

INTRON A

Interferon alfa-2b

Consumer Medicine Information

11 July 2006

What is in this leaflet

This leaflet answers some common questions about Intron A. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Intron A against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Intron A is used for

Intron A belongs to a group of medicines called interferons.

Interferons are a family of naturally occurring, small protein molecules. They are produced and secreted by cells in response to viral infections or various synthetic and biological inducers.

Interferons modify the response of the body's immune system to help fight infections, leukaemia and tumours.

Before you use Intron A

When you must not use it:

Do not use Intron A if you are allergic to:

- interferon alfa-2b or any of the ingredients listed at the end of this leaflet.

Do not use Intron A if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

If you are a woman of childbearing age make sure you do not become pregnant while using Intron A.

Do not use Intron A if packaging is torn or shows signs of tampering.

Do not use Intron A after the expiry date (EXP) printed on the pack.

If you use it after the expiry date it may have no effect at all, or worse, an unexpected effect.

If you are not sure whether you should start using Intron A, talk to your doctor.

Before you start to use it

You must tell your doctor:

1. if you are allergic to:

- any other medicines or any food, dyes or preservatives

2. if you have any of these medical conditions:

- heart disease, high blood pressure or you have ever had a heart attack
- poor kidney or liver function
- advanced liver disease
- hepatitis and have been treated recently with medicines that suppress the immune system
- a history of convulsions or mental disorder
- you have ever been treated for depression or any other psychiatric disorder
- a history of autoimmune disease or skin disease (psoriasis)
- a history of diabetes, lung disease or respiratory disease
- thyroid disease or blood clotting disorder

3. you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Be sure to tell your doctor if you are taking theophylline for asthma, as you may need to take different amounts of your medicine.

Use in Children

There is limited experience with the use of Intron A in children. Intron A is not intended for use in premature infants or neonates.

Effect on Fertility

Fertile women should not use Intron A unless effective contraception is used during treatment with Intron A.

Intron A should be used with caution in fertile men.

How to use Intron A

How much to inject

Your doctor has determined the exact schedule according to your needs. Your dose may be adjusted by your doctor during therapy according to your response.

Do not exceed the recommended dosage.

How to inject

Your doctor or nurse will tell you how to give the injection under the skin if you are injecting this medicine yourself.

Intron A can also be injected into a vein. This would normally be carried out by your doctor.

How to use Intron A

Intron A Injectable Solution is available in single dose vials or as a Redipen.

(a) How to use Intron A Solution in Vials

The solution may be injected directly under the skin after withdrawal of the appropriate doses from the vial with a sterile syringe and needle.

(b) How to use Intron A Redipen

Intron A Redipen is a disposable self-injectable dosing system.

For detailed instructions on how to use the Intron A Redipen, please read the insert enclosed in the pack.

The Redipen is designed to deliver 6 doses of Intron A. Each dose is 0.2 mL in volume. The Redipen can be adjusted to increase or decrease the dose, according to your doctor's instruction.

Needles have been provided for use with Intron A Redipen.

You must use a new needle each time a dose is given.

Make sure the Redipen is at room temperature (25°C) before injection. Take the Redipen out of the refrigerator about half-an-hour beforehand to allow the solution contained in the Redipen to reach room temperature.

Dispose of the needle safely after each dose and return the Redipen to the refrigerator immediately.

When to inject

If you are injecting this medicine yourself, use it at bedtime as interferons may cause unusual tiredness (flu-like symptoms).

How long to use it

Do not stop using this medicine without first checking with your doctor. Your doctor will determine when your treatment should be stopped.

If you forget to use it

If it is almost time for your injection, skip the injection you missed and take your next injection when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

Do not take a double injection to make up for the injection that you missed.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

You use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 - Australia or 0800 764 766 - New Zealand) for advice, or go to casualty at your nearest hospital, if you think you or anyone else may have used too much Intron A. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are using Intron A

Things you must do

Use Intron A exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are using Intron A.

Tell your doctor immediately if you become pregnant while you are using Intron A.

Things you must not do

Intron A may cause dizziness and drowsiness in some people. If you become drowsy from this medicine do not drive or use machinery.

Do not use it to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not switch to any other brands of interferon unless advised by your doctor as your response to other interferons may be different.

Things to be careful of

Check with your doctor about drinking alcoholic beverages or taking sleeping pills, sedatives or strong painkillers.

Your doctor may want you to drink extra fluids. This will help prevent low blood pressure while you are using Intron A.

Check with your doctor if you think you are developing symptoms associated with a cold or other respiratory infection.

While receiving Intron A, you may temporarily have a greater risk of getting an infection.

Check with your doctor immediately if you notice unusual bleeding or bruising.

Your blood may temporarily take a longer time to clot.

Tell your doctor if you notice

- any changes in your eyes or eyesight
- worsening psoriasis
- psychiatric symptoms, depression, irritability, aggressive behaviour

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Intron A.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Check with your doctor immediately if any of the following side effects occur:

- an allergic reaction such as hives or difficulty in breathing
- chest pain or irregular heartbeat
- confusion, depression, trouble sleeping, thinking or concentrating
- numbness or tingling sensation
- black or tar-like stools, blood in stool or urine, painful or difficult urination
- severe nosebleed
- fever or chills beginning after a few weeks of treatment

- lower back or side pain
- visual disturbances
- unusual bruising or bleeding

You may need urgent medical attention.

Tell your doctor if you notice any of the following and they worry you:

- flu symptoms including muscle ache, fever, chills and headache
- loss of appetite, taste change or dry mouth
- tiredness, sleepiness or dizziness
- feeling sick, vomiting or diarrhoea
- hair loss
- increased sweating
- irritability
- itching
- low blood pressure

These side effects may go away as your body adjusts to the medicine.

Tell your doctor, if they continue or are severe.

Other side effects not listed above may also occur in some patients.

Check with your doctor as soon as possible if you have any problems while using Intron A even if you do not think the problems are connected with the medicine or the side effects are not listed in this leaflet.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Intron A

Storage

Keep Intron A where children cannot reach it.

Before use: Store in the refrigerator (2° to 8°C). Do not freeze. Do not leave it in the car.

Intron A Injectable Solution:

Single Dose Vials

Use once and discard any residue.

Intron A Redipen:

Return the Redipen to the refrigerator immediately after use.

If you accidentally leave the Redipen outside the refrigerator, the solution will remain stable for a total of 48 hours at room temperature (25°C). Nevertheless, to reduce the chance of microbial contamination, you should try to remember to store the Redipen in the refrigerator at all times between use.

Discard the Redipen 14 days after injecting the first dose.

Disposal

Discard after the last dose is used.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Intron A Injectable Solution is a clear colourless solution.

Intron A Redipen is a plastic injector device containing Intron A Solution for Injection.

Check that you have the correct Intron A Redipen as prescribed by your doctor.

The Intron A Redipen Solution for Injection is available in three different strengths (with each Redipen containing 6 doses):

- the 18 MIU⁻/pen strength has a brown push button and brown colour coding strip (each dose contains 3 MIU of Intron A);
= MIU stands for million international units.
- the 30 MIU/pen strength has a light blue push button and light blue colour coding strip (each dose contains 5 MIU of Intron A);
- the 60 MIU/pen strength has a pink push button and pink colour coding strip (each dose contains 10 MIU of Intron A).

Ingredients

Intron A Solution for Injection

Each vial contains:

- interferon alfa-2b
- sodium phosphate dibasic
- sodium phosphate monobasic
- disodium edetate
- sodium chloride
- polysorbate 80
- water
- m-cresol as preservative

Intron A Redipen

Each Intron A Redipen contains the same ingredients as Intron A Solution.

Manufacturer

In Australia:
Schering-Plough Pty. Ltd.
11 Gibbon Road
Baulkham Hills NSW 2153
AUSTRALIA

In New Zealand:
Schering-Plough a division of Schering-Plough Animal Health Limited
36 Kitchener Street,
Auckland, New Zealand
Phone number (09) 375 9210.

Australian Registration Number

Intron A Injectable Solution

Single dose vials:

10 MIU/1 mL : AUST R 63274

18 MIU/3 mL : AUST R 60021

25 MIU/2.5 mL : AUST R 60024

Intron A Redipen

18 MIU/pen : AUST R 66126

30 MIU/pen : AUST R 66127

60 MIU/pen : AUST R 66128

Date of Preparation

11 July 2006