

Medication Guide **INFERGEN® (In-fer-jen)**

(interferon alfacon-1) Injection for subcutaneous use

Read this Medication Guide carefully before you start taking INFERGEN and each time you get a refill. There may be new information. This information does not take place of talking with your healthcare provider about your medical condition or treatment.

If you are taking INFERGEN with ribavirin, also read the Medication Guide for ribavirin capsules or tablets.

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

INFERGEN can cause serious side effects. Some of these side effects may cause death. Tell your healthcare provider right away if you have any of the symptoms listed below while taking INFERGEN.

1. Mental health problems and suicide: Some patients taking INFERGEN may develop mood or behavior problems, including:

- irritability (getting upset easily)
- depression (feeling hopeless or feeling bad about yourself)
- nervousness
- anxiety
- aggressive behavior
- **former drug addicts may fall back into drug addiction or overdose**
- thoughts of hurting yourself or others, or suicide

2. New or worsening autoimmune problems. Some people taking INFERGEN develop autoimmune problems (a condition where the body's immune cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus erythematosus and psoriasis. In some people who already have an autoimmune problem, it may get worse during your treatment with INFERGEN.

3. Heart problems: Some people who take INFERGEN may get heart problems, including:

- low blood pressure
- fast heart beat or abnormal heart beat
- chest pains
- heart attack or heart muscle problem (cardiomyopathy)

4. Stroke or symptoms of a stroke. Symptoms may include weakness, loss of coordination, and numbness. Stroke or symptoms of a stroke may happen in people who have some risk factors or no known risk factors for a stroke.

5. **Infections.** Some people who take INFERGEN may get an infection. Symptoms may include:

- fever
- chills
- pain and/or burning with urination
- urinating often
- bloody diarrhea
- coughing up mucous

Before taking INFERGEN, tell your healthcare provider right away if you:

- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and suicidal behavior
- have or ever had any problems with your heart, including heart attack or high blood pressure
- have any kind of autoimmune disease (where the body's immune system attacks the body's own cells), such as psoriasis, systemic lupus erythematosus, rheumatoid arthritis
- have or ever had bleeding or a blood clot
- have or ever had low blood cell counts
- have ever been addicted to drugs or alcohol

Call your healthcare provider right away if you get any of these problems while taking INFERGEN:

- new or worse mental health problems, such as thoughts of hurting yourself or others, or suicide
- trouble breathing or severe chest pain
- any new weakness, loss of coordination, or numbness
- fever, chills, burning and/or pain with urination, urinating often, bloody diarrhea

While taking INFERGEN, you should see a healthcare provider regularly for check-ups and blood tests to make sure that your treatment is working, and to check for side effects.

What is INFERGEN?

INFERGEN (interferon alfacon-1) is a prescription medicine used to treat adults with lasting chronic (lasting a long time) hepatitis C virus (HCV) infection and certain types of liver problems.

It is not known if INFERGEN is safe and will work if taken for more than 1 year.

It is not known if INFERGEN is safe and will work in people younger than 18 years old.

Who should not take INFERGEN?

Do not take INFERGEN if you:

- have certain types of other liver problems
- have certain types of hepatitis (autoimmune hepatitis)

- have had a serious allergic reaction to another alpha-interferon medicine or to any of the ingredients in INFERGEN. See the end of this Medication Guide for a complete list of the ingredients. Symptoms of a serious allergic reaction to alpha-interferon may include: itching, swelling of your face, tongue, throat, trouble breathing, feeling dizzy or faint, and chest pain.

Talk to your healthcare provider before taking INFERGEN if you have any of these conditions.

What should I tell my healthcare provider before taking INFERGEN?

Before you take INFERGEN, See “What is the most important information I should know about INFERGEN?” and tell your healthcare provider if you have:

- Liver problems (other than hepatitis C infection)
- Have or had lung problems such as chronic obstructive pulmonary disease (COPD)
- Thyroid problems
- Diabetes
- Colitis (inflammation of your intestine)
- Cancer
- Hepatitis B infection
- HIV infection
- Kidney problems
- Have high blood triglyceride levels (fat in your blood)
- Organ transplant and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system)
- Any other medical conditions
- You are pregnant or plan to become pregnant. It is not known if INFERGEN will harm your unborn baby. You should use effective birth control during treatment with INFERGEN. Talk to your healthcare provider about birth control choices for you during treatment with INFERGEN. Tell your healthcare provider if you become pregnant during treatment with INFERGEN.
- Are breast feeding or plan to breast-feed. It is not known if INFERGEN passes into your breast milk. You and your healthcare provider should decide if you will use INFERGEN or breast-feed.

Tell your healthcare provider about all the medicines you take including prescription or non-prescription medicines, vitamin and mineral supplements and herbal medicines. INFERGEN and certain other medicines may affect each other and cause side effects.

Especially tell your healthcare provider if you take the anti-hepatitis B medicine telbivudine (Tyzeka). Some people who take this medicine with INFERGEN develop nerve problems (peripheral neuropathy), such as continuing numbness, tingling, or burning feeling in the arms or legs, or problems walking.

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

How should I take INFERGEN?

- Take INFERGEN exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much INFERGEN to take and when to take it. Do not take more than your prescribed dose.
- Your healthcare provider will decide whether you will take INFERGEN by itself three times a week, or everyday with ribavirin.
- INFERGEN is given as an injection under your skin (subcutaneous injection). Your healthcare provider should show you how to prepare and measure your dose of INFERGEN, and how to inject your INFERGEN yourself before you use INFERGEN for the first time.
- You should not inject INFERGEN until your healthcare provider has shown you how to use INFERGEN the right way.
- INFERGEN comes in single ready-to-use vials. There is 1 dose of medicine in each vial. Do not change your dose unless your healthcare provider tells you to change it. It is important that you take INFERGEN exactly as your healthcare provider tells you. Too little INFERGEN may not be effective in treating your HCV infection and too much INFERGEN may cause side effects.
- Inject your dose of INFERGEN as prescribed, at the same time of day.
- If you miss a dose of INFERGEN, give yourself an injection as soon as you remember and then call your healthcare provider. Do not take your next scheduled dose until you have been told what you should do by your healthcare provider.
- If you take more than your prescribed amount of INFERGEN, call your healthcare provider right away. Your healthcare provider may want to examine you.

What are the possible side effects of INFERGEN?

Your healthcare provider should do regular blood tests before you start INFERGEN, and during treatment to see how the treatment is working and to check for side effects.

INFERGEN may cause serious side effects including:

- See **“What is the most important information I should know about INFERGEN?”**
- **Lung problems including:**
 - Trouble breathing
 - Pneumonia
 - Inflammation of lung tissue
 - New or worse high blood pressure of the lungs (pulmonary hypertension). This can be severe and may lead to death.

- **Severe liver problems, or worsening of liver problems, including liver failure and death.**
Symptoms may include:
 - Nausea
 - Loss of appetite
 - Tiredness
 - Diarrhea
 - Yellowing of your skin or the white part of your eyes
 - Bleeding more easily than normal
 - Swelling of your stomach area (abdomen)
 - Confusion
 - Sleepiness
 - You cannot be awakened (coma)

- **Swelling of your pancreas (pancreatitis), intestines (colitis), or kidneys.**
Symptoms may include:
 - Severe stomach area (abdomen) pain
 - Severe back pain
 - Nausea and vomiting
 - Bloody diarrhea or bloody bowel movements
 - Fever

- **Blood problems.** INFERGEN can affect your bone marrow and cause low white blood cell and platelet counts. In some people, these blood counts may fall to dangerously low levels. If your blood counts become very low, you can get infections, and problems with bleeding and bruising.

- **Serious allergic reactions and skin reactions. Symptoms may include:**

<ul style="list-style-type: none"> • Itching • Swelling of the face, eyes, lips, tongue, or throat • Trouble breathing • Anxiousness 	<ul style="list-style-type: none"> • Chest pain • Feeling faint • Skin rash, hives, sores in your mouth, or your skin blisters and peels
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- **Serious eye problem. INFERGEN may cause eye problems that may lead to** vision loss or blindness. You should have an eye exam before you start taking INFERGEN. If you have eye problems or have had them in the past, you may need eye exams right away if you are taking INFERGEN. Tell your healthcare provider or eye doctor right away if you have any vision changes while taking INFERGEN.

- **Nerve problems:** People who take INFERGEN or other interferon alpha products with telbivudine (Tyzeka) can have nerve problems such as continuing numbness, tingling, or

burning sensation in the arms or legs (peripheral neuropathy). Call your healthcare provider if you have any of these symptoms.

- **Thyroid problems.** Some people develop changes in their thyroid function. Symptoms of thyroid changes include:
 - Problems concentrating
 - Feeling cold or hot all of the time
 - Weight changes
 - Skin changes
- **Blood sugar problems.** Some people may develop high blood sugar or diabetes. If you have high blood sugar or diabetes that is not controlled before starting INFERGEN, talk to your healthcare provider before you take INFERGEN. If you develop high blood sugar or diabetes while taking INFERGEN, your healthcare provider may tell you to stop INFERGEN and prescribe a different medicine for you. Symptoms of high blood sugar or diabetes may include:
 - Increased thirst
 - Tiredness
 - Urinating more often than normal
 - Increased appetite
 - Weight loss
 - Your breath smells like fruit

Tell your healthcare provider right away if you have any of the symptoms listed above.

The most common side effects of INFERGEN include:

- **Flu-like symptoms.** Symptoms may include: headache, muscle aches, tiredness, chills and fever. Some of these symptoms may be decreased by injecting your INFERGEN dose at bedtime. Talk to your healthcare provider about other over-the-counter medicines that you can take to help prevent or decrease some of these symptoms.
- **Tiredness.** Many people become very tired during treatment with INFERGEN.
- **Stomach problems.** Nausea, loss of appetite, diarrhea and weight loss may happen with INFERGEN.
- **Hair thinning**

Tell your healthcare provider if you have any side effects that bother you or does not go away.

These are not all of the side effects of INFERGEN. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.

How should I store INFERGEN?

- Store INFERGEN in the refrigerator at 36°F to 46°F (2°C to 8°C).
- **Do not freeze INFERGEN. Do not use a vial of INFERGEN that has been frozen.**
- Keep INFERGEN away from direct sunlight.
- Do not use a vial of INFERGEN past the expiration date stamped on the label.
- Do not shake INFERGEN. If INFERGEN is shaken too hard, it will not work properly.

Keep INFERGEN and all medicines out of the reach of children.

General information about INFERGEN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INFERGEN for a condition for which it was not prescribed. Do not give INFERGEN to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about INFERGEN. If you would like more information, ask your healthcare provider. You can ask your healthcare provider or pharmacist for information about INFERGEN that was written for healthcare professionals.

For more information, go to www.infergen.com.

What are the ingredients in INFERGEN?

Active Ingredients: interferon alfacon-1

Inactive ingredients: sodium chloride, and sodium phosphate in Water for Injection.

Manufactured by:
Boehringer Ingelheim Pharma GmbH & Co.
Biberach, Germany

Manufactured for: Kadmon Pharmaceuticals, LLC
Warrendale, PA 15086, USA
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C002.00021 Rev (.:07/11)

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