

Obiltoxaximab SFL (*obiltoxaximab*)

Ufgu' YbYfU]'Y'b'CV]'hcl UI ja UV'G: @i' [U'ZY'b'\i k U'Uk'hcfl'nnUh'Z-UE

L'Qb'\i'CV]'hcl UI ja UV'G: @i' [U'YI'Y'bh' U3

CV]'hcl UI ja UV'G: @\i k U'a YX]]bU''h]bh' U'a UD_i fU'Ubh]V]'ch_U' U'-kura tal-UbhFU Y]'bU'U'hcfl'Uz' a UfXU'gyf'U'__Uk' UH'a]'-VUHYf'Y' *Bacillus anthracis*" i' bU'U'hcfl'U' h]ggYf''-dYfgi bU'h]Y' i''-marda billi man-b]Zg'h] VYX'gdcf]z''j] j]i ddUK' ZVUHYf'Y' attivi fil-]gYa' i']'ff]'UI I Uk' hcgg]b]dYf]_c'i']"

II-a YX]]bU'h]bh' U'k'_c''V]YI' h]ddfYj' Yb]UbhfU' Y]'bU'U'hcfl'U' Zb]Yfgi b]''^i bi' Yk' Zb]i bhU'h'a U'-ispori tal-VUHYf'Y' i' a YHU''-YVXU'_i fU'I]YfeU'c' fU'a U'h_i b'X]gdc]b]V'']

Obiltoxaximab SFL fih is-gi gh]bna attiva obiltoxaximab.

L-UbhFU Y'\]U'fUf]z'i' CV]'hcl UI ja UV'G: @]Y'XYbca]bUh'V' U'U'fa YX]]bU'cfZb]i' fa YX]]bU''h]bh' U' Zb] UfX'fUf]Z-24 H]DAwwissu &\$% "'5_Huf]'bZcfa Unn'cb]'Xk Uf]'X-XYbca]bUnn'cb]'cfZb]h]bghU'V'Uk b. ema.europa.eu/medicines/human/orphan-designations/eu3182065.

?]Z'Y'bh' U'CV]'hcl UI ja UV'G: @3

CV]'hcl UI ja UV'G: @]gh]U]b_]gYV'V]gg'V] YHU' H]D]HUV]V'i' [UbXi' Y'b[UHU' Zb]cgh]ZY'b' fYUnn'cb]'Y'Yh' allYf']]'gYj' Yf]'Y'gh' i']' i']' fU'h]a']bbi' Z' "

CV]'hcl UI ja UV'G: @]b[UH]V' U'U']bZ' 'cb]'k U' XU'fXf]ddE'Z]-j]bU'Z' e'dYf'cXi' H]D- \$'a]bi' HU''-X-Xc' U' rakkomandata tiddependi mill-d] 'HU'-]gYa' HU'-dUn'Ybh'E U'VY'a U']b[UHU'CV]'hcl UI ja UV'G: @Z]- dUn'Ybh]'Y'gh' i']'b[UHU'k' a YX]]b]V]YI']'ddfYj' Ybi' Yk']bUeegi' f-fYUnn'cb]'Y'Yh'U''Yf']]"

; U''U'_Huf]'bZcfa Unn'cb]'Xk Uf''-i' i' H]DCV]'hcl UI ja UV'G: @Z'Uf''-Z' Y'Yh'H]D]HUV] f]Z'Yk']_i' bhU'YU''h- HUV]V'Yk']'-]gd] Uf'h]Y[]_"

?]Z'U' XYa' CV]'hcl UI ja UV'G: @3

L-effetti gYf'Y' HU'-UbhfU' Y'\i a U'__Uk' UH'a]bb' hcgg]bU'']-VUHYf'Y' HU'-UbhfU' Y']'ddfcXi' i' "CV]'hcl UI ja UV' \i k U'Ubh'_cfd'a cbc'_cbU'z'h]d' H]Ddfch]Y'bUz'']'h]ZggU'V]YI' Y' Y'a UD_ca dcbYbhUH-tossina tal-UbhFU' Y' a gY'U']'Ubh] YbY'dfch]Y'h] HU'-UbhfU' Y']']'ddYfa Y'hi li t-hcgg]bU'h]X' c''Z] - Y''c]''6]]'hY' Y'a U'- Ubh]-YbY'dfch]Y'h] HU'-UbhfU' Yz]-a YX]]bU'\]U'a]ghYbb]U'']'rk UeeUZ''h-hcgg]bU'a]']'h]X' c''Z] - Y''c]]'HU'-]gYa' z'i' V]Y'_hbUeeUg'Yk' h]ddfYj' Yb]g-sintomi.

X'inhuma I-VYbYZ] 'g' HUDCV] hcl UI ja UV'G: @'' Uf i 'a]'-]ghi X'g3

CV]hcl UI ja UV'G: @\i k U__i bg]XfUhYZZ_U]Z]-_i fU'HUDUbfU Y]bU'Uhc'f'U'UVVU]'HUDghi X'g'Z e''- Ubb]a U]'':]h]Yhghi X'g'Z e'Ubb]a U]']bZYHh]V]g-sintomi, ir-fUH] HUDgcdfUj]j YbnU]j Uf'Uk 'VY'b'a UXk Uf' 30 u 60 % VDCV]hcl UI ja UV'G: @'a YHU'a eUVV'U'a UDS'gU''i 'V]-d'U YVc'f]i fU'Z]bhUE'':]'ghi X'g'Z' b' Ubb]a U]']bZYHh]f Yj Yk]-a YX]]bU'Yk 'd'U YVc'eUVY''a U']j]i ddUk]g-sintomi, is-gcdfUj]j YbnU]j Uf'UH' VY'b') \$i '%\$ \$i 'VDCV]hcl UI ja UV'G: @'g_cbh_Ya a ''-Ubb]a U]'f Yvew il-_i fU'a U'U'f'k UfU''i Yk]bZYHh]z'a YHU'a eUVV'U'a UDXUK_']'a U'b['UHUK ''-YVXU'd'U YVc''

X'inhuma r-f]g_'Uggc 'UH]a UDCV]hcl UI ja UV'G: @3

L-YZZYH]gY_cbXUf]'-U_HUf'_ca i b]VDCV]hcl UI ja UV'G: @f] 'g]h[i 'UZZYHk Uk 'gUdYf] bU'k U XU'%a]bb' kull 10E'li a U'k]['HUDfUg'z'dfi f]h'f'U __t'zi fh]_UF'U'f'fU'U]V]- U__t'z'fU'U]'z'gc['Uzi]['Z]g-sit tal-]bZ' 'cb]i 'h cggc_'ghcfXi h'

; U'-]ghU'g] U'HU'-YZZYH]gY_cbXUf]'i 'f-fYgh]nn'cb]Y]h'HUDCV]hcl UI ja UV'G: @'UfU''-Z' 'Yh'HUDHU['f]Z'

; U'ZY'b'CV]hcl UI ja UV'G: @']Y'Uk hcf]nnUhZ'-I 93

L-UbfU Y]bU'Uhc'f'U'\]U'a UfXU''h]ddYf]_c'U''- U''U'i '']rk UggU''] U'-a Yk hZ) \$i 'HU'-_U]'YH'' ; U'_Ya a]h-h]ze[] Uh'bUH' fU]' \i a U'fUf]' Uz'Uz''-]bZYnn'cb]Y]h'g]h[i 'gY i 'V] 'VU''ZDUVcfUhc'f]'ZY'b']i bi 'eYX'g' i 'ghi X'U'h]''-VUHfYf'z'i ''-UbfU Y]ghUd]h]b]i 'UH'Z]HU_] 'hYffcf]g]h[]''A]b UVVU'']b-numru tal-_U]'Yh'\i k U'XUeg'Y__'VUI' i ''-]bZYnn'cb]V] cX'XY]VYfU'hU'-]bX]j]Xk]'\]U'k]ge'dYf]_c'i Uz' a \i k]YI 'ZUH]V]']'rk Yh'e] 'ghi X'g'HU'-a YX]]bU'Z' e']-persuni. L-]ghi X'g'Z e''-animali wrew li I- a YX]]bU'U'YZZYH] U'V]YI 'h]_i fU''-UbfU Y i 'h]ddYf] 'Yb]''-mewt, u huwa mistenni li Obiltoxaximab G: @gY'U XYa 'V'-istess mod fuq il-dYf]g] b]'' : EXU_']' _cb YfbU'g-sigurt] -YZZYH]gY_cbXUf]'HUD Obiltoxaximab SFL Z]Yf]g] b]V]U]h'ca '\i a U'bcfa U'a Ybh' Z]YZ'Yk 'a cXYfUH]''; U'XUeghU'bh''- 5 Ybn]U'XXY]X]Yh]''-VYbYZ] 'g' HUDCV]hcl UI ja UV'G: @\i a U'U_VUf'a]f-f]g_'h]Y[i 'i '']'ghUd]] U'k hcf]nnUh[U''-i i 'Z-UE.

CV]hcl UI ja UV'G: @_Y]b'Uk hcf]nnUh]U' h]]f_cghUbn]HUDY 'Ynn'cb]j''8Ub'a]b UVVU'']a U'_Ybl 'dcgg]V]']h]b_]gYV]bZcfa Unn'cb]_ca d'i HU'Xk Uf'CV]hcl UI ja UV'G: @a]b UVVU'f-rarity] -a UfXU'i 'a]b UVVU' fU i b]YhYh]]''?i ''gYbUz''-5 Ybn]U'gY'fU'h]ff]Y Ua]bU'_i '']bZcfa Unn'cb] X]XU'']gg]f'X]gdcb]V]'i din il- UfgU' YbYfU]'h]]U' cfbUH]]Za Y h]Y ''

@]Ya U']bZcfa Unn'cb]] U'X\U'a]ghYbb]U' [U'CV]hcl UI ja UV'G: @3

A]b UVVU'' CV]hcl UI ja UV'G: @]Y'Uk hcf]nnUh]U' h]]f_cghUbn]HUDY 'Ynn'cb]z]''-_i a dUb]U'']he]Y[YX' Obiltoxaximab SFL fis-suq se tipprovdi aktar data Xk Uf'a YhcX]V]YI 'h_Y''Y''_Z]'-a YX]]bU'h]] UggcV]HUz'a cX]Z_Uh]i 'h]bY U'a]'-]gYa 'Z]gh' X'g'Z]-UVcfUhc'f]' '6UffU'a]bb'\Y__z'] UbX\U'h]] ddfY YbhUH]X'-data dwar I-YZZ_U 'U' i 'g-sigurt] -a YX]]bU'a U'h]]h]ze[] U'dchYbn'U']HU'-UbfU e.

L]] i f]eY[X]b'g]h]Y Xi 'V]YI 'g]] [i fU'h''-i i 'g] [i f'i 'YZZYH]j 'HUD CV]hcl UI ja UV'G: @3

Fis-gca a Uf'g' HU'-_UfU'h]f]g]h]]HU'-prodott u fil-Z' 'Yh'HUDHU['f]Z' Yk]b'_i]f-fU__ca UbXUnn'cb]Y]h'i ''- dYf]_Uk n'cb]Y]h]] [UbX\ca]i bi 'gY[k]h]a]'-profess'cb]gh]Z]-qasam tal-kura tas-gU U'i 'a]'- dUn'Ybh]] U''-i i 'g] [i f'i 'YZZYH]j 'HUDCV]hcl UI ja UV'G: @'

6 U'Z]-_U 'HU'-a YX]]b]_c''\Uz]X'-data dwar I-i i 'HUf]CV]hcl UI ja UV'G: @\]U'ggcf] Y'UH' kontinwament. L-YZZYH]gY_cbXUf]'ffUddi fHUh]VDCV]hcl UI ja Ub SFL huma evalwati bir-reqqa u kull Unn'cb]a Y h]Y U'\]a Y i XU'V]YI 'h]ddfchY]''-dUn'Ybh]''

Obiltoximab SFL (obiltoximab) f'U'Xk Uf'CV]'hcl UI]a UV'G: @

5_huf']bZcfa Unn'cb]'Xk Uf'CV]'hcl UI]a UV'G: @h]bghUV'Z]g-sit web tal-5 Ybn]'U. '
ema.europa.eu/medicines/human/EPAR/Obiltoximab-SFL

Prodott mediċinali li m.g, adux awtorizzat