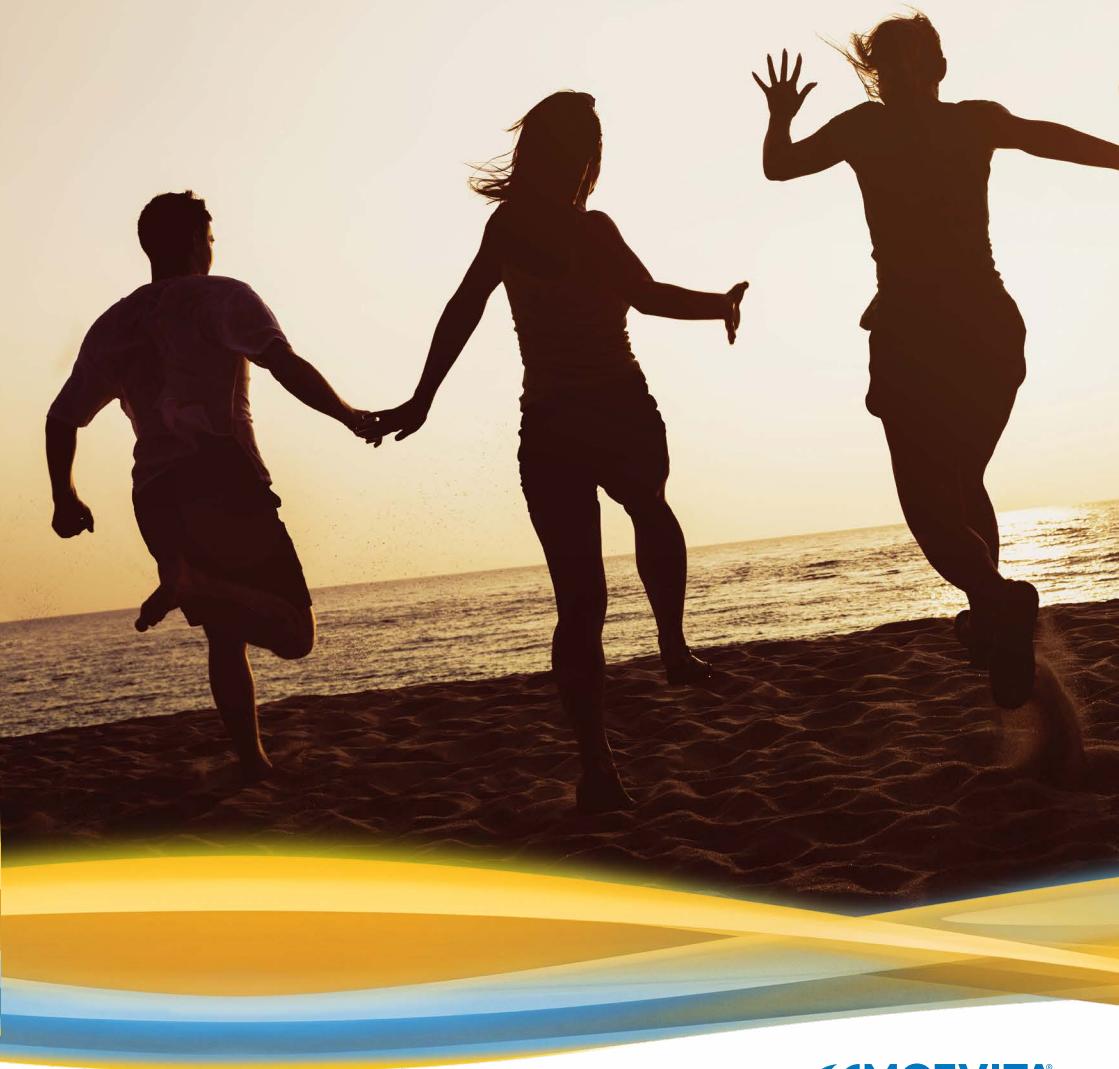




O mea e tatau ona e iloa e uiga i le AMGEVITA®



Tagai i le amgevita.co.nz e maua
ai vaega mo se fesoasoani



O lenei tamaitusi e mo tagata ua uma ona tusi mai a latou talavai o le AMGEVITA® (adalimumab) e le latou foma'i. O lenei tamaitusi e tatau ona faitau faatasī ma le AMGEVITA Consumer Medicine Information o loo maua mai lau foma'i talavai poo le tagai i le www.medsafe.govt.nz

Afai e iai ni au fesili talanoa i le vaega o loo tausia lou soifua maloloina.

**Mo nisi faamatalaga i le AMGEVITA pe ina ia lipotia se
mea tugā ua tupu poo se faaseā tau oloa, faafesootai le
Amgen Medical Information i le **0800 443 885** pe
imeli: medinfo.JAPAC@amgen.com**

O lenei tamaitusi na saunia e le Amgen New Zealand mo na o faamatalaga lautele. E leai se mea o iai e tatau ona faauigaina o le tuuina atu o fautuaga poo le faia o se fautuaga ma e lē tatau ona faalagolago i ai e fai ma faavae mo soo se faaiuga poo se gaioiga. E tāua tele le faalagolago o tagata mama'i i fautuaga e tuuina mai e foma'i soifua maloloina.

O le ā le AMGEVITA ma e faapefea ona aogā?^{1,2}

O le AMGEVITA o loo iai le adalimumab - o se vailaau faaola (biologic medicine) e galue i le vaega e puipuia faalenatura le tino mai faama'i ina ia faaitiitia ai le fula ma faaaogā e togafitia ai tulaga faama'ia.

O le AMGEVITA o se vailaau biosimilar, o lona uiga e telē le tutusa atu i le uluai vailaau adalimumab. Ua iloiloina le saogalemu ma le aogā o le AMGEVITA e pei o le uluai vailaau adalimumab i le togafitia o nisi tulaga afaina.

Aisea ua ou faaaogāina ai le AMGEVITA?¹

O le AMGEVITA o loo faaaogāina e togafitia ai tulaga faama'ia nei. Ua faatonuina e lau foma'i le AMGEVITA e fesoasoani e pulea se tasi o tulaga nei:

- Rheumatoid arthritis (RA)
- Polyarticular juvenile idiopathic arthritis (polyarticular JIA)
- Enthesitis-related arthritis (ERA)
- Psoriasis (S)
- Psoriatic arthritis (PsA)
- Ankylosing spondylitis (AS)
- Non-radiographic axial spondyloarthritis (nr-axSpA)
- Crohn's disease
- Ulcerative colitis
- Hidradenitis suppurativa (HS)
- Uveitis

Fesili i lau foma'i pe iai ni au fesili pe aisea ua faatonuina ai lenei vailaau mo oe. Atonu na faatonuina e lau foma'i mo se isi mafuaaga.

Aisea ua ou faaaogāina ai le AMGEVITA?¹

Ta'u i lau foma'i poo le foma'i talavai pe afai e ilitata lou tino i isi vailaau, meaai, mea e faasao poo vali.

Ae e te lei amataina togafitiga e tatau ona e ta'u i lau foma'i pe afai:

- O iai nisi ou ma'i
- Faaaogā isi vailaau (e aofia ai vailaau e maua ae lei tusia mai e se foma'i)
- O loo e ma'itaga, poo e fuafua e te ma'itaga
- E iai se faama'i, e aofia ai se ma'i pipisi faaumiumi i se tasi vaega o le tino (mo se faataitaiga, se ma'i papala o vae)
- Ua iai pe sa iai se faaletonu o lou toto, fatu, pe lē lava le malosi e tetee atu i faama'i, ma'i tugā o le fatu, soo se ituaiga o kanesa, faafitauli o fatuga'o poo le ate, ma nisi lava faafitauli tau soifua maloloina sa iai muamua.
- E maua i se faama'i o neula o le tino, e pei o le multiple sclerosis
- O fuafua e fai ni ou tuipuipui poo sou ta'otoga
- Na maua muamua i le māmāpala pe na e fesootai vavalalata i se tasi e maua i le māmāpala
- O loo e maua i se faama'i faaumiumi e faafaigata ai lau mānava (COPD), o loo e feavea'ia le virusi o le hepatitis B (HBV) pe o loo e aafia tonu i le hepatitis B
- E ilitata lou tino i le pa'u poo le latex

E LĒ TATAU ONA E FAAAOGĀINA LE AMGEVITA pe afai e ilitata lou tino i le adalimumab poo isi mea o loo lisiina i totonu o le product, pe afai o tau faaletonu pe ua matuā faaletonu lou fatu, pe afai e te maua i soo se ituaiga ma'i pipisi ogaoga (pei o le sepsis, māmāpala, poo isi ma'i ogaoga pipisi e mafai ona mafua mai vairusi, lega, parasite poo siama).¹

O le Consumer Medicine Information (CMI), e maua mai lau foma'i talavai poo le www.medsafe.govt.nz, maua nisi faamatalaga auiliili e uiga i le AMGEVITA. Faamolemole faitau lelei faamatalaga, ma afai e iai ni au fesili poo ni atugaluga, talanoa i lau foma'i, tausi soifua poo le foma'i talavai.

Ae faapefea pe afai o loo o'u inuina isi vailaau?

E tāua tele le ta'u atu i lau foma'i poo lau foma'i talavai pe afai o loo e inuina nisi vailaau, e aofia ai soo se mea e te faatauina e aunoa ma se talavai mai lau fale talavai, supamaketi, naturopath poo le faleoloa o meaai mo le soifua maloloina.

O nisi vailaau e ono faalavelave i le AMGEVITA ma aafia ai le auala e aogā ai pe faateleina ai le faama'ia pe a faaaogā le AMGEVITA. Aua ne'i faaaogāina faatasi le AMGEVITA ma le anakinra (Kineret) poo le abatacept (Orencia).

E te mauaina se lisi atoa o nei vailaau i le CMI.

E faapefea ona ou faaaogāina le AMGEVITA?¹

E tui le AMGEVITA i lalo o le pa'u o le tino. E mafai ona tui e oe, poo se tagata o lou aiga, se tagata o vaiai pe tausia oe, e faaaogā ai le peni tui poo se tui ua mua'i faatumu o le SureClick® pe a uma ona maua a'oa'oga. Mo nisi faamatalaga ma faatonuga faasolosolo i le faaaogāina, tagai i faatonuga mo le faaaogāina i itulau o loo mulimuli mai, pe tagai i le amgevita.co.nz e matamata i ata vitio o faatonuga.

O le ā se isi mea e tatau ona ou faia a'o faaaogāina le AMGEVITA?¹

O le a tuuina atu e lau foma'i faatonuga i le fua sa'o mo lou faafitauli. E tāua lou faaaogāina o au vailaau e pei ona faatonuina e lau foma'i. Afai e misi ona fai lou tui, ia tui le AMGEVITA i le taimi lava e te manatua ai. Ona fai lea o le isi tui e pei ona tatau ona faia i le aso na mua'i faatulaga ai. Aua le taumafai e tau faaatoa uma tui ia na misi e ala i le fai o nisi tui ua sili atu ma le tasi. Afai ua latalata i le taimi o le isi tui o le a sosoo, faapasi loa le tusi lena ua misi, ae fai le tui e sosoo ai e pei ona faatulaga ai. Afai e te lē o mautinoa poo le ā le mea e fai, fesili i lau foma'i poo le foma'i talavai.

E TATAU ona:

- Aua ne'i taofia lou faaaogāina o le AMGEVITA e aunoa ma lou siaki i lau foma'i.
- Toaga i au appointments ma lau foma'i ina ia mafai ona siaki lou aga'iga'i i luma.
- Siaki muamua i lau foma'i a o lei faia ni tuipupui poo ni ta'otoga (pe a talafeagai) o oe poo sau tama.
- Ta'u i le vaega o loo tausia lou soifua maloloina o loo e faaaogāina le AMGEVITA pe afai o le a amata ona e faaaogāina se isi vailaau fou.

E LĒ TATAU ona:

Suia le malosi o lou tui pe taofi lou togafitiga se'i vaganā ua ta'u atu e lau foma'i.

E tatau faapefea ona ou teuina le AMGEVITA?¹

E tatau ona teu le AMGEVITA i totonus o se pusa'aisa i le 2°C i le 8°C ma e lē tatau ona faafulisa. Teu lelei i totonus o le pusa ia puipuia mai le malamalama ma ia tuu i se nofoaga e lē mafai ona oo i ai tamaiti.

Pe a manaomia (mo se faataitaiga pe afaia o loo e faimalaga), e mafai ona teu le AMGEVITA i se potu o lona mafanafana (i lalo ifo o le 25°C) e puipuia ai mai le malamalama mo se umi e 14 aso. A mae'a le 14 aso e tatau ona lafoa'i e tusa lava pe na toe faafoi i le pusa'aisa.

O ā ni aafiaga e ono alia'e mulimuli ane?¹

I le taimi o togafitiga i le AMGEVITA o lou lamatiaga e mafai alia'e nisi o aafiaga mulimuli ane, e aofia ai ni faama'i pipisi. E tāua lou malamalama i nei aafiaga ma mafai ona mata'ituina.

O vailaau uma e mafai ona iai ni aafiaga e lē manaomia e alia'e mulimuli ane. O nisi taimi o ni aafiaga e ogaoga, ae o le tele o taimi e lē o lena le tulaga e iai. O nisi aafiaga e alia'e mulimuli ane o loo mātauina i le AMGEVITA atonu e leai ni āuga ma atonu e faato'a iloa lava pe a ave le toto e su'e.

O nisi o aafiaga e manaomia vave togafitiga faafoma'i, e aofia ai:¹

- **Faailoga o se mea e ilitata ai le tino.** – fufusi o le fatafata, faigata ona mānava, fulafula o foliga, laugutu ma le laulaufaiva, pata le tino, imageso
- **Faailoga o le faaletonu o le fatu** – lē lava le mānava pe a taumafai malosi e fai se mea pe taoto i lalo, poo le fulafula o vae
- **Faailoga o se ma'i pipisi** – fiva, leai se malosi, oso faapepē i le pa'u o le tino, faafitauli i ou nifo ma tainifo, poo le matuā tiga pe a alu lau fe'auvai.
- **Faafitauli i neula o le tino** – pepē pe ma'ini'ini le tino, suiga o le vaai po ua vaivai lou lima poo lou vae
- **Faailoga o le faaletonu o le toto** – fiva faifai pea, totoulia le tino, piliki gofie, pe sesega
- **Faailoga o le māmāpala** – e lē motu le tale, faasolo ina paee, faa'iva'ivā (lē lava le malosi), pe fiva
- **Faailoga o se ma'i pipisi o tisu vaivai** – se patupatu poo se faapepē poo se papala ua lē mafai ona pe

E lē o se lisi atoa lea o aafiaga e ono alia'e mulimuli ane e mafai ona tupu. Faamolemole faitau le AMGEVITA Consumer Medicine Information mo nisi faamatatalaga ma ta'u loa i lau foma'i pe a e lagona se mea e lē o masani ai a o togafitia oe i le AMGEVITA.

FAATONUGA MO LE FAAAOGĀINA: AMGEVITA SINGLE USE SURECLICK® PENI TUI UA MUAI FAATUMU¹³

Faamolemole tagai i le TAIALA I VAEGA a o e faagaso lo laasaga.

LAASAGA 1: SAUNIUNI

A Aveese se peni tui ua muai faatumu o le AMGEVITA SureClick mai le afifi.

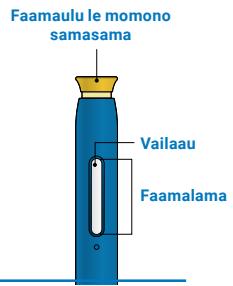
1. Sii sa'o i luga ma le faaeteete le peni tui ua muai faatumu o le SureClick mai le pusa.
 2. Toe tuu le uluai afifi ma soo se peni tui ua muai faatumu o le SureClick e lei faaaogāina i totonus o le pusa'aisa.
 3. Mo le puipuiga lelei o le tui, tuu le peni tui ua muai faatumu i totonus o se potu mafanafana mo le 15 i le 30 minute a o le'i faia le tui.
- ⦿ **Aua ne'i**
- ✗ toe tuu le peni tui ua muai faatumu o le SureClick i totonus o le pusa'aisa pe a oo ina maua lelei le mafanafana talafeagai o le potu.
 - ✗ taumafai e faamafanafana le peni tui ua muai faatumu o le SureClick e ala i le faaaogāina o se mea vevela e pei o se vai vevela poo le microwave.
 - ✗ tuu le peni ua muai faatumu i le susulu o le la.
 - ✗ lūlū le peni ua muai faatumu o le SureClick.
 - ✗ aveesea le momono samasama mai le peni ua muai faatumu o le SureClick.

B Asiasia le peni ua muai faatumu o le AMGEVITA SureClick.

Ia mautinoa o le vailaau o loo i totonus o le faamalama e manino ma leai se lanu seja oo ina iai sina samasama.

- ⦿ **Aua ne'i** faaaogāina le peni ua muai faatumu o le SureClick pe afafi:
- ✗ E nenefu po ua sui le lanu o le vailaau, poo iai ni mafugafuga poo ni mea ninii.
 - ✗ Soo se vaega e foliga mai ua ta'pe gau.
 - ✗ O le peni ua muai faatumu o le SureClick na pa'u i luga o se mea malō.
 - ✗ O loo misi le momono samasama pe lē o lelei ona faamau.
 - ✗ Ua pasi le aso e uma ai le aogā lena o loo lolomi i luga o le igoa.

I tulaga uma, valaau le Amgen Medical Information i le 0800 443 885. Afai e manao, o le a fiautuina oe e faafesoato'i le vaega o loo tauisia lou soifua maloloina ma faaaogā se peni tui fou ua muai faatumu.

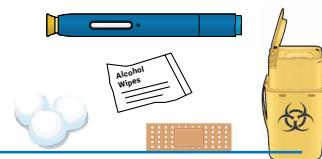


C Faaputupu uma mea e manaomia mo le faiga o lou tui.

Fufulu lelei ou lima i le fasimoli ma le vai.

I luga o se mafola mamā o loo malamalamala lelei e fai ai le galuega:

- Le peni tui fou ua muai faatumu o le fou SureClick
- Alcohol Wipes
- Polo vavae poo le fasikosi
- Fusī faapipi
- Container e lafoa'i i ai mea ma'ai



D Sauniuni ma faamamā le pito o lou tino lea o le a fai ai lou tui.

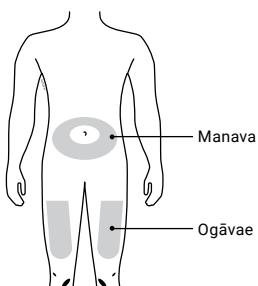
E mafai ona e faaaogā:

- Lou ogavae
- Vaega o le manava (abdomen), se'i vaganā le vaega e 5 cm (2 inisi) e faataamilio i lou pute

Faamamā le pito o lou tino lea o le a fai ai lou tui i se alcohol wipe.

Faamago lou pa'u.

- ⦿ Aua le toe lotaea le pito lenei a o lei faia lou tui. Filifili se isi pito i taimi uma e fai ai lou tui.
- Afai e te manao e faaaogā le pito lava lena e tasi e fai ai lou tui, ae ia faamautinoa e lē o le vaega tonu lava o le pito lea na fai ai le tui muamua.
- ⦿ Aua le tua pito na e galemulemu ai le pa'u, manu'a, mūmū, pe malō. Alofia le fai o le tui i vaega o loo iai ni ma'ilālla poo stretch marks.
- Afai o loo e aafia i le psoriasis, e tatau ona alofia le tui sa'o i luga, o ni vaega o le pa'u o loo ola e pei o se po'u, poo se faapepē, o loo mū, pa'upa'u'a.



LAASAGA 2: SAUNI LOA

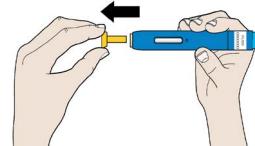
E

Toso sa'o ese le momono samasama pe a e sauni e tui.

O se mea masani le vaaia o le sisina ifo o se matāua o le vai i le pito o le nila poo le leoleo puipui samasama.

⦿ Aua ne'i

- ✗ mimiloa pe lolō'u i lalo le momono samasama.
- ✗ toe faamaulua le momono samasama i le peni tui ua muai faatumu o le SureClick.
- ✗ aveesea le momono samasama mai le peni ua mua'i faatumu o le SureClick seja e sauni e tui.

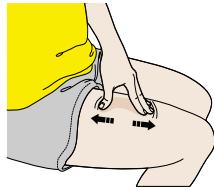


⦿ TĀUA: Tia'i le momono samasama i totonus o le container e lafoa'i i ai mea ma'ai.

F

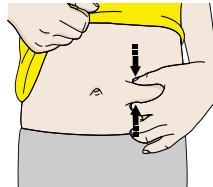
Falō pe 'iini le vaega o lou tino lea laa fai ai le tui ina ia malō se mafola e maua.

Metotia o le falō



Falō malosi le pa'u e ala i le faagaoia o lou limamatua ma tamatamailima i itu faafeagai, ma fai ai se vaega e tusa ma le 5 cm (2-inisi) le lautele.

POO le metotia o le 'lini



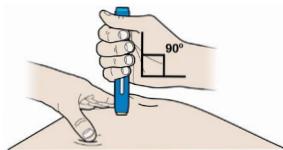
'lini mau le pa'u i le va o lou limamatua ma tamatamailima, e fai ai se vaega e tusa ma le 5 cm (2-inisi) le lautele.

⦿ TĀUA: Falō pea le pa'u pe 'iini pea le pa'u a o fai le tui.

LAASAGA 3: TUI

G

Taofi le falō pe 'iini. O lea ua tatala ese le momono samasama, tuu loa le peni tui ua muai faatumu o le SureClick i luga o lou pa'u i le 90 tikeri.



Ia mautinoa e te iloa atu le faamalama.

⦿ TĀUA: Aua ne'i pa'i i le faailo lanumoana amata.

H

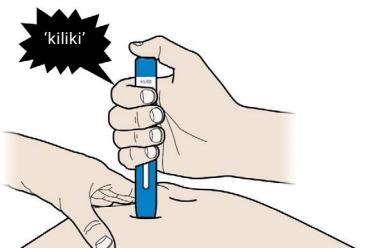
Oomi malosi le peni tui ua mua'i faatumu o le SureClick i lalo i luga o le pa'u seja i le toe gaoioi.



⦿ TĀUA: E tatala ona e oomi pea i lalo le pupui saogalemu samasama i lou pa'u e tatala ai le vaega e faagaoiai ae aua e te pa'i i le faailo lanumoana amata se'i e sauni e tui.

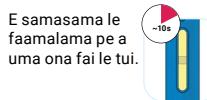
I

A e sauni loa e tui, oomi le faailo lanumoana amata.



J

Oomi pea i lalo i lou pa'u. E tusa ma le 10 sekone e fai ai lou tui.



E samasama le faamalama pe a uma ona fai le tui.

Mātau: A mae'a ona e aveese le peni ua mua'i faatumu mai lou pa'u, o le a otometi lava ona ufiufi le nila.



⦿ TĀUA: Pe a e aveese le peni ua mua'i faatumu o le SureClick, pe afai e lei liu samasama le faamalama, pe foliga mai o loo tui pea le vailaau, o lona uiga e te lei mauaina uma le fua o le tuiga atoa. Valaau vave le vaega o loo tausia lou soifua maloloina.

LAASAGA 4: FAAUMA

K

Lafoai le peni ua mua'i faatumu o le SureClick ma le nila pulou samasama.

- Tuu le peni tui ua mua'i faatumu o le SureClick ua uma ona faaaogā i totonu o se container e lafoa'i i ai mea ma'ai i le taimi lava e uma ai ona faaaogā. Aua ne'i tia'ia (lafoa'i) le peni tui ua mua'i faatumu i lapisi a le tou aiga.
- Talanoa i lau foma'i poo le foma'i talavai i le faiga sa'o e lafoa'i ai mea ua uma ona faaaogā.

Ⓐ Aua ne'i

- ✗ toe faaaogā le peni tui ua mua'i faatumu o le SureClick.
- ✗ toe faaaogā le peni tui ua mua'i faatumu o le SureClick poo le container e lafoa'i i ai mea ma'ai pe lafo i totonu o lapisi a le tou aiga.

Ⓑ TĀUA: Teu ese le container e lafoa'i i ai mea ma'ai ina ia lē faigofie ona maua e tamaiti.

Afai e leai sau container e lafoa'i i ai mea ma'ai, e mafai ona e faaaogāina se container a le tou aiga e:

- gaosi mai se uga mafafia
- mafai ona tapuni ma iai se tapuni e mau lelei pe a tapuni, o se tapuni e lē faigofie ona ta'e, e lē mafai ona toe to'ulu mai i fafo ni mea ma'ai e lafoa'i i ai
- tu sa'o ma mau lelei a o faaaogā
- lē sisina pe to'ulu mai ni mea i fafo ma o loo faamatala lelei mai i le label ina ia lapata'iia ai tagata i ni otaota matautia o loo i totonu o le container.



L

Iloilo lelei le pito o lou tino o le a fai ai le tui.

Afai e toto mai le vaega o lou tino lea e fai ai le tui, faaaogā se polo vavae poo se fasikosi e tootoo ai. **Aua** le ololina i se ie e solo ai le pito na fai ai le tui.

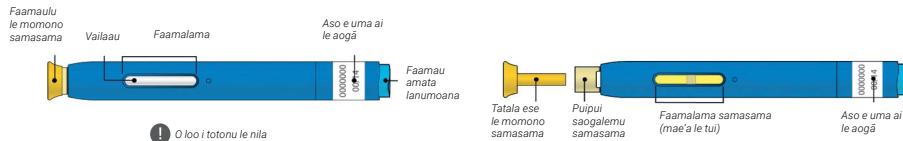
Faaaogā se fusi faapipii pe a manaomia.

Aafiaga e ono alia'e mulimuli ane i le pito e fai ai le tui¹

O aafiaga masani na lipotia le alia'e mulimuli ane e aofia ai aafiaga i le pito e fai ai le tui (mūmū, mageso, tiga pe fufula).

Faafesoota'i le vaega o loo tausia lou soifua maloloina poo le Amgen Medical Information i le 0800 443 885 pe a iai nisi o nei aafiaga e faapopoleina ai oe.

TAIALA I VAEGA



A o lei faaaogāina

A uma ona faaaogā

O faatonuga nei e patino i le Peni Tui ua Muai Faatumu o le SureClick. Afai na tusi mai mo oe e lau foma'i le Tui ua Muai Faatumu o le AMGEVITA, faamolemole toe iloilo le Faatonuga mo le Faaaogāina o loo i totonu o lau pusa o le talavai pe matamata i le vitio mo faatonuga i le amgevita.co.nz.



FAAMATALAGA FAAPITOA MO LE FAAAOGĀINA & TAULIMAINA ^{1,2}

- O le peni ua mua'i faatumu o le AMGEVITA SureClick ua fuafua e tasi lava le tuiga e fai ai mo le gasegase e toatasi.
- O le AMGEVITA SureClick ua fuafua e faaaogā i lalo o le ta'ita'iga ma le vaavaaiga a se foma'i. E mafai e tagata mama'i ona fai lava e latou o latou tui o le AMGEVITA pe a faia se a'o'aoga talafeagai i le auala e fai ai le tui.
- Mo le puipuiga lelei o le tui, tuu le peni ua mua'i faatumu i totonus o se potu mafanafana mo le 15 i le 30 minute a le'i faia le tui.
- Aua le soona lūlūina le peni ua mua'i faatumu o le AMGEVITA SureClick.
- Aua ne'i faaaogāina se peni ua mua'i faatumu o le AMGEVITA SureClick pe a pa'ū i lugu o se mea malo. Atonu e iai se vaega ua gau o le peni ua mua'i faatumu o le AMGEVITA SureClick e tusa lava pe e te lē o iloa atu.
- O le ufiufi o nila o le peni ua mua'i faatumu o le AMGEVITA SureClick e faia mai le pa'u faanatura mago, lea e iai le latex. Ta'u i le vaega e tausia lou soifua maloloina pe a ilitata lou tino i le latex.

LAPATAIGA FAAPITOA MO LE TEUINA ¹

- O le peni tui ua muai faatumu o le AMGEVITA SureClick e tatau ona tuu i le pusa'aisa i le malosi e 2°C i le 8°C. AUA LE TUUA I LE FULISA.
- Aua le faaaogāina pe afai na faa'aisa e tusa lava pe ua mataa le 'aisa.
- Teu i totonus o le pusa na mua'i aumai ai seia oo i le taimi o le faatonuga e puipuia ai mai le malamalamama.
- O le peni ua mua'i faatumu o le AMGEVITA SureClick e mafai ona teuina i se potu o le fua o le ea i totonus (e i lalo ifo o le 25°C) mo se vaitaimi e oo atu i le 14 aso, ma ia puipuia mai le malamalamama. O le peni ua mua'i faatumu o le AMGEVITA SureClick e tatau ona lafoa'i pe a lē faaaogāina i totonus o le 14 aso.
- Aua le faaaogāina le peni ua mua'i faatumu o le AMGEVITA SureClick pe a te'a le aso e uma ai le aogā.

E pei o vailaau uma, e mafai foi e lenei vailaau ona faapogai ai ni aafiaga e alia'e mulimuli ane, e ui lava e lē maua ai tagata uma. O le tele o aafiaga e alia'e mulimuli ane e amata lemu seia oo ina feololo. Peitai o nisi aafiaga atonu e ogoga ma manaomia ai se togafitiga. Afai e te maua i ni aafiaga mulimuli ane, talanoa i le vaega o loo tausia lou soifua maloloina poo se foma'i talavai i se taimi vave e mafai ai.¹

IMPORTANT INFORMATION ABOUT AMGEVITA: AMGEVITA® is a prescription medicine containing adalimumab. AMGEVITA is available as single use pre-filled syringe(s) (containing 20 mg or 40 mg adalimumab) or single-use pre-filled pens (containing 40 mg adalimumab). AMGEVITA is a biosimilar medicine comparable to Humira®.

What AMGEVITA is used for: AMGEVITA is used to reduce inflammation in patients with some inflammatory diseases, including rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa, and uveitis. **AMGEVITA has risks and benefits.** *Do not use AMGEVITA if you have:* an allergy to any medicines containing adalimumab or any of the other ingredients in AMGEVITA; a severe infection; tuberculosis (known as TB); moderate-severe heart failure; or if using a medicine containing abatacept (Orencia®) or anakinra. *Before you use AMGEVITA tell your doctor if you have:* a current infection or a history of infections that keep coming back (including TB, hepatitis B, fungal or any other infection); any conditions that increase the risk of infections; had close contact with someone with TB, or Hepatitis B virus (HBV) or are a carrier of HBV; conditions that affect protective nerve layers, such as multiple sclerosis; blood disorders; low resistance to infections or diseases; any serious heart conditions or cancers; disorders that occur when the immune system attacks and destroys healthy cells, tissues, or organs by mistake; lung diseases that make breathing difficult; inflammation of the middle layer of the eye (uveitis); kidney or liver problems; psoriasis (a type of skin disease) and have undergone phototherapy; or if you have any allergies. Your risk of getting serious infections or certain kinds of cancer may increase if you take AMGEVITA. In rare cases, these infections may be life-threatening. Tell your doctor if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to. *Tell your doctor immediately or go to your nearest hospital if you develop symptoms:* of an allergic reaction, such as chest tightness, shortness of breath or difficulty breathing, swelling of the face, lips or tongue, or a rash; heart problems, such as shortness of breath with exertion or lying down, swollen feet; or signs of blood disorders, such as a persistent fever, bruising, bleeding easily, paleness. Tell your doctor straight away if: symptoms of TB or any other infection appear during treatment (such as fever, persistent cough, weight loss, listlessness or lack of energy, skin sores, problems with your teeth and gums, burning when you pass urine, etc); you develop cancer, skin lesions (new skin spots or sores), or if existing lesions change appearance; nervous system disorders (such as numbness, or tingling, arm or leg weakness, double vision). Tell your doctor straight away if you become pregnant while using AMGEVITA. If you use AMGEVITA during pregnancy, your baby may have a higher risk of getting an infection. It is important that you tell your baby's doctors and other healthcare professionals about your AMGEVITA use during your pregnancy before the baby receives any vaccine. *Tell your doctor and other healthcare professionals:* if you are taking any other medicines, including any that you get without a prescription; if you are going to have surgery, or if you are scheduled for any vaccines. Patients taking AMGEVITA should not receive live vaccines. Tell all doctors, dentists, and pharmacists who are treating you that you are using AMGEVITA. **Common Side Effects:** Tell your doctor if you experience any side effects that make you feel unwell. The most common side effects of this medicine are injection site reactions (e.g. pain, swelling, redness); respiratory tract infections; ear or eye pain, inflammation of the eye or eye lid; mouth ulcers, pain or bleeding from the gums; burning or pain when passing urine or blood in the urine; skin bumps or sores that don't heal; headache or migraine, dizziness; muscle weakness or numbness; tummy pain, nausea, vomiting, reflux or heartburn; chest pain; rash, itching; finger or toe nail problems; hair loss; tiredness; muscle, joint or bone pain; bleeding or bruising more easily; depression or anxiety; increased heart rate; and infections caused by viruses, bacteria or fungi. Your doctor might also tell you about abnormal laboratory test results, such as reduced blood cell counts for example. **Ask your doctor if AMGEVITA is right for you. Use strictly as directed. Please read the safety information in the AMGEVITA Consumer Medicines Information (CMI), available at www.medsafe.govt.nz/Consumers/cmi/a/amgevita.pdf or telephone 0800 443 885 (free call).** If you have any questions about using AMGEVITA, or if symptoms continue, or you have side effects, speak to your healthcare professional.

From 1 March 2022, AMGEVITA is fully funded for most of the above conditions (under Special Authority) except for enthesitis-related arthritis and non-radiographic axial spondyloarthritis. Normal pharmacy prescription and doctor's charges will apply. Amgen (New Zealand) Limited, Auckland, New Zealand. Telephone: 0800 443 885. E-mail medinfo.JAPAC@amgen.com. V1. TAPS Approval No: MR797

References: 1. AMGEVITA® Consumer Medicine Information available at www.medsafe.govt.nz.
2. AMGEVITA® Approved Data Sheet. 3. AMGEVITA® SureClick Instructions for use 9 April 2021. Available at: https://www.amgevita.co.nz/-/media/Themes/Amgen/Amgevita-nz/Amgevita-nz/pdf/amgevita_nz_%20pf_pen_ifu (Accessed November 2022).

© 2023 Amgen. All rights reserved.

Amgen (New Zealand) Limited, Level 22, PwC Tower, 15 Customs Street West, Auckland 1010.

Telephone: 0800 443 885 | Email: medinfo.JAPAC@amgen.com

NZL-501-0923-80008. TAPS MR9745. Date of preparation: October 2023. AMG11695 Samoan.

