

MEDICATION GUIDE

INTRON[®] A (In-tron-aye)

(Interferon alfa-2b, recombinant)

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

If you are taking INTRON A with REBETOL, also read the Medication Guide for REBETOL[®] (ribavirin) Capsules and Oral Solution.

INTRON A alone is a treatment for certain types of cancers and hepatitis B virus. INTRON A by itself or with REBETOL is a treatment for some people infected with hepatitis C virus.

What is the most important information I should know about INTRON A?

INTRON A can cause serious side effects that:

- **may cause death, or**
- **may worsen certain serious diseases that you may already have.**

Tell your healthcare provider right away if you have any of the symptoms listed below while taking INTRON A. If symptoms get worse, or become severe and continue, your healthcare provider may tell you to stop taking INTRON A permanently. In many, but not all people, these symptoms go away after they stop taking INTRON A.

1. Heart problems. Some people who take INTRON A may develop heart problems, including:

- low blood pressure
- fast heart rate or abnormal heart beats
- trouble breathing or chest pain
- heart attacks or heart muscle problems (cardiomyopathy)

2. 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.

3. Mental health problems and suicide. INTRON A may cause you to develop mood or behavior problems that may get worse during treatment with INTRON A or after your last dose, including:

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

If you have these symptoms, your healthcare provider should carefully monitor you during treatment with INTRON A and for 6 months after your last dose.

4. New or worsening autoimmune disease. Some people taking INTRON A develop autoimmune diseases (a condition where the body's immune cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus erythematosus, sarcoidosis, and psoriasis. In some people who already have an autoimmune disease, the disease may get worse while on INTRON A.

5. Infections. Some people who take INTRON A may get an infection. Symptoms may include:

- fever
- chills
- bloody diarrhea
- burning or pain with urination
- urinating often
- coughing up mucus (phlegm) that is discolored (for example yellow or pink)

While taking INTRON A, 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 INTRON A?

INTRON A is a prescription medicine that is used:

- to treat adults with a blood cancer called hairy cell leukemia
- to treat certain adults with a type of skin cancer called malignant melanoma
- to treat adults with some types of Follicular Non-Hodgkin's Lymphoma along with certain chemotherapy medicines
- to treat certain adults with genital warts (condylomata acuminata), by injecting the medicine directly into the warts
- to treat certain adults with a type of cancer caused by AIDS, called AIDS-related Kaposi's Sarcoma
- alone to treat adults with chronic (lasting a long time) hepatitis C infection with stable liver problems
- with REBETOL to treat chronic (lasting a long time) hepatitis C infection in people 3 years and older with stable liver problems
- to treat chronic (lasting a long time) hepatitis B infection in people 1 year and older with stable liver problems

Who should not take INTRON A?

Do not take INTRON A if you:

- had a serious allergic reaction to another alpha interferon product or are allergic to any of the ingredients in INTRON A. See the end of this Medication Guide for a complete list of ingredients. Ask your healthcare provider if you are not sure.
- have certain types of hepatitis (autoimmune hepatitis)
- have certain other liver problems

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

What should I tell my healthcare provider before taking INTRON A?

Before you take INTRON A, tell your healthcare provider if you:

- **See “What is the most important information I should know about INTRON A?”**
- have or ever had any problems with your heart, including heart attack or have high blood pressure
- have or ever had bleeding problems or blood clots
- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and suicidal behavior
- 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 low blood cell counts
- have ever been addicted to drugs or alcohol
- have liver problems (other than hepatitis B or C)
- have or had lung problems, such as chronic obstructive pulmonary disease (COPD)
- have diabetes
- have colitis (inflammation of your intestine)
- have a condition that suppresses your immune system, such as cancer
- have hepatitis B or C infection
- have HIV infection (the virus that causes AIDS)
- have kidney problems
- have high blood triglyceride levels (fat in your blood)
- have an organ transplant and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system)
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if INTRON A will harm your unborn baby. You should use effective birth control during treatment with INTRON A. Talk to your healthcare provider about birth control choices for you during treatment with INTRON A. Tell your healthcare provider if you become pregnant during treatment with INTRON A.
- are breast-feeding or plan to breast-feed. It is not known if INTRON A passes into your breast milk. You and your healthcare provider should decide if you will use INTRON A or breast-feed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. INTRON A 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)
- the anti-HIV medicine zidovudine (Retrovir)
- theophylline (Theo-24, Elixophyllin, Uniphyl, Theolair). Your healthcare provider may need to monitor the amount of theophylline in your body and make changes to your theophylline dose.

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

How should I take INTRON A?

- INTRON A is given as an injection under the skin (subcutaneous) or into a muscle (intramuscular), into genital lesions, or as an injection into a vein (intravenous), depending on the condition that is being treated.
- Your healthcare provider will decide your dose of INTRON A and how often you will take it.
- If your healthcare provider decides that you can inject INTRON A for your condition, inject it exactly as prescribed, under your skin (subcutaneous injection) or into your muscle (intramuscular injection). Do not change your dose or how you inject INTRON A unless your healthcare provider tells you to.
- Do not take more than your prescribed dose.
- Your healthcare provider should show you how to prepare and measure your dose of INTRON A and how to inject yourself before you use INTRON A for the first time.
- You should not inject INTRON A until your healthcare provider has shown you how to use INTRON A the right way.
- INTRON A comes as:
 - a powder for injection in a vial that is used only 1 time (single-use vial). The powder must be mixed with water for injection (a diluent) before you inject it.
 - a solution for injection in a multi-dose vial
- See the attached Instructions for Use for detailed instructions for preparing and injecting a dose of INTRON A.
- If you miss a dose of INTRON A, take the missed dose as soon as possible during the same day or the next day, then continue on your regular dosing schedule. If several days go by after you miss a dose, check with your healthcare provider to see what to do.

- Do not inject more than 1 dose or take more than your prescribed dose without talking to your healthcare provider.
- If you take too much INTRON A, call your healthcare provider right away. Your healthcare provider may examine you more closely, and do blood tests.
- Your healthcare provider should do regular blood tests before you start INTRON A, and during your treatment to see how well the treatment is working and to check for side effects.

What are the possible side effects of INTRON A?

INTRON A may cause serious side effects including:

- **See "What is the most important information I should know about INTRON A?"**
- **Blood problems.** INTRON A 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 cell counts become very low, you can get infections or have bleeding problems.
- **Serious eye problems.** INTRON A may cause eye problems that may lead to vision loss or blindness. You should have an eye exam before you start taking INTRON A. If you have eye problems or have had them in the past, you may need eye exams while taking INTRON A. Tell your healthcare provider or eye doctor right away if you have any vision changes while taking INTRON A.
- **Thyroid problems.** Some people develop changes in the function of their thyroid. Symptoms of thyroid problems include:
 - problems concentrating
 - feeling cold or hot all the time
 - changes in your weight
 - skin changes
- **Blood sugar problems.** Some people may develop high blood sugar or diabetes. If you have high blood sugar or diabetes before starting INTRON A, talk to your healthcare provider before you take INTRON A. If you develop high blood sugar or diabetes while taking INTRON A, your healthcare provider may tell you to stop INTRON A 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
- **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.

You may need to have a chest X-ray or other tests if you develop fever, cough, shortness of breath, or other symptoms of a lung problem during treatment with INTRON A.

- **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)
- **Serious allergic reactions and skin reactions. Symptoms may include:**
 - itching
 - swelling of your face, eyes, lips, tongue, or throat
 - trouble breathing
 - anxiousness
 - chest pain
 - feeling faint
 - skin rash, hives, sores in your mouth, or your skin blisters and peels
- **Swelling of your pancreas (pancreatitis) and intestines (colitis).** Symptoms may include:
 - severe stomach area (abdomen) pain
 - severe back pain
 - nausea
 - vomiting
 - fever
- **New or worsening autoimmune disease.** Some patients taking INTRON A develop autoimmune diseases (a condition where the body's immune cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus erythematosus, sarcoidosis, and psoriasis. In some patients who already have an autoimmune disease, the disease may worsen while on INTRON A.
- **Nerve problems.** People who take INTRON A or other alpha interferon products with telbivudine (Tyzeka) can develop 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.
- **Growth problems in children.** Weight loss and slowed growth are common in children during combination treatment with INTRON A and REBETOL. Most children will go through a growth spurt and gain weight after treatment stops. Some children may not

reach the height that they were expected to have before treatment. Talk to your healthcare provider if you are concerned about your child's growth during treatment with INTRON A and REBETOL.

- **Dental and gum problems.**

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

The most common side effects of INTRON A include:

- **Flu-like symptoms.** Symptoms may include: headache, muscle aches, tiredness, and fever. Some of these symptoms may be decreased by injecting your INTRON A dose in the evening. Talk to your healthcare provider about which over-the-counter medicines you can take to help prevent or decrease some of the symptoms.
- **Tiredness.** Many people become very tired during treatment with INTRON A.
- **Appetite problems.** Nausea, loss of appetite, and weight loss can happen with INTRON A.
- **Skin reactions.** Redness, swelling, and itching are common at the injection site.
- **Hair thinning.**

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

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

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

How should I store INTRON A?

INTRON A Solution for Injection:

- Store in the refrigerator between 36°F to 46°F (2°C to 8°C).
- INTRON A Solution for Injection in Multidose vials for injection may be used to give more than 1 injection of medicine.
- Do not freeze.
- Throw away any unused INTRON A Solution for Injection remaining in the vial after one month.

INTRON A Powder for Injection:

Before mixing, store in the refrigerator between 36°F to 46°F (2°C to 8°C).

- After mixing the INTRON A Powder for Injection, use the solution right away or store the solution in the refrigerator for up to 24 hours between 36°F to 46°F (2°C to 8°C).
- Throw away any medicine left in the vial after you withdraw 1 dose.
- Do not freeze.

Keep INTRON A and all medicines out of the reach of children.

General Information about INTRON A

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use INTRON A for a condition for which it was not prescribed. Do not give INTRON A 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 INTRON A. If you would like more information, ask your healthcare provider. You can ask your healthcare provider or pharmacist for information about INTRON A that was written for health care professionals.

- For more information, go to www.IntronA.com or call 1-800-622-4477.

What are the ingredients in INTRON A?

Active ingredient: interferon alfa-2b

Inactive ingredients:

- **Powder for injection contains:** glycine, sodium phosphate dibasic, sodium phosphate monobasic, human albumin. Sterile water for injection is provided as a diluent.
- **Solution Multidose vials for injection contain:** sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic, edetate disodium, polysorbate 80, and m-cresol as a preservative.

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

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