 A5@F518BBO B0 ?V42815=O 0@B5@V0;L=>3> B8A:C. C65 @V4> ?@8 A8;L=>7C20=V, >A>1;82> C 4VB59

(=0?@8;04, ?@8 28?04>2>2B0=V 28A>8E 4>7 ?@5?0@0BC), <<6CBL G5@3C20B8A0 AB04VW AB8W =5@2>2>W A8AB5<8 B0 A5@F52>AC48=>W A8AB5<8. l8<0<8 AB8W =5@2>2>W A8AB5<8 <<6CBL 1CB8

70=5?>T=VABL, 71C465=O, 30;NF8=0FVW B0 C B06;8E 28?04:0E AC4<8. !8<0<8 ?@83=VG5=O F5=B@0;L=>W =5@2>2>W A8AB5<8 <<6CBL 1CB8 7=865=O B5=;82VABL B0 C =09B0G8E 28?04:0E.><0.

"0:>6 <6;825 28=8=5=O B0:8E A8 @>7H8@5=O 7V=8FL, ?VB;82VABL, 1;V4VABL, FV0=>7, =C4>B0. B0EV:0@4V0, 1@048:0@4V0, 0@8BVO, 7=865=O 0@B5@V0;L=>3> B8A:C, ?>@CH5=O :@>2>>1V3C,

=01@O: ;53=L, ?>@CH5=O 48E0=O B0 0?>=5, 3>=>2=89 1V;L, <6;82V AC4<8, 72C65=O ?5@8D5@8G=8E AC48=, ?>E;>40=O :V=V2>;, 1@>E>A?07

5@54>7C20=O, >A>1;82> C 4VB59, <65 <0B8 7=0G=89 2?;82 =0 F5=B@0;L=C =5@2>2C A8AB5<8, >5 B0 ?V42815=O 0@B5@V0;L=>3> B8A:C, l> 73>4< 73> 7=865=O

V:C20=O B06<3> ?5@54>7C20=O (=1 <3/>3) 1060=> @>7?>G0B8 ?@>B03>< 1 3>48=8 ?VA;O 70AB>AC20=O. V:C20=O =0 @0=VE AB04VOE ?@>820=O H:C=;0, ?@89>< 0:B82>20=>3> 2C3V;O; :=B@>;L

48E0=O B0 :@>2>>1V3C; C @07V =5>1EV4=>ABV HBCG=0 25=B8;OFVO ;535=L, 70157?5G5=O :8A<5< 70AB>A>2C20B8 ?@>B8AC4<=>V ?@5?0@0B8, =0?@8;04 15=7>4V075?0<, 4;O 7=865=O 0@B5@V0;L=>3>

B8A:C =5A5;5:B82=V a1;>0B>@8 (=0?@8;04 4>:A07>F8=, B5@07>F8=), 0AB>AC20=O AC48=>72C6C20;L=8E 70A>1V2 ?@>B8?>:070=5. B@>?V= 70AB>A>2C20B8 ;8H5 C @07V :V=VG=> 28@065=>W

1@048:0@4VW, l> AC?@>2>46CTBLAO 7=865=O< 0@B5@V0;L=>3> B8A:C.

>1VG=V 5D5:B8.

030;L=V ?>@CH5==Q 3>=>2=89 1V;L.

>@CH5=O 0 7 l>:C H;C=>2>=:8H:>2>3> B@0:BC=C4>B0.

=HV ?>@CH5=O Q 2V4GCBBO ?5GV=O 01> 4@07=5=O, ACEVABL A;87>2>W >1>;>=:8 =>A0.

"0:>6 4;O V=H8E ;V:0@AL:8E D>@< A?>AB5@V30;8A0 B0:V ?>1VG=V 5D5:B8: 70=5?>T=VABL, 157A=>=O, 2B<;N20=VABL (A>=;82VABL,<;02VABL), 30;NF8=0FVW (2 >A=>2>=>@5=5 A5@F518BBO,

B0EV:0@4V0, ?V42815=89 0@B5@V0;L=>89 B8A.; ACEVABL A;87>2>W >1>;>=:8 =>A0 B0 =>A>3>;B:8, GE0=O, 71V;LH5=O =01@O:C A;87>2>W >1>;>=:8 =>A0 ?VA;O 7=865=O 04VW ?@5?0@0BC, =>A>20

:@>2>B5G0, AC4<8 (>A>1;82> C 4VB59), @50:FFVW 3V?5@GCB;82>ABV, 2;NG0NG8 28A8?0=O, A25@1V6, 0=3V>=52@>B8G=89 =01@O.; 2V4GCBBO ?5GV=O C

"0:>6 ?>2V4<O;>AO ?@> B0:V ?>1VG=V 5D5:B8: A8AB5<V 0;5@3VG=V @50:FFVW, B@0=78B>@>V ?>@CH5=O 0 7 l>:C >@30=V2 7>@C, ?@8A:>@5=O 01> ?>@CH5=O A5@F52>3> @8B

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

\$0@<07>;V=® <65 ?V448;N20B8 4VN A8< 7 β-1>;0B>@0<8 <65 A?@8G8=0B8 1@>=EVO;L=89 A?07< 01> 7=865=O 0@B5@V0;L=>3> B8A:C. @8 70AB>AC20=V @07< 7 B@8F8;VG=8<8 01> B5B@0F8;VG=8<8

0=B845?@5A0=B0<8 =5 28;NG5=5 ?>A8;5=O A8AB5<=>W 4VW :A8;><5B07>;V=C. 0AB>AC20=O ?0@0;5;L=> 7 V=3V1VB>@0<8 ?@>B8?>:070=>.

"5@ABV. 3 @>:8.

5 70AB>A>2C20B8 ?@5?0@0B ?VA;O 70:V=G5=O B5@ABV, 2.070=>3> =0 C?0>2FV.

#<>28 715@V30=O.

15@V30B8 C 70E815=><. 15@V30B8 C =54>ABC?>.

#?0>2:0.

> 15 <; 01> 20 <; C D;0>=>V. > 1 D;0>=>C C ?0GFV.

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

57 @5F5?B0.