

JANSSEN PHARMACEUTICA (Pty) Ltd.

**STELARA® 45 mg/ 90 mg (Solution for subcutaneous injection: 43/30.1/0727 – 0728); and
STELARA® 130 mg (Solution for intravenous infusion after dilution) – line extension - 510851
Clean final Patient Information Leaflet (PIL)**

Submission date: 21 June 2018; **Reference:** RA/2018/06/098cp

Submission Type: Compliant response to CCC 10 May 2018 [ACC E/O_01 2018]

1

2

Clean final combined Patient Information Leaflet (PIL)

3

4

SCHEDULING STATUS

5

Schedule 4

6

7

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

8



STELARA® 45 mg and 90 mg (Solution for subcutaneous injection)

9

STELARA® 130 mg (Solution for intravenous infusion after dilution)

10

Ustekinumab

11

12

Read all of this leaflet carefully before you start using STELARA

13

- Keep this leaflet. You may need to read it again.

14

- If you have further questions, please ask your doctor or your pharmacist.

15

- STELARA has been prescribed for you personally and you should not share

16

your medicine with other people. It may harm them, even if their symptoms are

17

the same as yours.

18

19

1. WHAT STELARA CONTAINS

20

The active substance is ustekinumab. STELARA is available in three strengths:

21

45 mg ustekinumab in 0,5 mL of solution for subcutaneous injection;

22

90 mg ustekinumab in 1,0 mL of solution for subcutaneous injection; or

23

130 mg ustekinumab in 26 mL of solution for intravenous infusion.

24

25

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26 List of excipients:

27 45 mg or 90 mg Pre-filled syringe/vial

28 The other ingredients are: L-histidine, L-histidine monohydrochloride monohydrate,
29 polysorbate 80, sucrose and water for injection.

30

31 130 mg Single-use vial

32 The other ingredients are: EDTA disodium salt dihydrate, L-histidine, L-histidine
33 hydrochloride monohydrate, L-methionine, polysorbate 80, sucrose and water for
34 injection.

35

36 Contains sugar (sucrose).

37 STELARA 45 mg subcutaneous dose contains 38 mg of sucrose.

38 STELARA 90 mg subcutaneous dose contains 76 mg of sucrose.

39 STELARA 130 mg intravenous loading dose contains 2 210 mg sucrose per vial.

40

41 The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of
42 latex) which may cause allergic reactions in individuals sensitive to latex.

43

44 **2. WHAT STELARA IS USED FOR**

45 **• Plaque psoriasis - adults**

46 STELARA is intended for the treatment of moderate to severe plaque psoriasis in
47 adults. Plaque psoriasis is an inflammatory disease of the skin and nails.

48

49 **• Psoriatic arthritis – adults**

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50 Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by
51 psoriasis. If you have active psoriatic arthritis you will first be given other
52 medicines. If you don't respond well enough to these medicines, you may be
53 given STELARA.

54

55 • **Adults with moderately to severely active Crohn's disease**

56 Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's
57 disease you will first be given other medicines. If you do not respond well enough
58 or are intolerant to these medicines, you may be given STELARA to reduce the
59 signs and symptoms of your disease.

60

61 **3. BEFORE YOU USE STELARA**

62 **Do not use STELARA**

- 63 • if you are hypersensitive (allergic) to ustekinumab or any of the other ingredients
64 of STELARA.
- 65 • if you have tuberculosis (TB).

66

67 **Take special care with STELARA:**

68 Tell your doctor about all of your medical conditions before each treatment, including if you:

- 69 • **Ever had an allergic reaction to STELARA.** Ask your doctor if you are not
70 sure.
- 71 • **Have any kind of infection** even if it is very minor, or have any signs of an
72 infection. This could include fever, tiredness, cough, flu-like symptoms,
73 diarrhoea, dental problems and burning on urination. Also, tell your doctor if you
74 have any open cuts or sores, have an infection that won't go away or a history of
75 an infection that keeps coming back. This is important because STELARA may

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76 lower your ability to fight infections. Some infections could become serious and
77 lead to hospitalisation;

78 • **Have or have had any type of cancer.** Medicines such as STELARA that
79 decrease the activity of the immune system, may increase the risk of cancer.

80 • **Have any new or changing lesions** within psoriasis areas or on normal skin.

81 • **Have recently received or are scheduled to receive a vaccine.** Tell your doctor
82 if anyone in your house needs a vaccine. The viruses in some vaccines can spread ▼
83 to people with a weakened immune system, and can cause serious problems.

84 • **Are having or have ever had injections to treat allergies** – it is not known if
85 STELARA may affect these.

86 • **If you are having any other treatment therapies** – such as immunosuppressive
87 medicine (a medicine that inhibits the actions of your immune system) or
88 phototherapy (when your body is treated with specific Ultra Violet light) while using
89 STELARA. STELARA has an effect on your immune system and the combination
90 of these therapies may increase the risk of diseases related to a weakened
91 immune system. However, the combination of these therapies has not been
92 investigated.

93 • **Have an allergy to latex.**

94

95 Your doctor will assess your health before treatment. Tell your doctor about all of your
96 medical conditions.

97

98 **Using STELARA with food and drink:**

99 STELARA can be used with or without food or drink.

100

101

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102 **Pregnancy and Breastfeeding**

103 The effects of STELARA in pregnant women are not known. If you are pregnant or
104 breastfeeding your baby, please consult your doctor, pharmacist or other healthcare
105 professional for advice before using STELARA.

106

107 **Driving and using machinery:**

108 It is not known if STELARA will affect the ability to drive or use machines.

109

110 **Important information about some of the ingredients of STELARA:**

111 If you have been told by your doctor that you have an intolerance to some sugars, contact
112 your doctor before using STELARA. STELARA contains sucrose which may have an
113 effect on the control of your blood sugar if you have diabetes mellitus.

114

115 **Using other medicines with STELARA:**

116 Always tell your healthcare professional if you are taking any other medicine. (This
117 includes complementary or traditional medicines).

118

119 **4. HOW TO USE STELARA**

120 Do not share medicines prescribed for you with any other person.

121 Always use STELARA exactly as your doctor has told you. You should check with your
122 doctor if you are unsure.

123

124 Your doctor will tell you how long treatment with STELARA will last. Do not stop
125 treatment early because your symptoms may return. If you have the impression that the
126 effect of STELARA is too strong or too weak for you, tell your doctor or pharmacist.

127

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- 128 • For the treatment of psoriasis and psoriatic arthritis, STELARA is given by injection
129 under the skin.
- 130 • For the treatment of Crohn’s disease, the first dose of STELARA is given by
131 intravenous infusion, which means that the medicine will be given to you through a
132 needle placed in a vein. This dose is given by your healthcare provider. After
133 that, STELARA is given by injection under the skin.
- 134 • STELARA is intended for use under the guidance and supervision of your doctor.
135 If your doctor determines that it is appropriate, you may be able to administer
136 STELARA to yourself, after proper training in injection technique using the right
137 type of syringe and the amount (volume) to be injected (see the “Instructions for
138 injecting STELARA under the skin yourself”).
- 139 • Your doctor will determine the right dose of STELARA for you, the amount for
140 each injection and how often you should receive it. Make sure to discuss with your
141 doctor when you will receive injections and to come in for all your scheduled
142 follow-up appointments.

143

144 **If you use more STELARA than you should:**

145 If you have used more STELARA than you should (either by injecting too much on a
146 single occasion, or by using it too frequently), contact your doctor or pharmacist
147 immediately. Always have the outer carton of the medicine with you, even if it is empty.

148

149 **If you forget to use STELARA:**

150 Please contact your doctor or pharmacist. Do not take a double dose to make up for a
151 forgotten dose.

152

153

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154 **Effects when treatment with STELARA is stopped:**

155 It is not dangerous to stop using STELARA. However, the symptoms for which STELARA
156 was prescribed may return.

157

158 **5. POSSIBLE SIDE EFFECTS**

159 STELARA can have side effects.

160 Not all side effects reported for STELARA are included in this leaflet. Should your general
161 health worsen or if you experience any untoward effects while receiving STELARA,
162 please consult your doctor, pharmacist or other healthcare professional for advice.

163

164 If you experience any of the following side effects, tell your doctor immediately or go to
165 the casualty department at your nearest hospital:

166 • ***Infections (including tuberculosis)*** - signs of infection include: fever,
167 tiredness, (persistent) cough, shortness of breath, flu-like symptoms, night
168 sweats, diarrhoea, wounds, dental problems and burning on urination

169 • ***Allergic reaction*** - signs of serious allergic reactions include: skin rash; hives;
170 swelling of the face, lips, mouth or throat which may cause difficulty in swallowing
171 or breathing; low blood pressure, which can cause dizziness or light-headedness;
172 swelling of the hands, feet or ankles.

173 If you have a serious allergic reaction, your doctor may decide that you should not
174 use STELARA again.

175

176 These are all serious side effects. You may need urgent medical attention.

177

178 Other side effects that have been observed with STELARA are included below. Tell your
179 doctor if you experience any of these side effects.

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180

181 Frequently reported side effects:

- 182 • Diarrhoea
- 183 • Tiredness
- 184 • Dizziness
- 185 • Headache
- 186 • Itching
- 187 • Back or muscle pain
- 188 • Sore throat
- 189 • Redness and pain where the injection is given
- 190 • Nausea
- 191 • Joint pain
- 192 • Vomiting.

193

194 Less frequently reported side effects:

- 195 • Depression
- 196 • Blocked or stuffy nose
- 197 • Inflammation of tissue under the skin ('cellulitis'), showing as warmth, swelling, redness,
198 and pain of the skin
- 199 • Pain, swelling, itching, hardness, bleeding, bruising and irritation at the injection site
- 200 • Shingles (a type of painful rash with blisters)
- 201 • Pustular psoriasis (a change in psoriasis where redness and new tiny, yellow or
202 white skin blisters, sometimes accompanied by fever)
- 203 • An increase in redness and shedding of skin over a larger area of the body, which
204 may be itchy or painful (exfoliative dermatitis)

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- 205 • Peeling of the skin (skin exfoliation)
- 206 • Fungal infection (thrush) of the vulva and vagina
- 207 • Acne
- 208 • Loss of strength, weakness, or lack of energy (asthenia)
- 209 • Dental infections.

210

211 If you notice any side effects not mentioned in this leaflet, please inform your doctor or
212 pharmacist.

213

214 **6. STORING AND DISPOSING OF STELARA**

215 Store all medicines out of the reach of children.

216 Store in a refrigerator (2 °C – 8 °C). Do not freeze STELARA.

217

218 Do not use STELARA if you know, or think, that it may have been exposed to extreme
219 temperatures (such as accidentally frozen or heated).

220

221 Keep the product in the original outer carton in order to protect the solution from light.

222

223 Do not shake STELARA vials or pre-filled syringes. Prolonged vigorous shaking may
224 damage the product. Do not use the product if it has been shaken vigorously.

225

226 Do not use STELARA after the expiry date, which is stated on the label and the carton after
227 “EXP”. The expiry date refers to the last day of that month.

228

229 Do not use STELARA if the seal is broken.

230

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231 The solution is clear to slightly opalescent, colourless to light yellow and may contain a
232 few small translucent or white particles of protein. This appearance is not unusual for
233 solutions containing protein. Do not use STELARA if the liquid is discoloured, cloudy or
234 you can see other foreign particles floating in it.

235

236 Do not mix STELARA with other liquids for injection.

237

238 Any unused product remaining in the vial or syringe should not be restored and used
239 again.

240

241 Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains
242 or sewerage systems (e.g. toilets).

243

244 Used syringes and needles should be placed in a puncture-resistant container, like a
245 sharps container. Dispose of your sharps container according to your local regulations.

246 Empty vials, antiseptic wipes and other supplies can be disposed in your garbage.

247

248 **7. PRESENTATION OF STELARA**

249 STELARA 45 mg and 90 mg prefilled syringe/single use vial for subcutaneous injection is
250 supplied as a carton pack containing:

251 - 1 single-use clear, colourless vial (*Type 1 glass*), closed with a grey butyl rubber
252 stopper with a colourless Flurotec® coating and an aluminium seal with a light
253 green flip-off cap.

254

Or

255 - 1 single-use, clear, colourless Type 1 glass syringe with a fixed 27G, half-inch
256 needle with grey rubber needle shield. The needle shield is manufactured

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257 using a dry natural rubber (*a derivative of latex*). The syringe is stoppered with
258 a grey butyl rubber stopper with a colourless Flurotec® coating. The syringe is
259 fitted with a passive safety guard.

260

261 **STELARA 130 mg single-use vial for intravenous infusion**

262 STELARA 130 mg vial is supplied as a sterile solution in a single-use (Type 1), clear
263 colourless glass vial. The vial is stoppered with a grey butyl rubber coated stopper;
264 crimped to form a tight seal between the vial and the stopper with a seal comprised of a
265 silver aluminium shell with an attached polypropylene light green flip-off button that
266 protects the site of injection. It is packaged as 1 single use vial, in an outer carton to
267 protect from light.

268

269 **8. IDENTIFICATION OF STELARA**

270 **STELARA 45 mg and 90 mg Pre-filled syringe/vial for subcutaneous injections**

271 The solution is clear to slightly opalescent, colourless to light yellow. The solution may
272 contain a few small translucent or white protein particles.

273

274 **STELARA 130 mg single –use vial for intravenous infusion**

275 The solution is clear, colourless to light yellow.

276

277 **9. REGISTRATION NUMBERS**

278 STELARA 45 mg and 90 mg: 43/30.1/0727-0728

279 STELARA 130 mg: 51/30.1/0851

280

281

282

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283 **10. NAME AND ADDRESS OF REGISTRATION HOLDER**



286 JANSSEN PHARMACEUTICA (PTY) LTD

287 (Reg. No. 1980/011122/07)

288 2 Medical Road, Halfway House, Midrand, 1685

289 Tel: +27 (11) 518 7000

290 RA-JACZA-MedInfo@its.jnj.com

291

292 **11. DATE OF PUBLICATION**

293 - Date of registration of STELARA 45 mg and 90 mg: 27 July 2012

294 - Date of registration of STELARA 130 mg: 9 December 2019

295 - Date of most recently revised Patient Information Leaflet as approved by Council:

296 9 December 2019.

297

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298

299 **FURTHER INFORMATION**

300 **INSTRUCTIONS FOR ADMINISTRATION**

301 At the start of your therapy, STELARA may be injected by medical or nursing staff.

302 However, your doctor may decide that you may inject STELARA yourself. In this case,

303 you will receive training on how to inject STELARA. Call your doctor if you have any

304 questions about giving yourself an injection.

305

306 STELARA is not to be mixed with other liquids for injection.

307

308 **INSTRUCTIONS FOR INJECTING STELARA FROM A VIAL:**

309 Do not shake STELARA vials. Prolonged vigorous shaking may damage the product. Do

310 not use the product if it has been shaken vigorously.

311

312 **1. Check vials and assemble materials:**

313 If your dose is 45 mg you will receive one 45 mg vial of STELARA. If your dose is 90 mg,

314 you will receive either one 90 mg vial of STELARA or two 45 mg vials of STELARA.

315 • Take a vial(s) out of the refrigerator. If you have received two 45 mg vials for a 90 mg

316 dose, you will need to give yourself two injections one right after the other.

317 • Check the vial(s), to make sure that it is the right product, has not passed its expiration

318 date.

319 • Make sure the vial is not damaged, and the liquid is clear to slightly opalescent and

320 colourless to slightly yellow. DO NOT use if it is frozen, discoloured, cloudy or contains

321 large particulates.

322 • Thoroughly wash your hands with soap and warm water.

323 • Assemble and lay out on a clean surface everything you need such as a syringe, needle

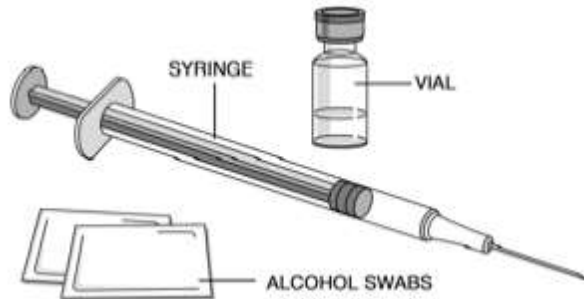
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324 and antiseptic swabs

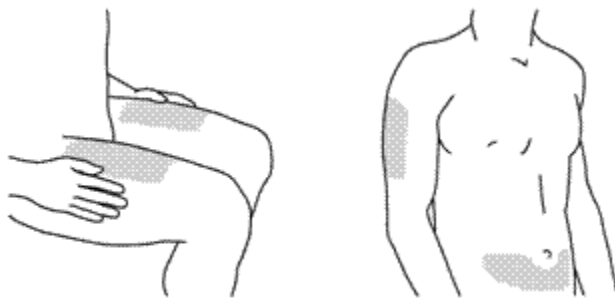


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326

327 **2. Choosing and preparing the injection site:**

- 328 • Choose an injection site. Good sites for the injection are the upper thigh or around the
329 belly (abdomen) at least 5 centimeters away from the navel. Avoid, if possible, areas of
330 skin that already show symptoms of psoriasis. If someone will assist in giving you the
331 injection, then he/she may also choose the upper arms or buttocks as injection site.



***Areas in gray are recommended injection sites.**

332

- 333 • Preparing injection site. Wipe the injection site with an alcohol swab. **DO NOT** touch
334 this area again before giving the injection.

335

336 **3. Preparing the dose:**

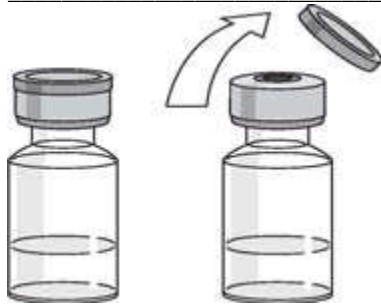
- 337 • Remove the cap from the top of the vial but do not remove the stopper.

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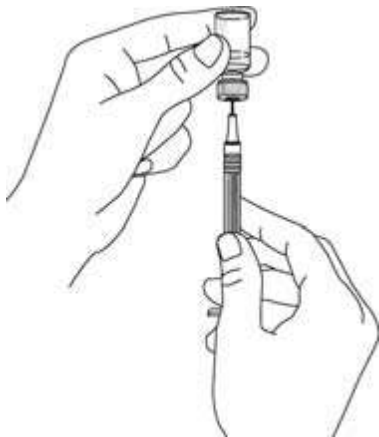
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338

- 339 • Clean the stopper with an antiseptic swab.
- 340 • Remove the needle cover. Do not touch the needle or allow the needle to touch
- 341 anything.
- 342 • Put the vial on a flat surface and push the syringe needle through the rubber stopper.
- 343 • Turn the vial and the syringe upside down. Pull on the syringe plunger to fill the syringe
- 344 with the amount of liquid prescribed by your doctor (0,5 mL - 1,0 mL). It is important that
- 345 the needle is always in the liquid in order to prevent air bubbles forming in the syringe.



346

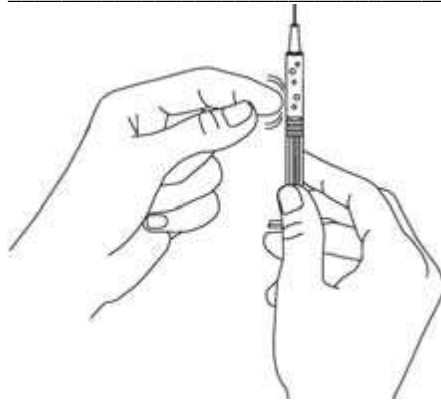
- 347 • Remove the needle from the vial. Hold the syringe with the needle pointing up to see if it
- 348 has any air bubbles inside. If there are air bubbles tap the side gently until the air
- 349 bubbles go to the top of the syringe and press the plunger until all of the air (but none of
- 350 the liquid) has been removed. Do not lay the syringe down or allow the needle to touch
- 351 anything.

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352

353

354 **4. Injecting the dose:**

355 • Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.

356 • Push the syringe needle into the pinched skin.

357 • Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it

358 slowly and evenly, keeping the skin gently pinched.



359

360

361 • When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

362 • Dispose of your used syringe in a safe container and dispose of your vial. See section

363 6, "Storing and Disposing of STELARA".

364

365 If your dose amount is 90 mg, and you received two 45 mg vials of STELARA then you

366 will need to give a second injection right after the first injection. Use a new needle and

367 syringe. Choose a different site for the second injection.

368

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369 **INSTRUCTIONS FOR INJECTING STELARA USING A PRE-FILLED SYRINGE**

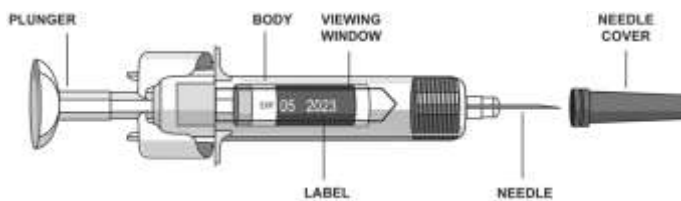
370 To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped
371 with a needle guard that is automatically activated to cover the needle after complete
372 delivery of the syringe content.

373 Do not shake STELARA at any time. Prolonged vigorous shaking may damage the
374 product. If the product has been shaken vigorously, don't use it.

375

376 **1. Preparing for pre-filled syringe use**

377



378

379

- 380 • Take the syringe out of the refrigerator
- 381 • Check the package to make sure that it is the right dose, either 45 mg or 90 mg as
382 prescribed by your doctor.
- 383 • Open the box and remove the pre-filled syringe. Check the expiration date on the
384 pre-filled syringe and the label of the box. If the expiration date has passed, don't
385 use it.
- 386 • Assemble the additional supplies you will need for your injection. These include an
387 antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe
388 disposal.
- 389 • Hold the pre-filled syringe with the covered needle pointing upward. Make sure
390 the syringe is not damaged. Look at the solution or liquid in the syringe to make
391 sure that it is clear to slightly opalescent and colourless to slightly yellow. **DO NOT**

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Clean final Patient Information Leaflet (PIL)**

Submission date: 21 June 2018; **Reference:** RA/2018/06/098cp

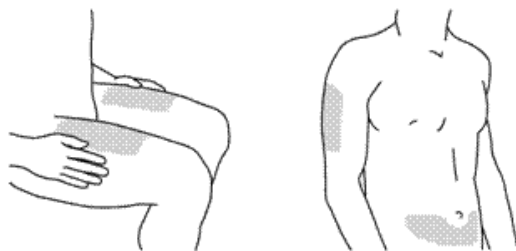
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392 use if it is frozen, discoloured, cloudy or contains large particles and contact your
393 healthcare provider for assistance.

- 394 • **DO NOT** remove the needle cover from the pre-filled syringe.
395 • **DO NOT** pull back on the plunger head at any time.

396

397 **2. Choosing and preparing the injection site***



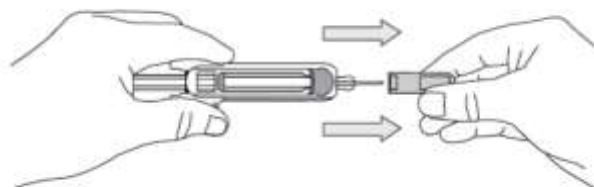
*Areas in gray are recommended injection sites.

398

- 399 • Good sites are the top of the thigh and around the tummy (abdomen) but about 2
400 inches away from the belly button (navel). Avoid, if possible, skin involved with
401 psoriasis. If your caregiver is giving you the injection, they may use the upper
402 arms as well.
- 403 • Thoroughly wash your hands with soap and warm water. Wipe the injection site
404 with an antiseptic wipe. **DO NOT** touch this area again before giving the injection.

405

406 **3. Injecting the medication**



407

- 408 • When you are ready to inject, pick up the pre-filled syringe, hold the body of the
409 syringe with one hand and pull the needle cover straight off. Throw the needle
410 cover into the trash. You may notice a small air bubble in the pre-filled syringe.

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411 You do not need to remove the air bubble. You may also see a drop of liquid at
412 the end of the needle – this is normal. Do not touch the needle or allow it to touch
413 any surface. **Note:** The needle cover should **NOT** be removed until you are ready
414 to inject the dose.

415 • Do not use syringe if it is dropped without the needle cover in place. If you drop
416 the syringe without the needle cover in place, please contact your healthcare
417 provider for assistance.

418 • Gently pinch the cleaned skin between your thumb and index finger. Don't
419 squeeze it.



420
421 • Push the syringe needle into the pinched skin.
422 • Push the plunger with your thumb as far as it will go to inject all of the liquid.
423 • Push it slowly and evenly, keeping the skin pinched.
424 • When the plunger meets the end of the syringe barrel, and all of the medication
425 has been injected, release the pinched skin and gently remove the needle.
426 Following complete injection, the needle guard will automatically extend over the
427 needle and lock as you take your hand off the plunger.



428

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430

431 **4. After the injection**

- 432 • Immediately dispose of the empty syringe into the sharps container. For your
433 safety and health and for the safety of others, needles and syringes must NEVER
434 be re-used. Dispose of sharps container according to your local regulations.



435

436 There may be a small amount of blood or liquid at the injection site, which is normal.
437 You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
438 Do not rub the injection site. You may cover the injection site with a small adhesive
439 bandage, if necessary.

440

441