

Obiltoxaximab SFL (*obiltoxaximab*)

DfYnYbhUFY [YbYfU ' U'CV] hcl UI ja UV'G: @]'a chj Y'Y'Ui hcf]n f]]
medicamentului 2 UE

7Y'Ygh'CV] hcl UI ja UV'G: @]'dYbhf' W'gY'i h]nYUn, 3

Obiltoxaximab SFL este un medicament utilizat în asociere cu antibiotice pentru tratarea antraxului
di 'a cbUf'z'c'VcU' [fUj ' Wli nUh 'XY'VUVWf]U' Bacillus anthracis" Df]b'Pd' 'a cbUf' 'gY' %o'Y'Y['Y'W'
dYfgcUbU'V'z'bfUUVWYUn 'VcU'U'W' bX']bgd]f 'b] hY'gcdcf] WfY' %o'cf[Ub]ga 'gY' hfUbgZcfa ' %o'VUVWf]]'UW]j Y'
]Y']VYfYUn 'hcl]bY'bcW] Y"

A YX]W]a Ybh' 'gY'i h]nYUn ']'dYbhf' 'dfY] Yb]fYU'UbhfU' i]'di 'a cbUf' 'U'dYfgcUbY'Y' WfY'Ui ']bhfU' %o;
V'z'bfUUVW' 'gcdcf]]'VUVWf]Y]]' %o'W]ni ' %o'WfY'bi 'Y]]gh' 'U't tratament disponibil.

CV] hcl UI ja UV'G: @ V'z' b]bY'gi VghUb U'UW]j 'cV] hcl UI ja UV"

Antraxul este rar, iar Obiltoxaximab SFL a fost desemnat „medicament orfan” (un medicament utilizat
%o'Vc']'fUFY'U'&['Ui [i gh'&\$% "'=bZcfa U]]'gi d]a YbhUFY'W' dfj]]fY' 'U'a YXicamentele desemnate orfane
dchZ] []gh' U]W]. ema.europa.eu/medicines/human/orphan-designations/eu3182065.

7i a 'gY'i h]nYUn 'CV] hcl UI ja UV'G: @3

Obiltoxaximab SFL sY'dcUh' CV]]bY'bi a U]dY'VUn 'XY'dfYgW]d]Y'a YX]W] ']'hfYVi]Y'UXa]b]ghfU' %o'f'-o
i b]]U]h' i bXY'fYUW]]Y'U'Yf[]W' gY] YfY'dchZ] hfU]U]h' fUd]X"

CV] hcl UI ja UV'G: @gY'UXa]b]ghfYUn 'gi V'Zcfa 'XY'dYfZ] nY]]bhfUj YbcUg' 'fd]W' fUFY' %o;j Yb' E' i b]W'Z'W'
durata de 90 XY'a]bi hY"'8cnU'fYV'z'a UbXUh 'XYd]bXY'XY [fYi]U]hYU'V'z'cdfU' 'U'dUWY]bhi' i]'abU]bh'XY'
UXa]b]ghfUFYU'CV] hcl UI ja UV'G: @dUWYb]'cf']'gY'dch]UXa]b]ghfU'a YX]W]a Ybh' dYbhf' 'dfY] Yb]fYU'gUi'
fYXi W'fYU'fYUW]]cf'U'Yf[]W"

DYbhf']bZcfa U.]]'gi d]a YbhUFY'W' dfj]]fY' 'U'i h]nYUn'CV] hcl UI ja UV'G: @Z'V]h]]'dfcgdYVW] 'gUi' UXfYgU]-
j]'a YX]W]i]'Xi a bYUj cUgh' 'gUi' Z]fa U]W]gh' i]"

7i a 'UW]cbYUn 'CV] hcl UI ja UV'G: @3

9ZYWY'Y' [fUj Y'U'Y'UbhfU' i]'gi bh'Wli nUh'XY'c'hcl]b' 'dfcXi g' 'XY'VUVWf]]Y'UbhfU' "'CV] hcl UI ja UVi'
este un abh]V'z'f'd'a cbc'WcbU'z'i b'h]d'XY'dfchY]b' z'WfY'U'Zcgh'V'z'bw'w'di hig' 'gY' 'Y['Y'XY'c'V'z'a dcbYbh' 'U'
hcl]bY]UbhfU' 'bi a]h' 'HUbh] [Yb'dfchYV'z'f'U'UbhfU' i]'i]'WfY-'dYfa]hY'UWYghY]U'g' 'd' hfi bX' %o'W' i 'Y'"

Prin legarea de antigenul protector al antraxului, medicamentul Uf'fYVi]'g' %d]YX]W'hcl]bU'g' d' hfi bX' %W'i' Y'Y'cf[Ub]ga i' i']z'fYXi W' bX'UghZ'Y'gUi' dfY] Yb]bX'g]a dhca Y'Y'

7Y'VYbYZ]V] U'dfYnYbhUhCV]hcl UI]a UV'G: @dY'dUfWfgi' 'ghi X]]cf3

Pe baza studiilor efectuate la animale, Obiltoxaimab SFL este considerat eficace în tratarea antraxului di 'a cbUf" ab' 'ghi X]]YZVW UHY'U'Ub]a U'Y']bZYWUHY' WfY' dfYnYbhUi']g]a dhca Yz'fUHY'Y'XY'gi' dfUj]Y' i]fY' au variat între 30 i']'*\$ % cu Obiltoxaimab SFL, comparativ cu 0 % - 6 % cu placebo (preparat]bUW]] E" abf-un studiu în care animalele infectate li s-a administrat medicamentul sau placebo înainte XY'UdUf]]U'g]a dhca Y'cfz'fUHU'XY'gi' dfUj]Y' i]fY'U'j Uf]U']b'fY') \$']'\$\$\$ % cu Obiltoxaimab SFL,]z' Z' bW]Y'XY'fUd]X]HUYU'W' WfY'Ui' Zcgh'fUHUHY'Ub]a U'Y'Y'Xi d']bZYWare, comparativ cu 0 % la animalele WfcfU']g-a administrat placebo.

7UfY'gi bhf]gWf]Y'UgcV]UHY'W'CV]hcl UI]a UV'G: @3

7Y'Y'a U]Z'fYV]YbhY'fYUW]]UXj YfgY'UgcV]UHY'W'CV]hcl UI]a UV'G: @fWfY'dchUZVWU'W'a i'h%'dYfgcUb' din 10) sunt dureri de cap, pruf]hfa]bWf]a YLz'i fh]Wf]Y'fYfi d']]dY'd]Y' %gc]h'XY'a]bWf]a YLz' Yfi d']]dY'd]Y'Z'hi gYz'Xi fYFY'U'cW'dYfZ' n]Y]]'gYbnU]Y'XY'Ua Y'YU' "

DYbhf']]ghU'W'a d'Yh' U'fYUW]]cf'UXj YfgY']'U'fYghf]W]]cf'UgcV]UHY'W'CV]hcl UI]a UV'G: @Vh]]' prospectul.

8Y'W'U'ZcghUi hcf]nUhCV]hcl UI]a UV'G: @%i 93

5bh'fUI i']di 'a cbUf'Ygh'c'VeU' WfY' di bY'j]U U' %dYf]V'z'Xi W' bX'U'XYW'g' %) \$ i' 'X]b'W'ni f]]'8Y']' ZcWfY'Y'bU' h'fU'Y'gi' bh'ZcUfhY'fUfYz']bZYW]]Y'dch]U' fYU'UW]XYbHU' %'UVcfU'hcUfY'Y'WfY'ghi X]]Un' bacteriaZ'Ub'fUI i']di h] bX'Z'i h]]nUh%U'UW'f] h'f'cf]ghY'"8]b'W'i nU'bi a' fi' i']a]WXY'W'ni f]]']XYcUfYW']bZYW]fYU']bhYb']cbU' U'dYfgcUbY'cf'YghY' dfYU'dYf]W'cUg' z'bi' YghY'dcg]V]]' YZYW'i UfYU'XY'ghi X]]' privind medicamentul la oameni. Studiile la animale au demobgh'U'W'a YX]W'a Ybhi' YghY'YZ]WUW' %' hfU'fYU'Ub'fUI i' i']' dfY] Yb]fYU'a c'fU']h']]]'gY'dfYVz'b]nYUn' W'CV]hcl UI]a UV'G: @j U'UW]cbU' %' U'W'U']a cX'U'cUa Yb]]' ab' WYU'W' d'f] Y' h'Y'g]] i' fUb' Uz'fYUW]]Y'UXj YfgY'U'Y'CV]hcl UI]a UV'G: @U' dYfgcUbY'Y'g' b' h'cUg'Y'gi' bh'XY'cV]W]]i' cUfY'gUi' 'a cXY'fUHY'"Df]bi' fa UfYz'U[Yb]U'U'ch f] h'W' VYbYZ]V]]Y' CV]hcl UI]a UV'G: @gi bh'a U]a Uf] XYW'hf]gWf]Y'UgcV]UHY']'UW'gh'a YX]W'a Ybh'dcU'Y'Z'Ui hcf]nUh'dYbhf' i' utilizare]z'UE.

5W'gh'a YX]W'a Ybh'U'Zcgh'Ui hcf]nUh%U'Vz'bX]]'YI'W'd]cbU'Yf]"5W'UghU' %gY'Ua b' W'z'X]b'W'i nU'fUf]h']] Vc]]']'X]b'a ch]j Y' h]]b]Z]W'z'bi'g'Ui' di hi h'cV]bY']bZcfa U]]V'a d'YHY'XYgdfY'CV]hcl UI]a UV'G: @'ab' Z]YWfY'Ubz'U[Yb]U'j U'U'U'nU']bZcfa U]]Y'bc'i' Ud' fi h'z']Uf'UW'Ugh' dfYnYbhUfY' [YbYfU']'U'Z' actualinUh'z'Xi d' W'n"

7Y']bZcfa U]]gY'U' hYUdh' %'Vz'bh]bi UfY'XYgdfY'CV]hcl UI]a UV'G: @3

5j] bX' %j]XYfY'W'CV]hcl UI]a UV'G: @U'Zcgh'Ui hcf]nUh%U'Vz'bX]]'YI'W'd]cbU'Yz'V'a dUb]U'WfY' V'a YfV]U']nYUn' CV]hcl UI]a UV'G: @j U'Z' fb]nU'XUHY'gi' d']a YbhUfY'df]]bX'a YhcXY'Y'XY'a' gi' fUfY'U' a cX']i] %WfY'a YX]W'a Ybhi' YghY'UVgcfV]h'z'a cX]Z]W'h']Y']a]bU'h]X]b'cf[Ub]ga' %'ghi X]]Y'XY'UVcfU'hc'f'" ab' d'i g'z' hfYVi]Y'Z' fb]nUHY'XUHY'df]]bX'YZ]WUW]UHYU']'g]] i' fUb' U'a YX]W'a Ybhi' i'] %h]a di' i' bi]Y] Ybhi' U' focar de antrax.

7Y'a gi f]gY]Ui 'dYbhf i i h]nUfYU'g][i f ']YZ]WVW'U'CV]hcl UI]a UV'G: @3

ab'FYni a UH'`WfUWVf]gh]V'cf'dfcXi gi 'i]]%dfcgdYVW'Ui 'Zcgh]bWl gY'fYVta UbX' f]]'a gi f]XY' dfYWl]Y'dYbhf i i h]nUfYU'g][i f ']YZ]WVW'U'CV]hcl UI]a UV'G: @Z'WfY'hfYVi]Y'fYgdYVWUHY'XY'dYfgcnalul a YX]W']XY'dUWYb]"

Ca pentru toate medicamentele, datele cu privire la utilizarea Obiltoximab SFL sunt monitorizate Vtb]bi i "'FYUW]]Y'UXj YfgY'fUdcfUHY'dYbhf i CV]hcl UI]a UV'G: @gi bhYj Ui UHY'W'UHYb]Y']gi bh'i UHY' a gi f]Y'bYWgUfY'dYbhf i 'dfchYW]U'dUWYb]cf"

5`hY]bZcfa U]]'XYgdfY'CV]hcl UI]a UV'G: @

=bZcfa U]]'gi d]a YbUfY'W'df]]fY'U'CV]hcl UI]a UV'G: @gi bhX]gdc]V]Y'dY'g]HY-i']U[Yb]Y].
ema.europa.eu/medicines/human/EPAR/Obiltoximab-SFL.

Produsul medicinal nu mai este autorizat