

849 **17.3 Medication Guide**

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MEDICATION GUIDE
SIMPONI[®] (SIM-po-nee)
(golimumab)

Read the Medication Guide that comes with SIMPONI before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment. It is important to remain under your doctor’s care while using SIMPONI.

What is the most important information I should know about SIMPONI?

SIMPONI is a medicine that affects your immune system. SIMPONI can lower the ability of your immune system to fight infections. Some people have serious infections while taking SIMPONI, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that spread throughout their body. Some people have died from these serious infections.

- Your doctor should test you for TB before starting SIMPONI.
- Your doctor should monitor you closely for signs and symptoms of TB during treatment with SIMPONI.

You should not start taking SIMPONI if you have any kind of infection unless your doctor says it is okay.

Before starting SIMPONI, tell your doctor if you:

- think you have an infection or have symptoms of an infection such as:
 - fever, sweat, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinate more often than normal
 - feel very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB
- live, have lived, or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may happen or become more severe if you use SIMPONI. Ask your doctor, if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B
- use the medicine Orencia (abatacept), Kineret (anakinra), or Rituxan (rituximab)

887
888 **After starting SIMPONI**, call your doctor right away if you have any symptoms of an
889 infection. SIMPONI can make you more likely to get infections or make worse any infection
890 that you have.

891
892 **Cancer**

- 893 • There have been cases of unusual cancers in children and teenage patients taking TNF-
894 blocking agents.
- 895 • For children and adults taking TNF-blocker medicines, including SIMPONI, the chances of
896 getting lymphoma or other cancers may increase.
- 897 • People with inflammatory diseases including rheumatoid arthritis, psoriatic arthritis, or
898 ankylosing spondylitis, especially those with very active disease, may be more likely to get
899 lymphoma.

900
901 **What is SIMPONI?**

902 SIMPONI is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker. SIMPONI is
903 used in adults:

- 904 • with the medicine methotrexate to treat moderately to severely active rheumatoid arthritis (RA)
- 905 • to treat active psoriatic arthritis (PsA) alone or with methotrexate
- 906 • to treat active ankylosing spondylitis (AS)

907 You may continue to use other medicines that help treat your condition while taking SIMPONI, such
908 as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by
909 your doctor.

910
911 **What should I tell my doctor before starting treatment with SIMPONI?**

912 SIMPONI may not be right for you. Before starting SIMPONI, tell your doctor about all your medical
913 conditions, including if you:

- 914 • have an infection (see “What is the most important information I should know about SIMPONI?”).
- 915 • have or have had lymphoma or any other type of cancer.
- 916 • have or had heart failure.
- 917 • have or have had a condition that affects your nervous system, such as multiple sclerosis.
- 918 • have recently received or are scheduled to receive a vaccine. People taking SIMPONI should not
919 receive live vaccines. People taking SIMPONI can receive non-live vaccines.
- 920 • are allergic to rubber or latex. The needle cover on the prefilled syringe and SmartJect autoinjector
921 contains dry natural rubber.
- 922 • are pregnant or planning to become pregnant. It is not known if SIMPONI will harm your unborn
923 baby.
- 924 • are breastfeeding. You and your doctor should decide if you will take SIMPONI or breastfeed.
925 You should not do both without talking to your doctor first.

926
927 **Tell your doctor about all the medicines you take**, including prescription and non-prescription
928 medicines, vitamins, and herbal supplements. Especially, tell your doctor if you use:

- 929 • ORENCIA (abatacept), KINERET (anakinra), or RITUXAN (rituximab). You should not take
930 SIMPONI while you are also taking ORENCIA or KINERET. Your doctor may not want to give
931 you SIMPONI if you have received RITUXAN recently.

- 932 • Another TNF-blocker medicine. You should not take SIMPONI while you are also taking
933 REMICADE (infliximab), HUMIRA (adalimumab), ENBREL (etanercept), or CIMZIA
934 (certolizumab pegol).
935 Ask your doctor if you are not sure if your medicine is one listed above.
936 Keep a list of all your medications with you to show your doctor and pharmacist each time you get a
937 new medicine.
938

939 **How should I use SIMPONI?**

- 940 • SIMPONI is given as an injection under the skin (subcutaneous injection or SC).
941 • SIMPONI should be injected one time each month.
942 • If your doctor decides that you or a caregiver may be able to give your injections of SIMPONI at
943 home, you should receive training on the right way to prepare and inject SIMPONI. Do not try to
944 inject SIMPONI yourself until you have been shown the right way to give the injections by your
945 doctor or nurse.
946 • Use SIMPONI exactly as prescribed by your doctor.
947 • SIMPONI comes in a prefilled syringe or SmartJect™ autoinjector. Your doctor will prescribe the
948 type that is best for you.
949 • See the detailed *Patient Instructions for Use* at the end of this Medication Guide for instructions
950 about the right way to prepare and give your SIMPONI injections at home.
951 • Do not miss any doses of SIMPONI. If you forget to use SIMPONI, inject your dose as soon as
952 you remember. Then, take your next dose at your regular scheduled time. In case you are not sure
953 when to inject SIMPONI, call your doctor or pharmacist.
954

955 **What are the possible side effects with SIMPONI?**

956 SIMPONI can cause serious side effects, including:

957
958 See “**What is the most important information I should know about SIMPONI?**”
959

960 **Serious Infections**

961

962 **Hepatitis B infection in people who carry the virus in their blood.**

- 963 • If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become
964 active while you use SIMPONI. Your doctor may do blood tests before you start treatment with
965 SIMPONI and while you are using SIMPONI. Tell your doctor if you have any of the following
966 symptoms of a possible hepatitis B infection:
- feel very tired
 - skin or eyes look yellow
 - little or no appetite
 - vomiting
 - muscle aches
 - dark urine
 - clay-colored bowel movements
 - fevers
 - chills
 - stomach discomfort
 - skin rash

967

968 **Heart failure, including new heart failure or worsening of heart failure that you already have.**

969 New or worse heart failure can happen in people who use TNF-blocker medicines like SIMPONI.

- 970 • If you have heart failure, your condition should be watched closely while you take SIMPONI.

- 971 • Call your doctor right away if you get new or worsening symptoms of heart failure while taking
972 SIMPONI (such as shortness of breath or swelling of your lower legs or feet).

973
974 **Nervous System Problems**

975 Rarely, people using TNF-blocker medicines, including SIMPONI, have nervous system problems
976 such as multiple sclerosis.

- 977 • Tell your doctor right away if you get any of these symptoms:
- 978 • vision changes
 - 979 • weakness in your arms or legs
 - 980 • numbness or tingling in any part of your body

981
982 **Liver Problems**

983 Liver problems can happen in people who use TNF-blocker medicines, including SIMPONI. These
984 problems can lead to liver failure and death. Call your doctor right away if you have any of these
985 symptoms:

- 986 • feel very tired
- 987 • skin or eyes look yellow
- 988 • poor appetite or vomiting
- 989 • pain on the right side of your stomach (abdomen)

990
991 **Blood Problems**

992 Low blood counts have been seen with other TNF-blockers. Your body may not make enough blood
993 cells that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding
994 easily, or looking pale. Your doctor will check your blood counts before and during treatment with
995 SIMPONI.

996
997 **Common side effects with SIMPONI include:**

- upper respiratory tract infection
- nausea
- abnormal liver tests
- redness at the site of injection
- high blood pressure
- bronchitis
- dizziness
- sinus infection (sinusitis)
- flu
- runny nose
- fever
- cold sores
- numbness or tingling

998
999 **Other side effects with SIMPONI include:**

- 1000 • **Immune System Problems.** Rarely, people using TNF-blocker medicines have developed
1001 symptoms that are like the symptoms of Lupus. Tell your doctor if you have any of these
1002 symptoms:
- 1003 • a rash on your cheeks or other parts of the body
 - 1004 • sensitivity to the sun
 - 1005 • new joint or muscle pains
 - 1006 • becoming very tired
 - 1007 • chest pain or shortness of breath
 - 1008 • swelling of the feet, ankles, and/or legs

1009
1010 • **Psoriasis.** Some people using SIMPONI had new psoriasis or worsening of psoriasis they already
1011 had. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus.
1012 Your doctor may decide to stop your treatment with SIMPONI.
1013
1014 • **Allergic Reactions.** Allergic reactions can happen in people who use TNF-blocker medicines.
1015 Call your doctor right away if you have any of these symptoms of an allergic reaction:
1016 • hives
1017 • swollen face
1018 • breathing trouble
1019 • chest pain
1020 These are not all of the side effects with SIMPONI. Tell your doctor about any side effect that bothers
1021 you or does not go away. Call your doctor for medical advice about side effects. You may report side
1022 effects to the FDA at 1-800-FDA-1088.
1023
1024 **How do I store SIMPONI?**
1025 • Refrigerate SIMPONI at 36°F to 46°F (2°C to 8°C).
1026 • Do not freeze SIMPONI.
1027 • Keep SIMPONI in the carton to protect it from light when not being used.
1028 • Do not shake SIMPONI.
1029
1030 **Keep SIMPONI and all medicines out of the reach of children.**
1031
1032 **General Information about SIMPONI**
1033 • Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide.
1034 Do not use SIMPONI for a condition for which it was not prescribed.
1035 • Do not give SIMPONI to other people, even if they have the same condition that you have. It may
1036 harm them.
1037 • This Medication Guide summarizes the most important information about SIMPONI. If you
1038 would like more information, talk to your doctor. You can ask your doctor or pharmacist for
1039 information about SIMPONI that is written for health professionals. For more information go to
1040 www.simpsoni.com or call 1-800-457-6399.
1041
1042 **What are the ingredients in SIMPONI?**
1043 Active ingredient: golimumab.
1044 Inactive ingredients: L-histidine, L-histidine monohydrochloride monohydrate, sorbitol, polysorbate
1045 80, and water for injection. SIMPONI does not contain preservatives.

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Patient Instructions for Use
SIMPONI® (SIM-po-nee)
(golimumab)
SmartJect™ autoinjector

1052 If your doctor decides that you or a caregiver may be able to give your injections of SIMPONI at
1053 home, you should receive training on the right way to prepare and inject SIMPONI. **Do not** try to
1054 inject SIMPONI yourself until you have been shown the right way to give the injections by your
1055 doctor or nurse.

1056
1057 It is important to read, understand, and follow these instructions so that you inject SIMPONI the right
1058 way. Call your doctor if you or your caregiver has any questions about the right way to inject
1059 SIMPONI.

1060
1061 Important information about your SmartJect autoinjector:

- 1062
- 1063 • When the button on the SmartJect autoinjector is pressed to give the dose of SIMPONI you will
1064 hear a loud ‘click’ sound. It is very important that you practice injecting SIMPONI with your
1065 doctor or nurse so that you are not startled by this click when you start giving the injections to
1066 yourself at home.
 - 1067 • If you pull the SmartJect autoinjector away from the skin before the injection is completed, you
1068 may not get your full dose of medicine and may lose some of the medicine.
- 1069

1070 **Do not:**

- 1071 • shake the SmartJect autoinjector at any time
 - 1072 • remove the SmartJect autoinjector cap until you get to that step
- 1073

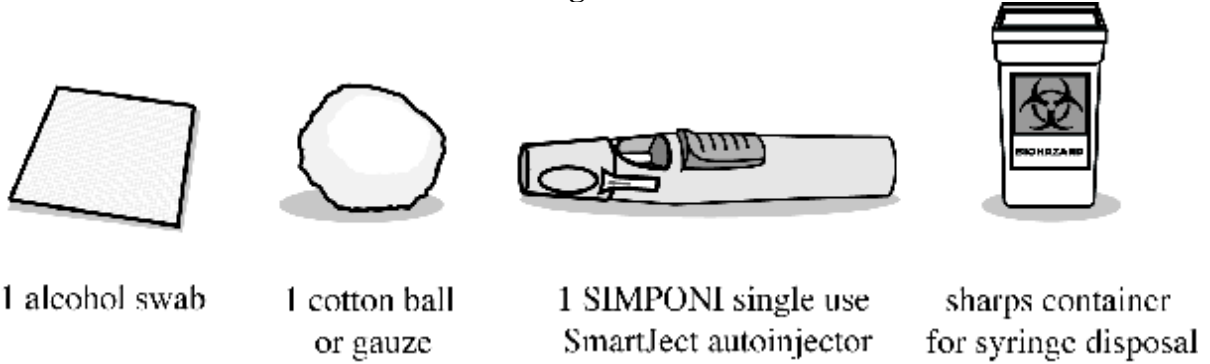
1074 **Step 1: Gather and inspect the supplies for your injection**

1075
1076 You will need these supplies for an injection of SIMPONI. See Figure 1.

- 1077 • 1 alcohol swab
 - 1078 • 1 cotton ball or gauze
 - 1079 • 1 SIMPONI prefilled SmartJect autoinjector
 - 1080 • sharps container for autoinjector disposal
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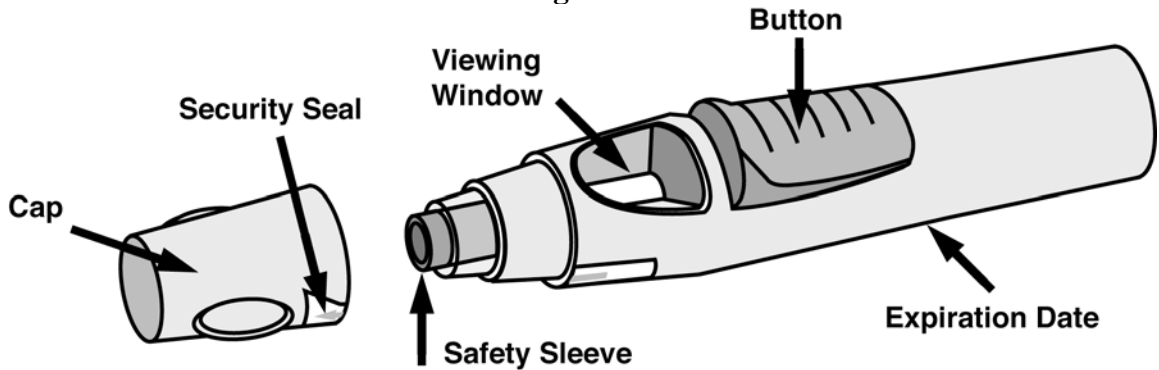
Figure 1



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The figure below shows what the SmartJect autoinjector looks like. See Figure 2.

Figure 2



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1.1 Check Expiration Date

- Check the expiration date (“EXP”) on the SmartJect autoinjector.
- You can also check the expiration date printed on the carton.
- If the expiration date has passed, do not use the SmartJect autoinjector. Call your doctor or pharmacist, or call 1-800-457-6399 for help.

1.2 Check Security Seal

- Check the security seal around the cap of the SmartJect autoinjector. If the security seal is broken, do not use the SmartJect autoinjector.

1.3 Wait 30 minutes

- To ensure proper injection, allow the autoinjector to sit at room temperature outside the carton for 30 minutes and out of the reach of children.



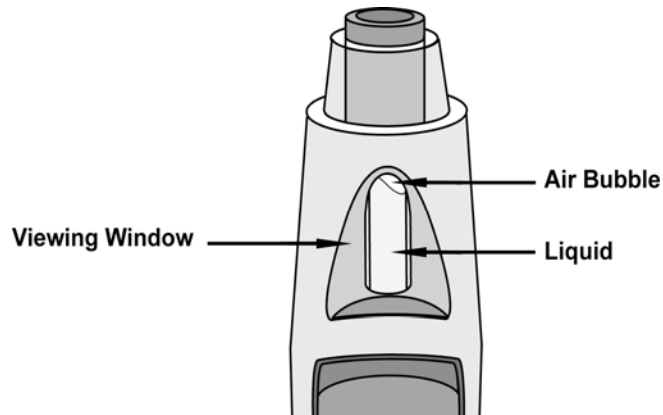
Do not warm the SmartJect autoinjector in any other way (For example, **do not** warm it in a microwave or in hot water).

Do not remove the SmartJect autoinjector cap while allowing it to reach room temperature.

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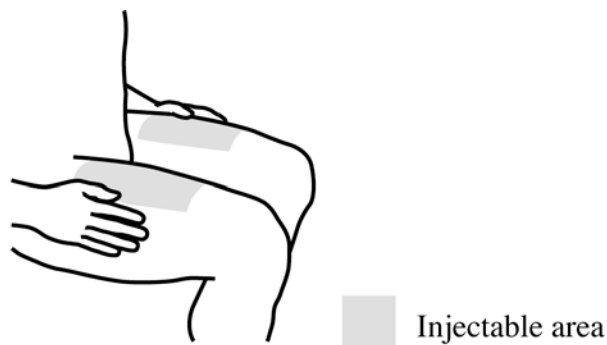
- 1119
1120 **1.4 Check the Liquid in the SmartJect autoinjector**
1121 • Look through the viewing window of the SmartJect autoinjector. See Figure 3. Make sure that the
1122 liquid in the prefilled syringe is clear and colorless to slightly yellow in color. You may see a small
1123 amount of tiny particles that are white, or that you can see through. Do not inject the liquid if it is
1124 cloudy or discolored, or has large particles in it.
1125 • You may also notice an air bubble. This is normal. See Figure 3.

1126
1127 **Figure 3**
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- 1129
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1131 **Step 2: Choose and prepare the injection site**
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1133 **2.1 Choose the Injection Site**
1134 • The recommended injection site is the front of your middle thighs. See Figure 4.
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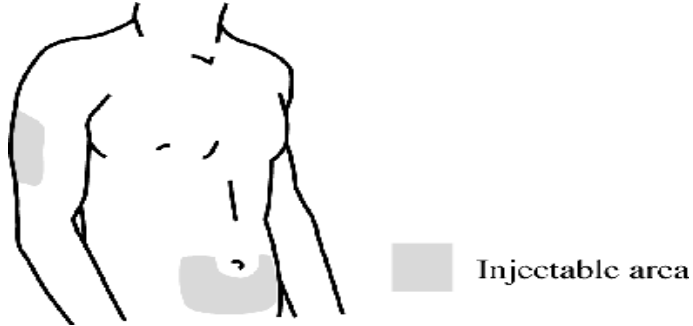
1136
1137 **Figure 4**
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1141 • You can also use the lower part of the abdomen below the navel (belly button), except for the two-
1142 inch area directly around the navel. See Figure 5.
1143 • If a caregiver is giving you the injection, the outer area of the upper arms may also be used. See
1144 Figure 5.
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Figure 5



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- **Do not** inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

1152

2.2 Prepare the Injection Site

- Wash your hands well with soap and warm water.
- Wipe the injection site with an alcohol swab.
- **Do not** touch this area again before giving the injection. Allow the skin to dry before injecting.
- **Do not** fan or blow on the clean area.

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Step 3: Injecting SIMPONI using the single dose SmartJect autoinjector

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3.1 Remove the Cap

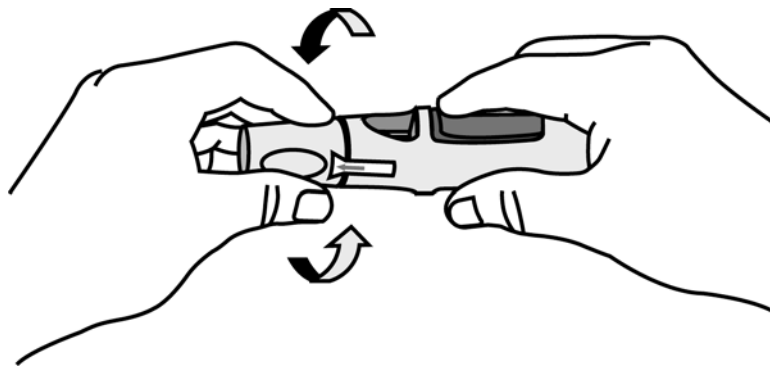
- Do not remove the cap until you are ready to inject SIMPONI. Inject SIMPONI within 5 minutes after the cap has been removed.
- When you are ready to inject, twist the cap slightly to break the security seal. See Figure 6.

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Figure 6



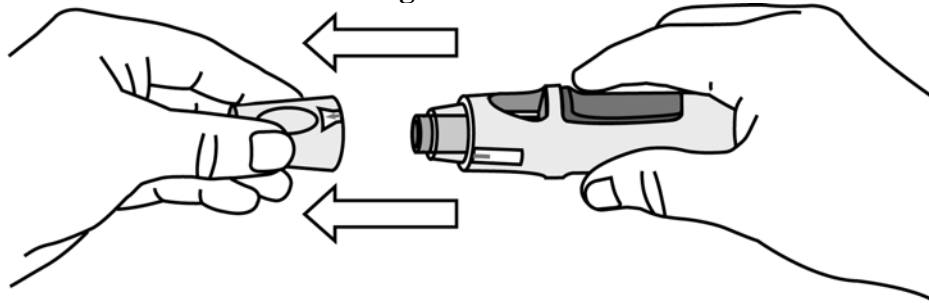
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- Pull the cap off and throw it in the trash right away. See Figure 7.

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Figure 7



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- **Do not** put the cap back on because it may damage the needle inside the SmartJect autoinjector.
- **Do not** use your SmartJect autoinjector if it is dropped without the cap in place.

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3.2 Push the SmartJect autoinjector against the skin

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- Hold the SmartJect autoinjector comfortably in your hand.

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- Do not press the button. Push the open end of the SmartJect autoinjector firmly against the skin at **90-degree angle**. See Figure 8.

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Figure 8

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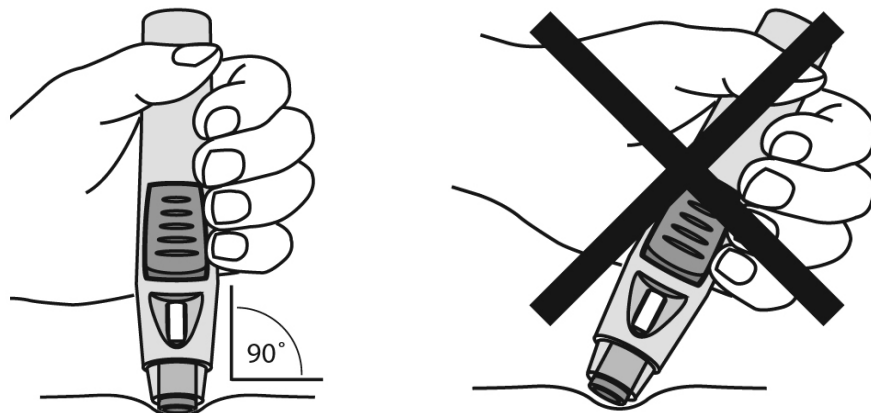
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- Use **your** free hand to pinch and hold the skin at the injection site. This may make injecting easier.

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3.3 Press button to inject

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- Continue to hold the SmartJect autoinjector firmly against the skin, and press the button with your fingers (see Figure 9) or thumb (see Figure 10). You will not be able to push in the button unless the SmartJect autoinjector is pushed firmly against your skin.

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Figure 9



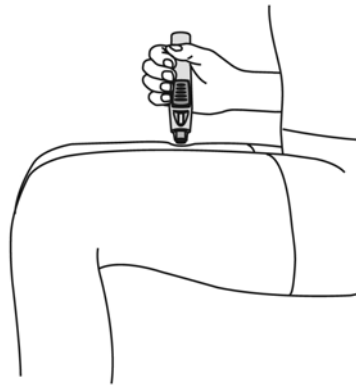
Figure 10



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- After the button is pressed, it will stay pressed in so you do not need to keep pressure on it. See Figure 11.

Figure 11



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- You will hear a loud 'click' sound. This means that the injection has started. Do not pull the SmartJect autoinjector away from your skin. If you pull the SmartJect autoinjector away from the skin, you may not get your full dose of medicine. See Figure 12.
- **Do not** lift the SmartJect autoinjector yet.

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3.4 Wait for Second "Click"

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- Keep holding the SmartJect autoinjector against your skin until you hear the second 'click' sound. It usually takes about 3 to 6 seconds, but may take up to 15 seconds for you to hear the second 'click' sound. See Figure 13.
- The second 'click' sound means that the injection is finished and the needle has pulled back (retracted) into the SmartJect autoinjector.
- Lift the SmartJect autoinjector from the injection site. See Figure 14.
- If you have hearing problems, count for 15 seconds from the time you pressed the button and then lift the SmartJect autoinjector from the injection site.

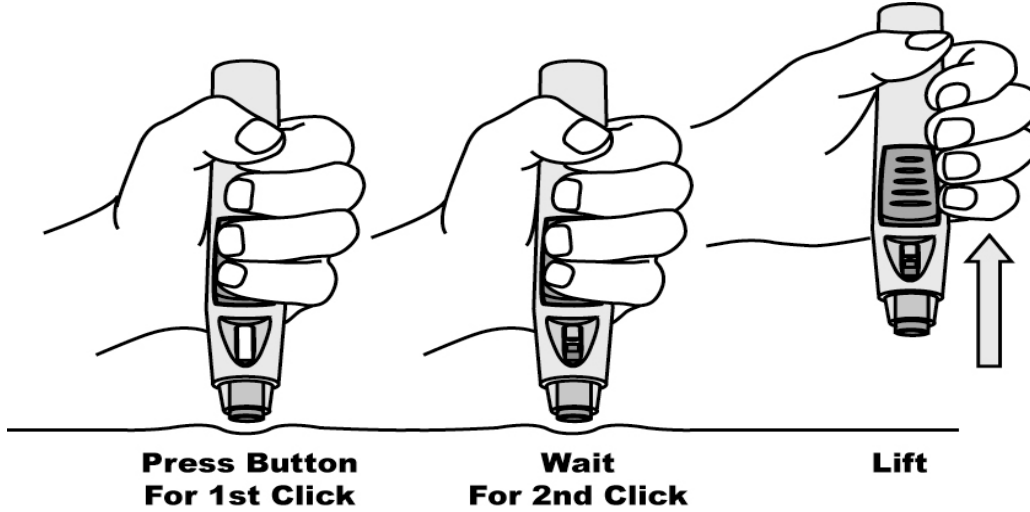
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Figure 12

Figure 13

Figure 14



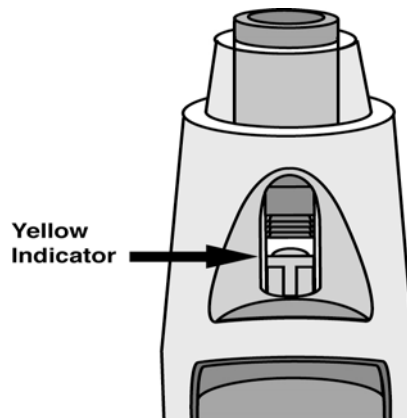
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Step 4: After the injection

4.1 Check the Viewing Window

- After you finish injecting, check the viewing window to see the yellow indicator. See Figure 15. This means the SmartJect autoinjector has worked the right way.

Figure 15



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- If you do not see the yellow indicator in the viewing window, call 1-800-457-6399 for help.

4.2 Dispose of the used SmartJect autoinjector

- Place the used SmartJect autoinjector into a closable puncture-resistant container. You may use a sharps container (such as a red biohazard container), a hard plastic container (such as a detergent bottle), or a metal container (such as an empty coffee can). See Figure 16.

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Figure 16



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- Ask your doctor for instructions on the right way to throw away (dispose of) the container. There may be local or state laws about how you should throw away used needles and syringes.
- Do not throw away your used SmartJect autoinjector in household trash. Do not recycle.

4.3 Use Cotton Ball or Gauze

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

Patient Instructions for Use
SIMPONI[®]
Prefilled Syringe

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1289 If your doctor decides that you or a caregiver may be able to give your injections of SIMPONI at
1290 home, you should receive training on the right way to prepare and inject SIMPONI. **Do not** try to
1291 inject SIMPONI yourself until you have been shown the right way to give the injections by your
1292 doctor or nurse.

1293
1294 It is important to read, understand, and follow these instructions so that you inject SIMPONI the right
1295 way. Call your doctor if you or your caregiver has any questions about the right way to inject
1296 SIMPONI.

1297
1298 Important information about your prefilled syringe:

1299
1300 • Always hold the prefilled syringe by the body of the syringe.

1301
1302 **Do not:**

- 1303 • pull back on the plunger at any time.
- 1304 • shake the SIMPONI prefilled syringe. This may damage the medicine.
- 1305 • remove the needle cover from the prefilled syringe until you get to that step.
- 1306 • touch the needle guard activation clips to prevent covering the needle with the needle guard too
1307 soon (See Figure 2).
- 1308 • use SIMPONI if it has been frozen or if it has been kept at a room temperature that is too warm.
1309 See the Medication Guide section: “How should I store SIMPONI?”
- 1310 • use your SIMPONI prefilled syringe if it looks damaged.

1311
1312 **Step 1: Gather the supplies for your injection**

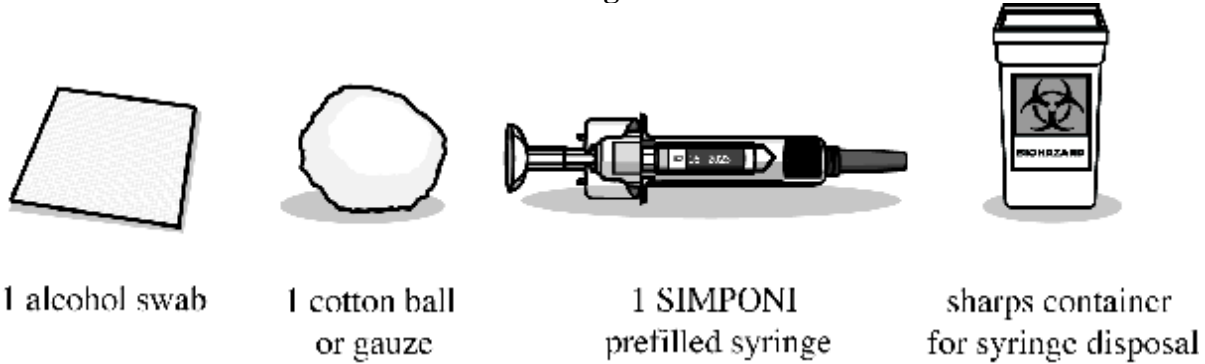
1313
1314 You will need these supplies for an injection of SIMPONI. See Figure 1.

- 1315 • 1 alcohol swab
- 1316 • 1 cotton ball or gauze
- 1317 • 1 SIMPONI prefilled syringe
- 1318 • sharps container for syringe disposal

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Figure 1



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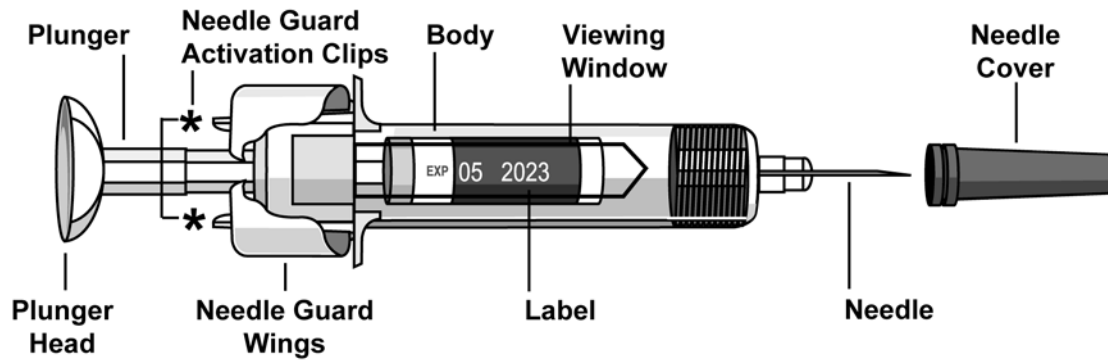
1323 The diagram below shows what the prefilled syringe looks like. See Figure 2.

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Figure 2



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1329 **Step 2: Get ready to use your prefilled syringe**

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1331 **2.1 Check the Expiration Date**

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1337 **2.2 Wait 30 minutes**

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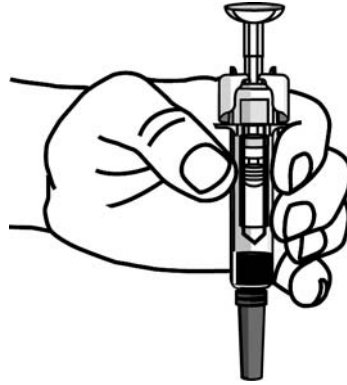
1345 **2.3 Check the Liquid in the Prefilled Syringe**

- Hold your SIMPONI prefilled syringe by the body with the covered needle pointing down. See Figure 3.



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Figure 3



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- Look at the liquid through the viewing window of the prefilled syringe. Make sure that the liquid in the prefilled syringe is clear and colorless to slightly yellow in color. You may see a small amount of tiny particles that are white, or that you can see through. Do not inject the liquid if it is cloudy or discolored, or has large particles in it.
- You may also see an air bubble. This is normal.

Step 3: Choose and prepare the injection site

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3.1 Choose the Injection Site

- The recommended injection site is the front of your middle thighs. See Figure 4.

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Figure 4

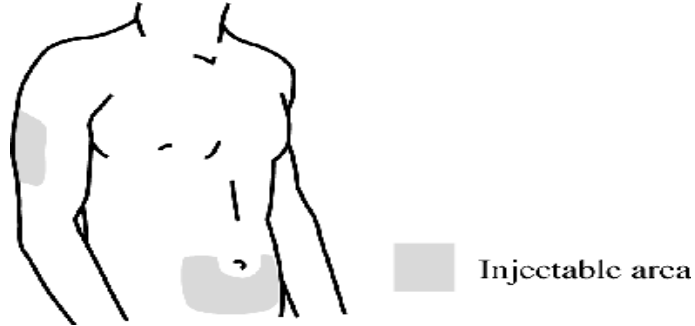


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- You can also use the lower part of the abdomen below the navel (belly button), except for the two-inch area directly around the navel. See Figure 5.
- If a caregiver is giving you the injection, the outer area of the upper arms may also be used. See Figure 5.

1371
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Figure 5



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Do not inject into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

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3.2 Prepare the Injection Site

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- Wash your hands well with soap and warm water.
- Wipe the injection site with an alcohol swab.
- **Do not** touch this area again before giving the injection. Let your skin dry before injecting.
- **Do not** fan or blow on the clean area.

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Step 4: Inject SIMPONI

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Do not remove the needle cover until you are ready to inject SIMPONI. Inject SIMPONI within 5 minutes after you remove the needle cover.

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4.1 Remove the Needle Cover

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- **Do not** touch the plunger while removing the needle cover.
- Hold the body of the prefilled syringe with one hand, and pull the needle cover straight off. See Figure 6.

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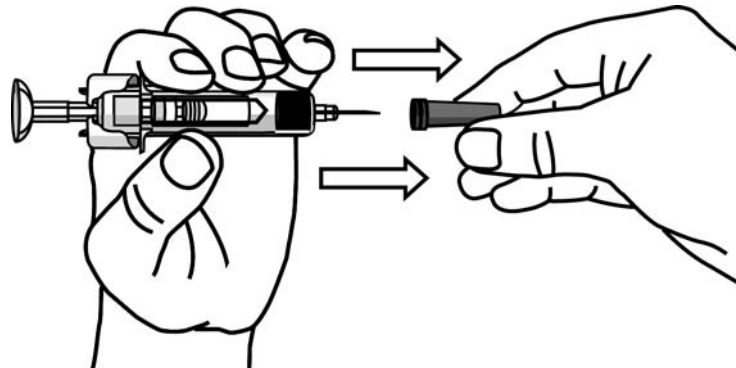
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Figure 6



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- 1399
- Put the needle cover in the trash.
 - 1400 • You may see an air bubble in the prefilled syringe. This is normal.
 - 1401 • You may also see a drop of liquid at the end of the needle. This is normal.
 - 1402 • **Do not** touch the needle or let it touch any surface.
 - 1403 • **Do not** use the prefilled syringe if it is dropped without the needle cover in place.

1404

4.2 Position the prefilled syringe and inject SIMPONI

- 1405
- Hold the body of the prefilled syringe in one hand between the thumb and index fingers. See Figure 7.

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Figure 7



- 1411
- **Do not** pull back on the plunger at any time.
 - 1412 • Use the other hand to gently pinch the area of skin that you previously cleaned. Hold firmly.
 - 1413 • Use a quick, dart-like motion to insert the needle into the pinched skin at about a **45-degree angle**.
 - 1414 • See Figure 8.

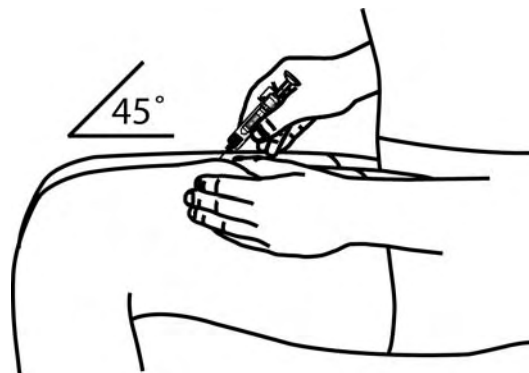
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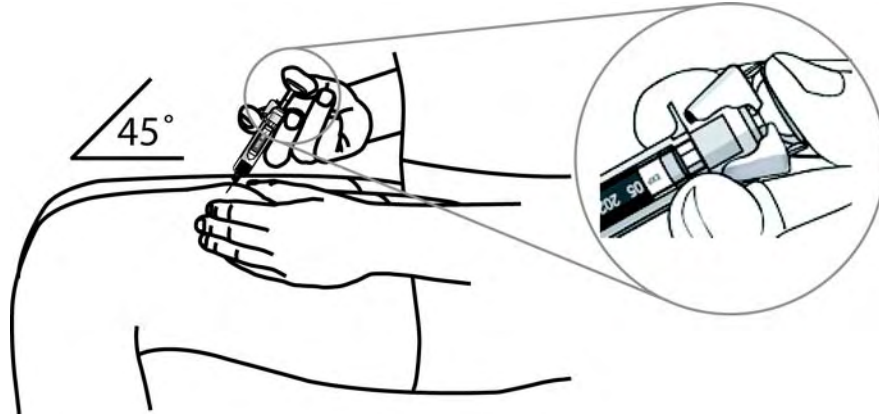
Figure 8



- 1419
- Inject all of the medicine by using your thumb to push in the plunger until the plunger head is completely between the needle guard wings. See Figure 9.

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Figure 9



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- When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin.
- Slowly take your thumb off the plunger head. This will let the empty syringe move up until the entire needle is covered by the needle guard. See Figure 10.

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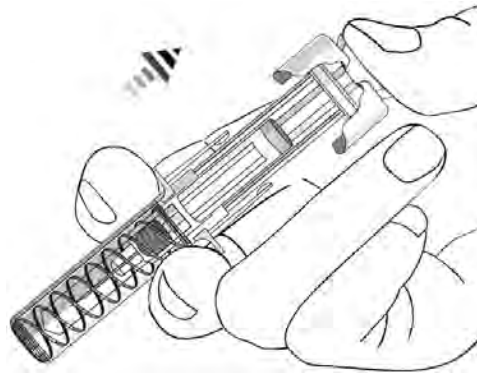
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Figure 10



1446 **Step 5: After the injection**

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1448 **5.1 Dispose of the used prefilled syringe**

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- 1450 • Place the used prefilled syringe in a closable puncture-resistant container. You may use a sharps
1451 container (such as a red biohazard container), a hard plastic container (such as a detergent bottle),
1452 or a metal container (such as an empty coffee can). For the safety and health of you and others,
1453 needles and used syringes **must never** be re-used. See Figure 11.

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1458 **Figure 11**

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- 1495 • Ask your doctor for instructions on the right way to throw away (dispose of) the container. There
1496 may be local or state laws about how you should throw away used needles and syringes.

- 1497 • Do not throw away your used prefilled syringe in household trash. Do not recycle.

1498

1499 **5.2 Use Cotton Ball or Gauze**

- 1500 • There may be a small amount of blood or liquid at the injection site, which is normal.
- 1501 • You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the
1502 injection site.
- 1503 • You may cover the injection site with a small adhesive bandage, if needed.

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1505 Centocor Ortho Biotech Inc.
1506 Horsham, PA 19044
1507 US License No. 1821
1508
1509 Revised: 7/2010
1510
1511 This Medication Guide has been approved by the U.S. Food and Drug Administration.
1512