

1
2
3 **Kineret[®]**
4 **(anakinra)**
5

6 **Information for Patients and Caregivers**
7

8
9 **This patient package insert contains information and directions for patients and their**
10 **caregivers on self-injection of Kineret[®]. This insert does not include all information about**
11 **Kineret[®]. You should discuss any questions about treatment with Kineret[®] with your**
12 **doctor.**
13

14 **What is Kineret[®] ?**
15

16 Kineret[™] is a medicine that is used to reduce the pain and swelling associated with moderate to
17 severe active rheumatoid arthritis.
18

19 **How does Kineret[®] work?**
20

21 Kineret[™] is a man-made protein that is similar to a naturally occurring protein called interleukin-
22 1 receptor antagonist (IL-1ra) found in the body. In people with rheumatoid arthritis (RA), the
23 body produces too much of certain proteins that lead to joint damage. One of these proteins is
24 called Interleukin-1 (IL-1). Too much IL-1 contributes to the pain, swelling, and stiffness
25 associated with RA. Kineret can block the action of IL-1.
26

27 Only you and your doctor can determine how well Kineret[™] is working for you. The time it
28 takes to see improvement in symptoms varies from person to person. In clinical studies, some
29 patients saw their arthritis symptoms improve in about 4 weeks after starting Kineret treatment.
30

31 **Who should not use Kineret[®] ?**
32

33 You should not use Kineret if you have an infection that requires treatment with prescription
34 antibiotics or an infection that is serious enough for you to be admitted to the hospital.
35

36 You should not use Kineret if you have an allergy to proteins made from bacteria cells (*E. coli*),
37 or any of the ingredients in Kineret[™].
38

39 You should not use Kineret if you are taking Enbrel (etanercept) or Remicade (infliximab) unless
40 your doctor has told you to. When Kineret is used with Enbrel or Remicade you may increase
41 your risk of getting a serious infection.
42
43
44
45
46

47 **What important information do I need to know about taking Kineretä ?**
48

49 Patients taking Kineret have a greater chance of developing a serious infection. If you have an
50 infection, tell your doctor **before** you start taking Kineret. If you get an infection that does not
51 go away while taking Kineret, tell your doctor right away.
52

53 If you have asthma you could be at increased risk for getting a serious infection.
54

55 If you are using Enbrel (etanercept) or Remicade (infliximab) under your doctor's orders, you
56 could also be at greater risk for getting a serious infection.
57

58 Kineret may cause the number of one type of white blood cell to decrease. You will need to
59 have blood tests before starting treatment with Kineret, then monthly for three months. After the
60 first three months you will be asked to have your blood checked every three months for up to one
61 year.
62

63 **What are other possible side effects of Kineretä ?**
64

65 Most people have a reaction at the site where Kineret is injected. These reactions include
66 redness, swelling, bruising, itching and/or stinging. Most of the time the reactions are mild and
67 last about 2-4 weeks (see section titled "**Helpful hints**" for how to manage some of these effects)
68

69 The Kineret™ needle cover contains latex. If you know you are allergic to latex, talk to your
70 doctor before using Kineret™.
71

72 If you experience any side effects that concern you, or if you develop an infection call your
73 doctor.
74

75 **Can I use Kineretä if I am pregnant or breast-feeding?**
76

77 Kineret™ has not been studied in pregnant women or nursing mothers. If you are pregnant or
78 breast feeding, talk to your doctor before using Kineret™.
79

80 **How should I store Kineretä ?**
81

82 Store Kineret™ in the refrigerator 36° to 46° F (2° to 8° C) until you are ready to prepare your
83 injection. Do not freeze. Do not use a syringe that has been left at room temperature for longer
84 than 24 hours.
85

86 If you are traveling, make sure you store Kineret™ at the correct temperature. For a
87 complimentary travel cooler, call toll free: 1-866-Kineret. If you have questions, consult with
88 your doctor or pharmacist.
89
90
91
92

93 **How do I use Kineretä ?**

94

95 Your doctor should have instructed you on how to inject Kineret™, how often it should be
96 injected, and the proper disposal method for used Kineret™ syringes.

97

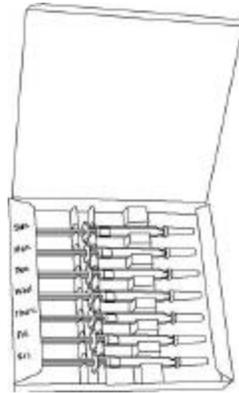
98 Kineret™ should be administered once every 24 hours. Try to inject Kineret™ at the same time
99 each day on a schedule that works best for you.

100

101

101
102
103
104
105
106

Each Kineret™ dose comes in a 1 mL prefilled glass syringe. There are 7 syringes in each box, one for each of the 7 days of the week. Use a new syringe each day. Use the Kineret™ prefilled syringe that matches the day of the week until all 7 are used.



107
108

Use each Kineret™ prefilled syringe only once, and be sure to inject all of the solution in the syringe. If you notice some solution remaining in the syringe, do not re-inject. You should discard the syringe with any remaining solution in the puncture proof container.

112

Dispose of the syringe as instructed under the **Disposal of syringe and supplies** section.

114

If you drop a syringe, **do not use the syringe**. This is for your safety in case the syringe is broken, or the needle is bent or dirty. Dispose of the syringe and replace it with a new one. Take the new syringe from what would be the last day of the week in your current box. For example, if you start on Wednesday, the last day of the week in your series is Tuesday. After using all the remaining syringes in your current box, start your next box.

119

What do I need to know to prepare and give a Kineretä injection?

121

122

Preparing for injection

123

1. Assemble the supplies needed for injection:

125

- alcohol wipe,
- dry gauze or cotton-ball,
- small adhesive bandage, (Tip: open adhesive bandage prior to injection).
- Kineret™ syringe, and
- a puncture-resistant container for disposing your used syringes.

126

127

128

129

130

131

132

2. Remove the prefilled syringe from the box that matches the day of the week. Place all of the remaining syringes back in the refrigerator.

133

134

135

3. Do not shake the prefilled syringe. If the solution is foamy, allow the prefilled syringe to sit for a few minutes until it clears.

136

137

138
139
140
141
142
143
144
145
146
147
148
149
150
151
152
153
154
155
156
157
158
159
160
161
162
163

4. Check the expiration date printed on the syringe label. If the syringe has expired, call your pharmacist for instructions.

5. Do not use Kineret™ if the contents of the prefilled syringe appear discolored or cloudy, or if there is anything floating in it. Call your doctor or pharmacist if you have any questions about the way the solution looks.

Selecting and preparing the injection site

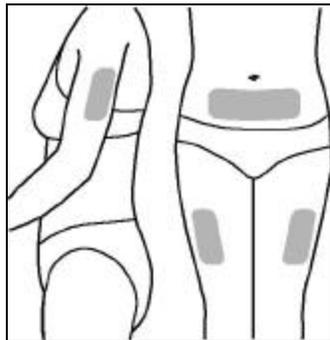
6. Wash your hands thoroughly with soap and warm water.

7. Choose an area of the body for the injection. Recommended injection sites include the following:

- Outer thighs
- Stomach

If someone is giving you an injection you can also use:

- Back of arms
- Buttocks

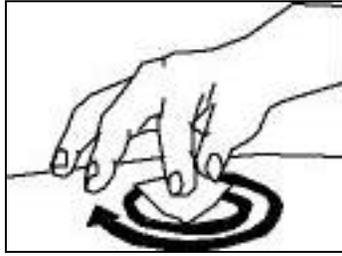


164
165
166
167
168
169
170
171
172

It is important to change the injection site each time you use Kineret™ to reduce the possibility of soreness or redness. While you do not have to change the area of the body for the injection each day, the new injection should be given at least 1 inch from the previous day's injection site. Do not to inject yourself close to a vein that you can see under the surface of your skin.

172
173
174

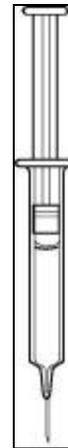
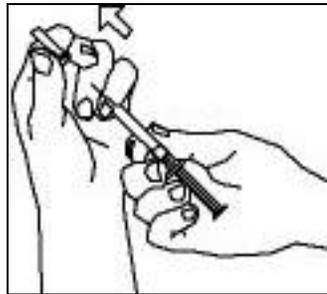
8. Clean the injection site with an alcohol wipe using a circular motion, starting from the middle and going out. Let the area dry completely.



175
176
177
178
179
180
181
182
183
184

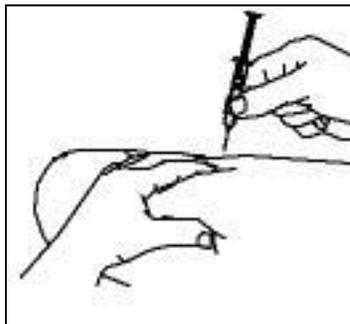
Administering the subcutaneous injection

9. Hold the syringe and pull the needle cover off. Twisting the needle cover while pulling will help in the removal. Do not touch the needle. You may notice a small air bubble in the prefilled syringe. You do not have to remove the air bubble before injecting. Injecting the solution with the air bubble is harmless.



185
186
187
188
189
190

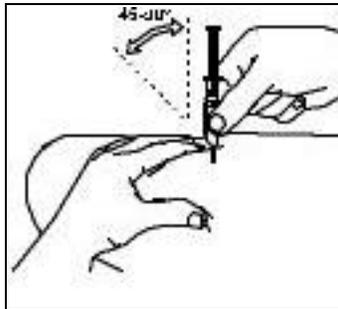
10. Hold the syringe in the hand you use to inject yourself. If possible, use your other hand to pinch a fold of skin at the clean injection site. Do not lay the syringe down or allow the needle to touch anything.



191
192

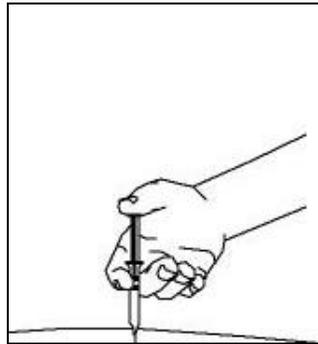
192
193
194
195

11. Hold the syringe firmly between your thumb and fingers so that you have steady control. Insert the needle into the skin with a quick, short motion at a 45 to 90 degree angle. The needle should be inserted at least half way.



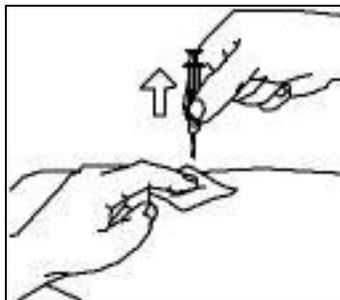
196
197
198
199
200

12. After the needle is inserted, you can gently let go of the skin. Be sure the needle remains in your skin. Slowly push the plunger down into the syringe until it stops.



201
202
203
204
205

13. Remove the needle and do not re-cap it. Press dry gauze over the injection site. (Do not use an alcohol wipe).



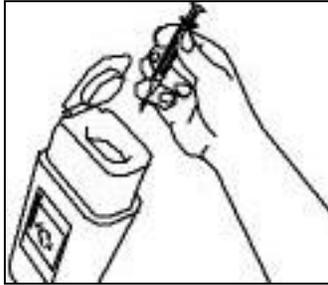
206
207
208
209

14. You may want to apply a small adhesive bandage over the injection site.

209
210
211
212
213
214
215
216

Disposal of the syringe and supplies

15. Place the entire used syringe in a puncture-resistant container. A coffee can with a plastic lid, a hard plastic container with a screw-on top may be used, or puncture resistant containers, like a Home Sharps Container, can be purchased at your local pharmacy.



217
218
219
220
221
222
223
224
225
226
227
228
229

Talk to your doctor, nurse, or pharmacist, about how to properly dispose a filled container of your used syringes. There may be special local and state laws for disposing used needles and syringes. **Do not throw the filled container in the household trash and do not recycle.**

The needle cover, alcohol wipes, and other used supplies can be thrown out with your regular trash.

Always keep all syringes, injection supplies, and disposal containers out of the reach of children.

229
230 **Helpful hints**
231

Problem	Solution
Swelling or bruising at injection site	Apply cold pack on injection site immediately after injection.
Itching at injection site	Talk to your doctor.
Pain during and/or after injection	<p>Try different injection locations. The stomach might be the best site due to the low number of nerve cells.</p> <p>Let the Kineret™ solution warm to room temperature prior to injection. This usually takes about 60-90 minutes at room temperature.</p> <p>Apply a cold pack on the injection site a few minutes prior to your injection.</p> <p>Allow the injection site to dry before injecting Kineret™; injecting through a site that is still moist from an alcohol wipe may cause stinging.</p> <p>Wiping the injection site with an alcohol wipe after you inject Kineret™ is not necessary and may cause stinging.</p>
Remembering to take medication	Try to inject Kineret™ at the same time each day. Schedule your Kineret™ injections with another task you do each day, such as getting dressed in the morning.
Difficulty with self-injection	Medical devices are available that are designed to help you with self-injections. Ask your doctor or nurse for more information about them, or call toll-free: 1-866-Kineret.

232
233
234 To build a good understanding about your therapy with Kineret™, call the Kineret Customer Call
235 Center weekdays from 8:00 a.m. to 11:00 p. m. EST. On weekends, you can leave a message
236 and someone will call you back shortly.

237
238 You can:

- 239
- 240 • Talk to a nurse about Kineret™ or issues related to self-injection
 - 241
 - 242 • Speak with a reimbursement counselor about your insurance coverage

243

244

245 Kineret Customer Call Center: Call toll-free at 1-866-Kineret (1-866-546-3738)

246

247 Amgen Inc.

248

249 One Amgen Center Drive

250

251 Thousand Oaks, CA 91320-1799

252

253 © 2001 Amgen Inc. All rights reserved.

254

255 Issue Date: XX/XX/XX