

Obiltoxaximab SFL (*obiltoksaksimabs*)

Obiltoxaximab SFL d fg_Uhg'i b'_ d Wh g']f' fY]ghf hgj' 9G

Kas ir *Obiltoxaximab SFL* i b'_ d Wh g']Yhc3

Obiltoxaximab SFL]f'n 'Ygž'_c']Yhc'_cd 'Uf'Ubh]V]ch]_ a ž'_U] fgh h]]YY'dcyUbUg'j Y]X ']Y[h'_i b'_ VU_h f]Ug' *Bacillus anthracis*]nfU]g h'_bcd]Yhbi 'g]a Vi ' — G]V f]Ug'a 'f]' =YY'dcyUbU'bcna 'ž'_U'Wj '_g' gUg]a ghž']YY'dc'ch'gdcfUgž'_Ug'cf[Ub]ga 'd f] Y]Xc 'Ug'dUf'U_h] a 'VU_h f]^ a 'i b']nXU'U'_U]h[i g' hc_g bi g"

ü g'n 'Yg']Yhc' Uf']YY'dcyUbUg'j Y]X ']Y[h'_G]V f]Ug'a 'fU'dfcZ'U_gY]Wj '_]Ya ž'_i f]bcb '_gUg_Uf' 'Uf' VU_h f]Y'gdcf a 'i b'_UX'W]H]d]Ya 'fchU' fgh ýUbU'bU']YY'Ua U"

Obiltoxaximab SFL gUh f'U_hj c'j]Y'i 'cV]hc_gU_gla UVi "

G]V f]Ug'a 'f]g']f' fYhU' 'g]a VUz'i b'&\$% " gada 24. Ui [i gh 'Obiltoxaximab SFL h]U'd]Yý]fgh' fV fY n i 'fYh'gUg'cdUa i 'g]a Vi ' fgh ýUbU]dUFYXn h'_n i 'ghUh gg'G _'U]bZcfa 'W]U'dUf'fYh' g]a Vi ' fgh ýUbU]dUFYXn hc'_n i 'ghUh gU'd]Yý]f'UhbfcXUa U. ema.europa.eu/medicines/human/orphan-designations/eu3182065.

?]Yhc 'Obiltoxaximab SFL3

Obiltoxaximab SFL j Uf']Y[X_h]Yg'h]U]dfYh'fYWdh]i b'^]Yj UXU'j]Yh ž'_i f'j Uf' hf] fgh h'ga U[Ug' U'Yf]g_Ug'fYU'W]Ug"

Obiltoxaximab SFL ievada vienas 90 a]b yi '][Ug']bZ n]Ug'fd]]Ybi t'j Y]X 'j b "'=YhY]W]a 'XYj U'f' Uh_Uf' U'bc'dUW]YbH]a 'Ug'Ug' 'D]fa g' *Obiltoxaximab SFL* liehcýUbUg'dUW]YbH]Ya 'j Uf'Xch'n 'Yg'U'Yf]g_c' fYU'W]l'dfcZ'U_gY'j U] a Un]b ýUbU"

DUD]Xi ']bZcfa 'W]l'dUf' *Obiltoxaximab SFL* ']Yhc'Ubi 'g_Uhh'n i ']Yhc'UbUg']bghfi '_W] 'j U] 'Ui h h' fghUa ' vai farmaceitam.

? 'Obiltoxaximab SFL XUfVc'Ug3

G]V f]Ug'a 'fU'bcd]Yhbc']YhY_a]]nfU]gU'G]V f]Ug'a 'fU'VU_h f]Y' ']nfU]g h]g'hc_g bg' 'C V]hc_gU_g]a UVg']f' a cbc'_cb 'U'Ubh]j]Y'Už'c'VU'h a j]Y'i 'j Y]Xgž'_Ug']ngf X 'gž'_U]d]YgU]gh'hc'G]V f]Ug'a 'fU'hc_g bU'XU U]ž'_c'X j 'dUf'fG]V f]Ug'a 'fU'U]ngUf' 'cyc'Ubh]j bi 'ž'_Ug' 'Ui 'hc_g bUa ']Y_ 'h'y b 'g' 'DUfYXnUa gž'_Už' d]YgU]gh'ch]Yg'G]V f]Ug'a 'fU'U]ngUf' 'cyc'Ua 'Ubh]j bUa ž'_y g'n 'Yg'UdH f' g'hc_g bU']Y_ 'yUbi 'cf[Ub]ga U' ý b gž'gUa Un]bchj U]bcj 'fych'g]a dhca i g"

? X] Obiltoxaximab SFL]Y[i j i a]Uh_` h`d h`i a cg3

DUA Uh`c h]Yg i n`d h`i a]Ya 'Uf'Xnj b]Y_]Ya ž Obiltoxaximab SFL h]Y_`i ng_UhUg'dUf'YZY_hj a ']
]YY`dcyUbUg'j Y]X ']Y['H'G]V f]`Ug'a fU' fgh ýUbUj" Hf]`cg'd h`i a cg'Uf']bZ]Wh]Y_`Xnj b]Y_]Ya ž_i f]Y_]
V]U'g]a dhca]ž]nXnj cýUbUg'f X h`j'V]`UfcVYy g`bc'Udhi j Yb]`30 i `` Xn'*\$ i ``]Yh`c'h Obiltoxaximab
SFL gU' Xnj b` 1 a 'Uf'\$-6 i `` fgh `ch'Uf'd'UVWVc'f]`hj i `` fgh ýUbi t" D h`i a ``z_i f']bZ]Wh]Y_`Xnj b]Y_]
d]fa g`g]a dhca i 'dUf X ýUb g`gU a U'ý g'n 'Yg'j U]`d'UVWVc'Xnj]XnY'V]`UfcVYy g`bc) \$ `` Xn'%\$%,
]Yh`c'h Obiltoxaximab SFLž Uh_Uf V 'bc'h ž]W_` hf]`d W]bZ]WýUb g`Xnj b]Y_]Ya 'h_Uj Y]_hU' fgh ýUbUž
gU' Xnj bch'Uf'bYj]Ybi 'bc'h]Y_`i f'gU a U'd'UVWVc"

? Xg'f]g_g`dUgh j ž]Yh`c'h Obiltoxaximab SFL3

J]gV]Yy _ g`Obiltoxaximab SFL V'U_i gdUf X VUg'f]`Uf'fUgh]Yg `` Xn'1 no 10 Wj _]Ya t]f' [Uj Ugg dYgž
dfi f hg'fb]YnYtž b` hFyBfY fb]Yncy]]ng]h a]ž]ng]h a]ž_`Ydi gžg dYg]bZ n]`Ug]`jYh`b`fY]Vcb]g"
D]`bi 'j]gi 'V'U_i gdUf X Vi 'i b`]YfcVYyč`i a i 'gUfU_ghi ž]Yh`c'h Obiltoxaximab SFLž g_Uhhn i ``]YhcyUbUg'
]bghfi _W^ "

? d WObiltoxaximab SFL]f'fY]ghf HUg'9G3

G]V f]`Ug'a f]g']f'Xnj VUj`V ghu a U'g]a VUž_`Ug]nfU]gU`b j]) \$ 1`[UX `i a i `` @U]`[Ub'XUV]g_`Y`
i n`Yga c`i a]`f' ch]`fYh]ž]bZ]WýUb g`[UX `i a]`j Uf'`bY`Ui y]`fUgh]Yg `` UVcfUhc]f]`gž`d hch`VU_h f]`Ugž`i b`
G]V f]`Ug'a f]j`j Uf'`na Ubhch`hYfcf]gh i nVfi _i a cg'`H `` [UX `i a i 'g_U]h]`f`h]`a Ung`i b`hý]`]bZ]Wh`
Wj _i g`f`d f _`V ghu]ž`bUj]Ygd `Ua g`j Y]_hyc`n i `d h`i a i g`Uf'Wj _]Ya `` D h`i a]`Uf'Xnj b]Y_]Ya
d]Yf X `Už_U`ý g'n 'Yg]`f`YZY_hj Ug'G]V f]`Ug'a fU' fgh ýUbU]`i b`Yh`i `` [UX `i a i 'bcj f`yUbUž`i b`
paredzams, ka Obiltoxaximab SFL i n`Wj _]Ya 'XUWcg]Yg`HUX `dUyUj Y]X `` Bc`Xfcy`i a U`j]YXc_U`
Obiltoxaximab SFL V'U_i gdUf X VUg'j Yg`Y]Ya 'Wj _]Ya 'dUfUgh]`f`j]Y[`Ug'j U]`a f`yUbUg``H X 'U Ybh fU`
bc` a Už_U`Y[i j i a gž`]Yh`c'h Obiltoxaximab SFLž d fgb]YXn`y`c`n i 'fUX hc`f]g_i i b`n 'Yg'j Uf'fY]ghf h`
]YhcyUbUj`9G"

Obiltoxaximab SFL]f'fY]ghf HUg'`i n`a i a U`_ fh ū`HUg`bcna ž`_U`gU_Uf `Uf'ý g`g]a VUg`fYh a i i b`
h]g_i]Ya Yg`i X `bUj V]`g]Ygd `Ua g`j Y]_h]`d]b`[i `]bZcfa Wj`i dUf`Obiltoxaximab SFLž`5 Ybh fU`_Uhf`i
[UX i`d fVUj X g`j]gi 'Ui b]Y[h]`]bZcfa Wj`i b`j U`Uxn VUg`[UX `i a `Uh`Ui b]b g`yc`_cdglj]`i a i "

? XU]bZcfa Wj`U`dUf` Obiltoxaximab SFL j ``]f'gU[UjX a U3

H `_ Obiltoxaximab SFL]f'fY]ghf HUg'`n`a i a U`_ fh ū`i n`a i a gž`_Ug`d]YX j `h]f[`` Obiltoxaximab
SFLž`gb]Y[g`dUd`Xi XUh`i g`dUf`a Yhcx a ž`Uf`_i f`a`bcj`fh`i`i ng _ýUbUg`d f]Y]Xc`yUbUg`i b`
]nj UX ýUbi `bc`cf`[Ub]ga U`UVcfUhc]f]`Ug`d h`i a cg'`H`f`_h`^`]Ygb]YXn`XUh`dUf`n`i `YZY_hj`j h`j`i b`
Xfcy`i a i]Ygd `Ua U`G]V f]`Ug'a fU`i n`Yga c`i a U`U`_ "

? U`h]Y_`XUf hgž`U`[UfUbh h` Xfcy`i i b`YZY_hj i ` Obiltoxaximab SFL `]YhcyUbi 3

N`i `UdfU_gh`i b`]YhcyUbUg`]bg`hfi _W^`h]_U`]Yh`Yf]`]YhY`i a]`i b`d]Yg`UfXn VUg`dUg`i a]ž`_Ug`^`]Yj`fc`
j Yg`Y`VUg`Udf dYg`gdYW`]gh]Y_`i b`dUW`Ybh]Y_`ž`U`[UfUbh h` Xfcy`i i b`YZY_hj i ` Obiltoxaximab SFL
`]YhcyUbi "

H dUh_` dUf`j`g`a`n` a ž`XUh`dUf` Obiltoxaximab SFL `]YhcyUbi `h]Y_`dUgh`j`[i nfUi Xn h`N` ch g`Uf`
Obiltoxaximab SFL `]YhcyUbi `gU]ghh g`V`U_i gdUf X VUg`h]Y_`f`d`[i`n` fh`H`gž`i b`h]Y_`j Y]_h]`j`g`dUW`Ybh`
aizsUfXn VUj`bYd]YV`Yy`a]Y`dUg`i a]"

7]HJ]bzcf a WU'dUf Obiltoxaximab SFL

G _ _U'bzcf a WU'dUf Obiltoxaximab SFL]f'UhfcXUa U'U Ybh fUg'ha Y_ U'j]Yhb .
[ema.europa.eu/medicinYgAiaUb#9D5F#CV\]hcl UI ja UV-SFL](http://ema.europa.eu/medicinYgAiaUb#9D5F#CV]hcl UI ja UV-SFL)

z€les vairs nav re•istr•tas