

562 **MEDICATION GUIDE**

563

564 **INFERGEN<sup>®</sup>**

565 **(Interferon alfacon-1)**

566 **Suspension for Injection**

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568 Read this Medication Guide carefully before you start taking Infergen (Ín-fer-jen). Read the  
569 Medication Guide each time you refill your prescription because new information may have  
570 been added. You should also make sure that the pharmacist has given you the interferon your  
571 healthcare provider prescribed for you. The information in this Medication Guide does not take  
572 the place of talking with your healthcare provider about your medical condition or treatment.

573

574 **What is the most important information I should know about Infergen?**

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576 Infergen is one of the treatments used for some people who are infected with the hepatitis C  
577 virus (HCV). Infergen can have serious side effects that, in a few people, may lead to death.  
578 Before starting treatment, talk to your healthcare provider about the possible benefits of  
579 Infergen and its possible side effects to decide if Infergen is right for you. While taking  
580 Infergen, you will need to see your healthcare provider regularly for medical exams and lab  
581 tests to make sure your treatment is working and to check for side effects.

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583 **The most serious possible side effects of Infergen include:**

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585 **Mental health problems:** Infergen may cause mood or behavior problems. Some of the signs  
586 of these problems include irritability (getting upset easily), depression (feeling hopeless or  
587 feeling bad about yourself), nervousness, anxiety, or aggressive behavior. Some patients may  
588 have thoughts of hurting or killing themselves or other people or may attempt to do so.

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590 **Tell your healthcare provider if you are being treated for a mental illness or had**  
591 **treatment in the past for any mental illness, including depression and suicidal thoughts.**

592 Former drug addicts may lapse back into drug addiction or overdose. You should tell your  
593 healthcare provider if you have ever been addicted to drugs or alcohol.

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595 **Blood problems (bone marrow toxicity):** Infergen can cause a drop in the numbers of two  
596 types of blood cells (white blood cells and platelets). Infections and bleeding can happen if  
597 these blood counts fall to dangerously low levels.

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599 **Heart problems:** Infergen may cause high blood pressure, a very fast heart beat, chest pains,  
600 and a heart attack. Patients who have heart problems may have a higher chance for heart  
601 problems with Infergen. **Tell your healthcare provider if you have or have had any heart**  
602 **problems.**

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604 **Autoimmune problems:** These are diseases that happen when the body's own immune system  
605 begins to attack itself. Infergen may cause autoimmune disorders such as psoriasis or thyroid  
606 problems. Infergen may worsen an autoimmune disease that you already have.

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608 **Body organ problems:** Infergen may cause problems with your lungs (such as trouble  
609 breathing or pneumonia), and stomach pains, nausea and vomiting, and eye problems that can

610 cause blurred vision or cause you to lose your vision. Cases of weakness, loss of coordination  
611 and numbness due to stroke have been reported in patients taking Infergen, including patients  
612 with few or no reported risk factors for stroke.

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614 **Call your healthcare provider right away if you develop any of the following:**

- 615 • depression or have thoughts about hurting or killing yourself or others
- 616 • trouble breathing
- 617 • severe chest pain
- 618 • severe stomach or lower back pain, bloody diarrhea or bloody bowel movements
- 619 • poor eyesight
- 620 • skin turns yellow
- 621 • become pregnant
- 622 • a high fever
- 623 • unusual easy bruising, or bleeding

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625 For other possible side effects, please read the section “What are the possible side effects of  
626 Infergen?” in this Medication Guide (below).

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628 **What is Infergen?**

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630 Infergen (Interferon alfacon-1) is a medicine used to treat adults with lasting (chronic) hepatitis  
631 C virus (HCV) infection. HCV is a liver disease that is caused by the hepatitis C virus and is  
632 spread by contact with the blood of a person carrying the hepatitis C virus. Most people who  
633 get HCV carry the virus in their blood for the rest of their lives. Most of these people will have  
634 some liver damage, but many do not feel sick from the disease. Some people will develop a  
635 badly damaged or scarred liver (cirrhosis). Cirrhosis can cause the liver to stop working.

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637 Your healthcare provider will tell you if the hepatitis C virus you have is resistant (type 1 virus)  
638 or easier to treat (type 2 or 3 virus) and the chance of treatments working. Infergen may lower  
639 the amount of the hepatitis C virus in the body so that it cannot be measured by blood tests.  
640 Your healthcare provider should do regular blood tests to check for side effects and your  
641 response to treatment.

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643 It is not known if Infergen can cure HCV (permanently get rid of the virus) or if it can prevent  
644 liver failure or liver cancer that is caused by HCV infection.

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646 Infergen therapy alone or in combination with other treatments will not prevent a person with  
647 HCV from giving another person the HCV infection.

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649 **Who should not take Infergen?**

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651 **Do not take Infergen if you:**

- 652 • are pregnant or breast feeding or planning to become pregnant
- 653 • have autoimmune hepatitis (hepatitis caused by your immune system attacking your liver)
- 654 • had an allergic reaction to another alpha-interferon medicine or are allergic to any of the  
655 ingredients in Infergen (See the ingredient listing at the end of this Medication Guide)

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657 **Before starting Infergen, tell your healthcare provider if you have or ever had any of the**  
658 **following conditions or serious medical problems:**

- 659 • depression or anxiety
- 660 • sleep problems
- 661 • drug or alcohol addiction or abuse
- 662 • high blood pressure
- 663 • heart problems
- 664 • liver problems (other than HCV)
- 665 • autoimmune disease such as psoriasis, systemic lupus erythematosus, or rheumatoid
- 666 arthritis
- 667 • thyroid problems
- 668 • diabetes
- 669 • colitis (an inflammation of the bowels)
- 670 • cancer
- 671 • hepatitis B infection
- 672 • HIV infection
- 673 • kidney problems
- 674 • blood disorders
- 675 • taking a medication that suppresses your immune system

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677 Tell your healthcare provider about all the medicines you take including prescription or non-  
678 prescription medicines, vitamin and mineral supplements and herbal medicines.

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680 Know the medicines you take. Keep a list of them to show your healthcare provider and  
681 pharmacist each time you get a new medicine.

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683 **How should I take Infergen?**  
684 **See the instructions for injecting Infergen (“How do I prepare and inject the Infergen**  
685 **dose?”) later in this Medication Guide.**

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687 • Infergen is given as an injection under your skin. Your healthcare provider will inject your  
688 Infergen when you first start using it. Your healthcare provider will decide if you, a family  
689 member, or a friend is able to inject your Infergen at home. Your healthcare provider will  
690 teach you or the person that will be giving your injections, the right way to prepare and  
691 inject Infergen. Make sure you understand the instructions before you inject Infergen at  
692 home.
- 693 • Infergen comes in ready-to-use vials. There is one dose of medicine in each vial. Your  
694 healthcare provider will tell you the amount (your dose) to inject. Do not change your dose  
695 unless your healthcare provider tells you to change it. It is important that you take Infergen  
696 exactly as your healthcare provider tells you. Too little Infergen may not be effective in  
697 treating your HCV infection and too much Infergen may cause side effects.
- 698 • Inject your dose of Infergen three times a week, at the same time of day.
- 699 • If you miss a dose of Infergen, give yourself an injection as soon as you remember and then  
700 call your healthcare provider. Do not take your next scheduled dose until you have been  
701 told what you should do by your healthcare provider.

- 702 • If you take more than your prescribed amount of Infergen, call your healthcare provider  
703 right away. Your healthcare provider may want to examine you.  
704 • Once you start treatment with Infergen, do not switch to another brand of interferon without  
705 talking to your healthcare provider. Other interferons may not have the same effect on the  
706 treatment of your disease. Switching brands will also require a change in your dose.  
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708 You must get regular blood tests to help your healthcare provider check to see how the treatment  
709 is working and to check for side effects.  
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### 711 **What should I avoid while taking Infergen?**

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- 713 • Avoid becoming pregnant while taking Infergen. Infergen may cause harm to an unborn  
714 child or cause you to lose your baby (miscarry).
  - 715 • Do not breastfeed your baby while taking Infergen.
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### 717 **What are the possible side effects of Infergen?**

#### 718 **Infergen can cause serious side effects including:**

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- 720 • **mental health problems**
  - 721 • **blood problems**
  - 722 • **heart problems**
  - 723 • **autoimmune problems**
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725 See “What is the most important information I should know about Infergen?”  
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#### 727 **Infergen can cause serious allergic reactions. Stop Infergen and get medical treatment 728 right away if you have:**

- 729
- 730 • hives
  - 731 • swelling around your eyes or lips
  - 732 • swelling in your mouth or throat
  - 733 • trouble breathing
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#### 735 **Some of the common but less serious side effects with Infergen include:**

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- 737 • **Flu-like symptoms.** Infergen causes “flu-like” symptoms in most patients. Symptoms  
738 include headache, muscle aches, tiredness, chills and fever that usually lessen after the first  
739 few weeks of therapy. If you inject your Infergen dose at bedtime, you may be able to sleep  
740 through the symptoms. You may also take a fever and pain reducer such as acetaminophen  
741 or ibuprofen, to help relieve or reduce the flu-like symptoms.
  - 742 • **Tiredness (fatigue).** Infergen causes extreme tiredness in many patients.
  - 743 • **Upset stomach.** Nausea, loss of appetite, diarrhea and weight loss may happen.
  - 744 • **Blood sugar problems.** Infergen may affect blood sugar levels and cause high blood sugar  
745 or diabetes.
  - 746 • **Skin reactions at the injection site.** Redness, rash, itching, a lump, swelling, or bruising  
747 that does not go away may happen at the site of injection. Call your healthcare provider if  
748 these symptoms do not go away after several days.

749 • **Hair thinning.** Hair thinning may happen during Infergen treatment, but hair loss stops  
750 and hair growth returns after you stop taking Infergen.

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752 These are not all of the side effects of Infergen. Your healthcare provider or pharmacist can  
753 give you a more complete list that has all the side effects.

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755 If you are worried about side effects or find them troublesome, talk to your healthcare provider.

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## 758 **HOW DO I PREPARE AND INJECT THE INFERGEN DOSE?**

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760 Find a clean, comfortable, well-lit place and remove a vial of Infergen from the refrigerator and  
761 allow it to reach room temperature.

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763 1. Assemble the supplies you will need for your injection:

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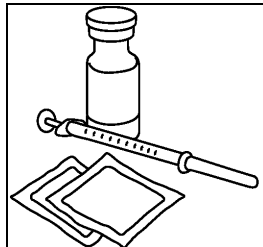
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- A vial of Infergen
- One sterile disposable syringe and needle
- Several alcohol swabs and
- A puncture-proof container to dispose of the needle and syringe when you are done



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772 2. Make sure you have the right syringe to use with Infergen. It is important to use a  
773 syringe that is marked in tenths of milliliters (mLs), for example, 0.1 mL. Your  
774 healthcare provider may refer to a mL as a cc (1 mL = 1 cc). Failure to use the right  
775 syringe can lead to a mistake in dosage. You may receive too little or too much  
776 Infergen.

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778 3. Check the date on the vial of Infergen and make sure that the date has not passed, and  
779 look at the liquid inside the vial.

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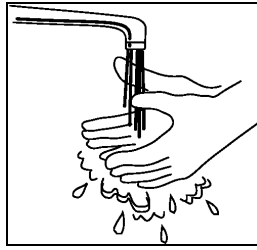
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- Do not use the Infergen if:
  - The liquid is cloudy
  - The liquid is not clear and colorless
  - The liquid has particles
  - The expiration date has passed

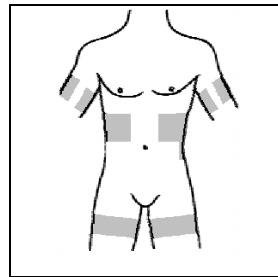
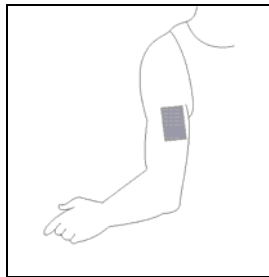
4. Wash your hands thoroughly with soap and water.



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**SELECT AND PREPARE THE INJECTION SITE ON YOUR BODY**

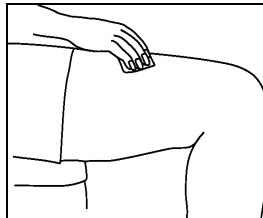
5. Pick a site for your injection.
- Back of the upper arms (if someone is giving you the injection)
  - Upper stomach area (abdomen), except for the belly button (navel) and waist areas
  - Upper thighs



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You should change the site for injection each time you inject to avoid soreness at any one site.

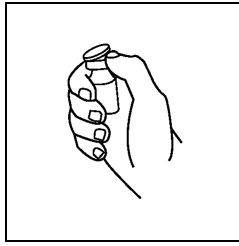
6. Clean the injection site with an alcohol swab. Use circular motions from the inside to the outside. Keep the used alcohol swab nearby.



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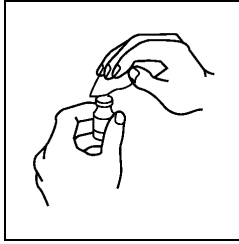
**PREPARING THE DOSE**

7. Remove the colored cap from the vial, exposing the rubber stopper.



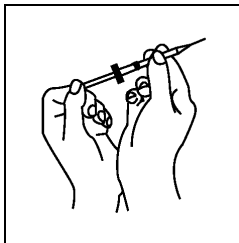
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8. Clean the rubber stopper with a new alcohol swab, and then cover the stopper with the swab.



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9. Remove the syringe and needle from their packages. If either package looks like it has been opened or damaged, do not use the syringe or needle; dispose of it in the puncture-proof disposal container.
10. Remove the needle cover and pull the plunger back and draw air into the syringe. The amount of air you draw into the syringe should be the same amount as the dose of medicine your healthcare provider has prescribed.

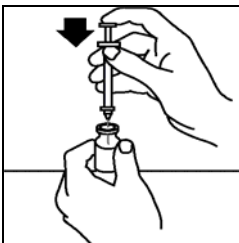


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11. Remove the alcohol wipe from the top of the vial and insert the needle straight through the center of the rubber stopper.

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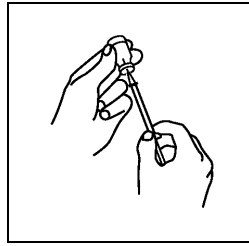
12. Push the plunger of the syringe down to inject the air into the air space above the liquid in the vial. The air injected into the vial will allow Infergen to be easily withdrawn from the vial into the syringe.



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13. Keeping the needle in the vial, turn the vial upside down and make sure that the tip of the needle is in the liquid.



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14. Slowly pull the plunger back and let the medicine enter the syringe, filling it to the line that equals the dose your healthcare provider prescribed.

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15. Keeping the needle in the vial, check for air bubbles in the syringe. Air bubbles are harmless but can reduce the dose you should be receiving. To remove the air bubbles, gently tap the syringe with your fingers until the bubbles rise to the needle-end of the syringe barrel. Then push the plunger in to force the air out of the syringe.

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Make sure the tip of the needle is in the liquid and slowly pull back on the plunger until the liquid in the syringe reaches the mark that correctly matches the amount of your dose.

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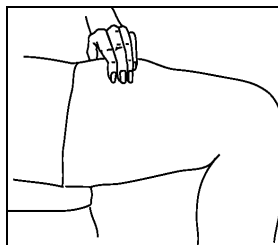
16. Take the needle out of the vial and hold the syringe needle facing up in the hand that you will use to inject yourself. Do not lay the syringe down or allow the needle to touch anything.

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## INJECTING THE DOSE

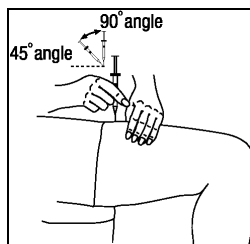
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17. Use the other hand to pinch a fold of skin at the site you cleaned for an injection.



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18. Hold the syringe the way you would hold a pencil and insert the needle either straight up and down (90 degree angle) or at a slight angle (45 degree angle) to the skin.

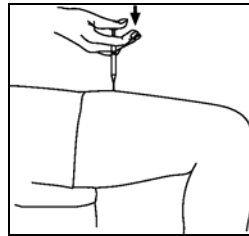


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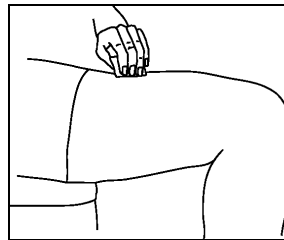
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19. After the needle is in, let go of the skin. Pull the plunger back slightly. **If blood appears, do not inject Infergen, because the needle has entered a blood vessel.** Withdraw the syringe and discard it. Prepare a new syringe and inject at a new site. Repeat this procedure at the second site, checking for blood before injecting.
20. If no blood appears, slowly push down on the plunger all the way, until all the medicine is gone from the syringe.



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21. Pull the needle out of the skin at the same angle you put it in and place an alcohol swab over the injection site, then press for several seconds.



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22. Promptly place the needle and syringe in the puncture-proof disposal container. **Never reuse the syringe or needle. Do not recap the needle.**

## 888 Disposal

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Dispose of syringes and needles as directed by your healthcare provider or pharmacist. There may be special state and local laws.

Place all used needles, needle covers, and syringes in a special container called a “Sharps Container” or a hard plastic container, or a metal container with a plastic lid. Do not use glass or clear plastic containers, or any container that will allow the needles to stick through them.

Always keep the container out of the reach of children.

**Do not recycle containers or throw full containers into the household trash.**

**How should I store Infergen?**

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- 906 • Store Infergen in the refrigerator at 36° to 46°F (2° to 8°C), but not in the freezer
- 907 compartment.
- 908 • Do not let Infergen freeze or leave it in direct sunlight.
- 909 • Do not use a vial of Infergen that has been frozen or past the expiration date stamped on the
- 910 label. If you think that the Infergen has been frozen or left in direct sunlight, do not use it,
- 911 and call your healthcare provider or nurse for instructions.
- 912 • To transport Infergen, keep the vials cool and avoid extreme temperature changes.
- 913 • Do not shake Infergen. If Infergen is shaken too hard, it will not work properly.
- 914 • **Keep Infergen and all medicines out of the reach of children.**

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### 917 **General advice about prescription medicines**

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919 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.  
920 If you have any concerns about Infergen, ask your healthcare provider. Your healthcare  
921 provider or pharmacist can give you information about Infergen that was written for healthcare  
922 professionals. Do not use Infergen for a condition for which it was not prescribed. Do not  
923 share this medicine with other people.

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### 926 **Ingredients**

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928 Interferon alfacon-1 in a sterile, preservative-free solution of sodium chloride, sodium  
929 phosphate, and Water for Injection, USP.

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932 This Medication Guide has been approved by the U.S. Food and Drug Administration.

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934  **VALEANT™**

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938 3265704

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