

Obiltoxaximab SFL (*obiltoxaximabum*)

D Y\`YX`dfc`d `dfUj Y_`CV]`hcl UI]a UV`G: @U`dfc `Vm`d `dfUj Y_`fY[]ghfcj zb`
v EU

7c`Y`d `dfUj Y_`CV]`hcl UI]a UV`G: @U_` Ya i `gY`dci`y] z 3

D `dfUj Y_`CV]`hcl UI]a UV`G: @Y`f]j `d `dfUj Y_`dci`y] Ub`ij kombinaci s`f Vci `Ubh[V]ch]_mi`_f V`
d]Vb`Ac`UbhfUI i`z`Vt`y`Y`nzj Uybf`cbYa cVb` b`nd` gcVYbf`VU`hYf]f`"Bacillus anthracis" PD]Vb`i`nbUa Ybz`z`
yY`XUbz`cgcVU`gY`hba`hc`cbYa cVb` b`ta`bU`Un]j XYW`cj zb`ta`gdcf`znY`_hYf` Vb`gY`j`h`Y`j`nj]bci`_U`h] b`f`
VU`hYf]Y`U`bzg`YXb`i`j`c`i`f`y`cX]`j`f`hcl]bm`

HYbhc`f`]j `d `dfUj Y_`gY`dci`y] z`hU`f`_`dfYj YbW`d]Vb`Ac`UbhfUI i`i`cgcVz`_hYf]f`gY`XcghU`mXc`_cbHU`h`
s`h`a`]hc`VU`hYf]z`b`ta`]gdcf`Ua`]z`U`j`d`dUXYW`z`_Xm]yz`Xbz`i`]bz`j`cXbz`f`VU`bYb`f`_X]gdcn]W`

D `dfUj Y_`CV]`hcl UI]a UV`G: @cVgU\i`Y`f`]j`c`i`z`h`i`cV]`hcl UI]a UV`

5bhfUI`Y`j`nz`Vb`f`cbYa cVb` b`f`U`d` `dfUj Y_`CV]`hcl UI]a UV`G: @Vm`cnbU`Yb`XbY`&("gfdbU`&\$%`_U`c`
P`f`]j `d `dfUj Y_`dfc`j`nz`Vb`z`cbYa cVb` b`f`"8U`y]f]bZcfa UW`c`hca`hc`j`nz`Vb`fa`cbYa cVb` b`f`bU`YnbYhY`
nXY. ema.europa.eu/medicines/human/orphan-designations/eu3182065.

>U_`gY`d `dfUj Y_`CV]`hcl UI]a UV`G: @dci`y] z 3

J`XY`^`d` `dfUj`_i`CV]`hcl UI]a UV`G: @Y`j`znzb`bU`f`_U`g`_`d`YXd]g`"D`dfUj Y_`Vma`_`V`hdcXzj`zb`
v`a`]gh`z`_XY`Y`a`cybf`f`m`Y`fYU[`cj`Uh`bU`nzj`Uybf`U`Yf[]W`f`fYU`_W`"

D `dfUj Y_`CV]`hcl UI]a UV`G: @gY`dcXzj`z`Zcfa`ci`YXbcfz`ncj`f`]bZ`nY`f]Udzb`Z`Xc`y]f`mdc`XcVi`_`\$`a`]bi`h`
Doporu`Ybz`Xzj`_U`nzj`]g]bU`h`Ygbf`_`a`c]bcgh`dUWY`bHU`"D`YX`dcXzb`ta`d` `dfUj`_i`CV]`hcl UI]a UV`G: @Y`
a`cybf`dUWY`bh`a`_dcXU`h`f`]j`f`d` `dfUj`_m`_`dfYj`YbW`U`Yf[]W`_`Vb`fYU`_W`bYVc`Y`Y`W`ca`YnYb`f`

J`W`]bZcfa`UW`c`dci`y]`zb`f`d` `dfUj`_i`CV]`hcl UI]a UV`G: @bU`YnbYhY`j`d`WU`c`j`f`]bZcfa`UW`bYVc`gY`
cVfU`hY`bU`g]`f`c`f`_U`Y`_`]`f`z`fb`z`U`"

>U_`d` `dfUj Y_`CV]`hcl UI]a UV`G: @d` gcV]z 3

Nzj`Uybf`_`_`]b`_m`UbhfUI i`gci`nd`gcVYbmi`hcl]bYa`z`_hYf`_VU`hYf]Y`nd`gcVi`_W`UbhfUI`dfcXi`_i`_f`
CV]`hcl UI]a UV`Y`a`cbc`_cbz`b`f`dfch]`z`h`U`z`Vt`y`Y`_m`d`V`f`_c]`]b`z`_hYfz`_VmU`j`nj]`bi`hU`hU`z`UVmgY`bUj`znU`U`
bU`g`cy`_i`_hcl]bi`UbhfUI i`nj`Ubc]`b`dfchY`_h]`b`f`Ubh]`[`Yb`UbhfUI i`i`z`_hYfz`i`a`cy`_i`Y`j`gh`d`hcl]bi`Xc`Vi`b`_`"

D YXdc_zXz'gYž'yY'buJ znzbta'gY'bu'dfchY_hj] b#Ubhj[Yb'UbhfUI i'f]j c'nUVFU i'Y'j ghi di' hcl]bi'Xc'
Vi b' _h'Už' ta'y'na # i'Y'd #nbU_mbYVc' 'ja' d' YXWzn#'

>U_f'd #bcgmid #dfUj _i 'CV]'hcl UI]a UV'G: @Vmmidfc_znzbmj df V \i'ghi X]#3

BU'nz_UX' ghi X]#bU'nj #UH'VW'Y'd #dfUj Y_'CV]'hcl UI]a UV'G: @dcj Uy'cj zb'j fza W'f' Vmid]Wb#c'
UbhfUI i'nU'•]bb' "J fza W'f' ghi X]#i']bZ_cj Ub' W'nj #Uh'gd #nbU_mgY'a #mid Yy]h'dc\mVcj U'm
v'f'cna Yn#d]V'jyb' 'cX'" \$ do 60 i' i'd #dfUj _i 'CV]'hcl UI]a UV'G: @j Y'gfcj bzb#g \$'Uy'* % u placeba
fbY'•]bbf\c'd #dfUj _i E'"J Y'ghi X]#j Y' _h'f'f'V'm]bZ_cj Ub' a' nj #Uh' a' dcXzj zb'f']j' i'd #dfUj Y_'bYVc'
plUWVc'Y'yh' d' YX'ha ž'bYy'gY'dfc'Y'j]mid #nbU_nž'gY'a #U'd Yy]h'dc\mVcj U'U'cX') \$ do 100 i' i'd]
i'y] zb#d #dfUj _i 'CV]'hcl UI]a UV'G: @j n'zj]g'cgh]bU'hca ž'nU'U_X'ci \c'dc'bU_UyYb]Vmi'i' nj #Uh'
nU\z'YbU'f' VUž'd] Ya'y'nY'nj #Uhž'_h'f' a' V'mc'dcXzj zbc'd'UWVcž'bYd Yy]c'yž'Xbf'

>U_z'f]n]_U'gci'gdc'YbU'gd #dfUj _Ya 'CV]'hcl UI]a UV'G: @3

BY^Ugh'Y'ta]'bYyž'Xci W'a]'•]b_mid #dfUj _i 'CV]'hcl UI]a UV'G: @f_h'f'f' a' c\ci' dcgh]\bci h'Uy'%cgcVi'
n'#\$t'gci'Vc'Ygh'\U' mž'dfi f]h' g'f'g' X' b#ž'_cd]j'_U'f'g'j X]j z'j n'fz'y'_Už'j n'fz'y'_Už'_Uyel, bolest v a' t'gh'
Ud'_UW']bž' n'Y'U'dc'W'h'nzj fUh]"

i'd'b'g'YnbUa' b'Yyž'Xci W'W'•]b'_U'ca YnYb#d #dfUj _i 'CV]'hcl UI]a UV'G: @Y'i j YXYb'j d' #U'c'j'f'
informaci.

BU'nz_UX' Y\c'V'm'd #dfUj Y_'CV]'hcl UI]a UV'G: @fY[]ghfcj zb'j 9I 3

D]Wb#UbhfUI'Y'y]c'hc\fcy'i #M'cbYa c'Wb b#ž'_h'f'f'j 50 i' i'd #dUX' j YXY'_• a' fh#'=Xm'y'gY'd]f'cnYbz'
j'nd'Ubi h#bz'_Unmj m'g_mti #j'Y'a]n' #X'_Už'a' y'Y'b'Y'U'gh'bc'i' b'z'\c'Xci'Xc' #h'_j' g_mti']bZ'_W'f'
v'U'VcfUhc' #W'ž'_h'f'f'f'mtc'VU_h'f'f'Y'n'ci a' U'ž'U'UbhfUI' a' y'Y'V' h'dci' y]h'd']h'f'c'f'g]h]W' W'• hc'W'W'"
Jnhledem k' hca i' ž'y'Y'dc' Y'h'd #dUX' 'Y' h'U'_b' h'U'_U'• a' m'g'b'f']bZ_cj zb#cgcV'Y'd #j'y'b'YVndY' b'f'ž'b'Yb#'
a' c'y'b'f'd'f'c'f'g'h'g'h' X]Y'h'c'h'c'f']j'f'c'd' #dfUj _i 'i']X#'G'h' X]Y'bU'nj #UH'VW' d'f'c'z'nU'mž'y'Y' h'Yb'h'c'f']j'
d' #dfUj Y_'Y'•]bb']j' f' V' UbhfUI i' U'd'f'Y' Y'bW'Y'• a' fh#ž'U'd YXdc_zXz'gYž'yY'd #dfUj Y_'CV]'hcl UI]a UV'
G: @Vi XY'i']X#d' g'cV]h'gh'Y'b' a' nd' g'cV'Y'a' "N\YX]g_U'VYndY' b'cgh]'gci' b'Yyž'Xci W'•]b_mid #dfUj _i'
CV]'hcl UI]a UV'G: @i' n'X'f'Uj W']X#c'V] m_Y'a #b'f'Uy'gh'YXb' n'zj Uy'b'f'"5[Yb'hi f'U'd'f'c'h' f'c'n\c'X'Už'y'Y'
d' #bcgmid #dfUj _i 'CV]'hcl UI]a UV'G: @d' Y'j' m'j' #Y'Y'c'f'n]_Už'_U'a' y'Y' h'U'_V' h'f'Y[]ghfcj zb'_dci' y]h#j' EU.

D #dfUj Y_'CV]'hcl UI]a UV'G: @V'm'f'Y[]ghfcj zb'nU']j' #ja Y' b' W'c'_c'bcgh]ž'b'YVc' j'n\YX'Ya' '_Y'j' n'z'W'f'
dcj Un'Y'h'c'h'c'cb'Ya c'Wb b'f'U'n'Y'h]W' W'X' j'cX' b'YVmc'a' c'y'b'f'c'd' #dfUj _i 'CV]'hcl UI]a UV'G: @ntg_Uh'
• d'b'f']bZ'c'fa UW'"5[Yb'hi f'U'_Uy'X'c'f'c' b' j' n'c'X'b'c'h'f'U'_f'_c']bcj'f']bZ'c'fa UW'U'h'Y'b'h'c'd' Y\YX'Vi XY'dc'X'Y'
dch YV'mU'_h' U']h'c'j' zb'

>U_f']bZcfa UW'c'd #dfUj _i 'CV]'hcl UI]a UV'G: @bYVmmXc'gi X'd YX'c'y'Ybn#3

>Y'_c'y'd #dfUj Y_'CV]'hcl UI]a UV'G: @V'm'f'Y[]ghfcj zb'nU']j' #ja Y' b' W'c'_c'bcgh]ž'gdc'Y' b'cgh]ž'_h'f'z'
d' #dfUj Y_'CV]'hcl UI]a UV'G: @XcXzj z' b'U'h'f'ž'd' YX'c'y'ž'XU'y'ž'• XU'Y'c'a' Y'h'c'Xz'W'a' Yb#h'c'z'U'_Y'
d' #dfUj Y_'j' 'U'VcfUhc'fb#W' ghi X]#W'j' gh'YVzj z'bž'a' cX]Z_cj zb'U'c'X'gh'f'U' c'j' zb'n' h'U'"BUj #W'W'ma' m'V' h'
d' YX'c'y'Ybm'• XU'Y'c'•]b'bcgh]U'VYndY' b'cgh]'f']j'f'c'd' #dfUj _i 'd']a' c'y'b'f'a' d'f'cdi'_bi' h'U'bh'f'UI' i' "

**>U_z'cdUh Yb#gci' i' d'Uh' c'j' zbU'_nU'Y'gh' b#VYndY' b'f\c'U'•]bbf\c'
dci' y]j' zb#d #dfUj _i 'CV]'hcl UI]a UV'G: @3**

8c'gci' \fbi'• XU^'c'd' #dfUj _i 'U'd' #U'c'j'f']bZ'c'fa UW'V'mU'nU'f'bi' h'U'X'cd'c'f'i' Yb#U'cdUh Yb#d'f'c'VYndY' b'f'
U'•]bb'f'd'c'i' y]j' zb#d #dfUj _i 'CV]'hcl UI]a UV'G: @'_h'f'z'V'ma' 'U'V' h'X'c'X'f'yc'j' z'bU'n'X'f'Uj' c'h]W' a']
d'f'U'W'ej' b#m] d'U'V'Y'b'm'f'

>U_c'i j yYw f j] W'd d fUj _ 'gci '• XU'Y'c'dci yj z b#d d fUj _i 'CV]'hcl UI]a UV'G: @df V yb ' g'YXcj zbm' BYyzXci W#•]b_mbU\ z'yYbf'j souvislosti s d d fUj _Ya 'CV]'hcl UI]a UV'G: @'gci 'dY 'j] \cXbcWbmU'gci 'i]b bUj Yy_Yfz 'bYnVntbz 'cdUh Ybž'UVmVmic'Wfzb bc'nXfUj #dUWYbh "

8U'y#]bZcfa UW'c'd d fUj _i 'CV]'hcl UI]a UV'G: @

8U'y#]bZcfa UW'c'd d fUj _i 'CV]'hcl UI]a UV'G: @'gcu k X]gdcn]W'bu'bhYfbYhcj W'ghfzb_zW'U[Ybh fmbU' adrese ema.europa.eu/medicines/human/EPAR/Obiltoxaximab-SFL.

Př. pavek Ji, nen. registrovfn