

## BETAFERON®

Interferon beta-1b

### Consumer Medicine Information

#### WHAT IS IN THIS LEAFLET

This leaflet has been written to provide you with some background information on BETAFERON and how you should use this medicine. Your doctor and pharmacist have detailed information on BETAFERON; they are trained to help you to understand why you are taking this medicine.

Read this information carefully before you start taking BETAFERON. Keep this leaflet in a handy place; you may wish to refer to it again before you have finished taking this medication. Please contact either your doctor, clinic or pharmacist if you have any questions about your treatment with BETAFERON or if you have any problems or difficulties before, during or after taking BETAFERON.

It is important to remember that BETAFERON is a PRESCRIPTION ONLY MEDICINE - you should only use BETAFERON as directed by your doctor.

#### PRODUCT DESCRIPTION

Betaferon is the brand name for a medication containing Interferon beta-1b. Each single pack of Betaferon contains 15 vials of Interferon beta-1b and 15 pre-filled syringes of 0.54% sodium chloride (salt) solution.

Each mL of Interferon beta-1b contains 8 million IU (international units) or 0.25mg, together with the inactive ingredients, human albumin and mannitol.

#### WHAT IS BETAFERON USED FOR AND HOW DOES IT WORK?

Multiple sclerosis (MS) is a disease of the central nervous system (CNS) (i.e. brain and spinal cord) and its exact cause is unknown. An abnormal response by the body's immune system is thought to play an important part in the process which damages the CNS.

Interferon beta-1b has been shown to change the immune system response.

Interferons are part of a group of substances called cytokines, which are naturally occurring proteins.

Betaferon is for use in patients who for the first time have experienced symptoms which indicate a high risk for development of multiple sclerosis. Your doctor will rule out any other reasons which could explain these symptoms before you are treated.

Betaferon is for use in patients who are able to walk and who have relapsing-remitting multiple sclerosis. This is the form of multiple sclerosis where patients experience attacks of CNS problems (for example of visual disturbances, arm/leg weakness, loss of bowel/bladder control) separated by periods of complete or incomplete recovery.

Betaferon is also for use in patients with secondary progressive multiple sclerosis. This is the form of multiple sclerosis where patients progressively experience deterioration of signs and symptoms. In patients with this type of MS Betaferon has been shown to slow down the progression of the disease for up to 12 months. This delay occurred in patients with or without relapses and with all levels of disability.

In people with both types of multiple sclerosis, Betaferon has been shown to reduce how often attacks occur, to decrease the severity of the attacks, to increase the time between attacks and to lower the number of times people need to be hospitalised because of attacks.

Also, Betaferon has been shown to have a marked effect on those physical changes in the brain that can be detected by a special kind of brain scan.

#### BEFORE YOU USE BETAFERON

You must not use Betaferon if:

- you are allergic to interferon beta, human albumin or mannitol

Tell your doctor if:

- you wish to become pregnant while using Betaferon. While using Betaferon women of childbearing age should take appropriate contraceptive measures. If you do become pregnant you should stop your treatment and contact your doctor immediately
- you wish to breastfeed
- you have had any fits or seizures
- have been or are depressed or have had thoughts of suicide
- have any heart problems
- you are taking other medicines used to control attacks of Multiple Sclerosis as use with such medicines (other than prednisone/prednisolone/ACTH) is not recommended
- you are taking any other medicines as care must be taken when Betaferon is used with some other drugs. These drugs include some widely used drugs used to treat fever and pain
- you have any blood disorders
- you have a bone marrow disorder
- you have kidney disease.
- you have thyroid disease
- you have liver disease
- you have had pancreatitis
- you have hypertriglyceridaemia (an elevation in a special type of blood lipid)

What else you should know

- This product contains human albumin and hence carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jacob disease (CJD) also is considered extremely remote.
- It is not known if Betaferon can decrease your ability to have children in the future.
- Your doctor may take blood tests prior to commencing and regularly during treatment with Betaferon to test for changes in your blood count, liver function and thyroid function

#### HOW TO USE BETAFERON PROPERLY

The treatment with Interferon beta-1b should be started under the supervision of a specialist doctor experienced in the treatment of your disease.

The length of treatment will be decided by you and your doctor.

Before administration, the Betaferon solution for injection has to be prepared from a vial of Betaferon and 1.2 mL of liquid from a pre-filled syringe of diluent. 1.0 mL of the prepared Betaferon solution for injection is then injected subcutaneously (under the skin) every other day. This is equal to 8 million IU (0.25 mg).

For those patients who for the first time have experienced symptoms which indicate a high risk for development of multiple sclerosis, treatment should be started at a low dose of 0.25 mL (0.0625 mg). The dose will then be increased slowly to a final dose of 1.0 mL (0.25 mg) which is equal to 8 million IU.

The dose should be increased at every fourth injection in four steps (0.25 mL, 0.5 mL, 0.75 mL, 1.0 mL). The time period for the dose increase may be modified depending on side effects you may experience at the start of treatment. Your doctor will decide this together with you.

Administration will either be done by your doctor or his/her assistant or by yourself after you have been carefully and sufficiently instructed and trained. To assist you in subcutaneous self-administration of Betaferon, detailed instructions for self-injection are set out below. These instructions also tell you how the Betaferon solution for injection is prepared.

To reduce the risk of the injection solution becoming contaminated it should be used as soon as possible after it is prepared. If storage is necessary, keep in the refrigerator (not freezer) at 2 deg C to 8 deg C and use within 3 hours of preparation.

#### Self-injection procedure

The following instructions are intended to explain how to prepare Betaferon for administration and how to proceed in injecting Betaferon yourself. Please read the instructions carefully and follow them step by step. Your doctor or his/her assistant will instruct and assist you in learning the procedure and the technique of self-administration. Do not attempt self-administration until you are sure that you understand the requirements of preparing the injection solution and giving the injection to yourself.

The instructions comprise the following main steps:

1. **Preparing for self-injection.**
2. **Injecting the required volume of diluent (1.2mL) into the vial of Betaferon.**
3. **Drawing up the required volume of the solution for injection (1.0mL) into the syringe.**
4. **Choosing and preparing the injection site and injecting the Betaferon solution (1.0 mL) subcutaneously (under the skin).**

Preparing for self-injection.

1. Collect all your equipment before you begin the process.

You will need:

- pre-filled syringe of diluent for Betaferon (sodium chloride solution 0.54%)
- vial of Betaferon
- 21-gauge needle (for reconstitution)
- orange capped fixed needle syringe (for injection)
- alcohol wipes

- disposal unit (a container for used syringes and needles)
2. Wash your hands thoroughly with soap and water.
  3. Remove the protective cap from the vial of Betaferon.
  4. Use the alcohol wipe to clean the top of the Betaferon vial - move in one direction and use one wipe.

NOTE: Leave the alcohol wipe on top of the vial until you are ready to use it.

#### Injecting the required volume of diluent (1.2 mL) into the vial of Betaferon.

NOTE: Find the Betaferon vial and throw away the alcohol wipe on top of it.

1. Resting your hands on a stable surface, remove the pre-filled diluent syringe from its wrapping. Remove the cap from the base of the pre-filled syringe by pulling. Be careful not to touch the exposed end of the syringe. Do not push the plunger.
2. Take the 21-gauge needle out of its wrapping and place it firmly onto the tip (nozzle) of the syringe. Remove the needle guard from the needle. Do not touch the needle.
3. Holding the Betaferon vial on a stable surface, slowly insert the needle of the syringe (containing 1.2 mL of liquid) all the way through the stopper of the vial.
4. Push the plunger down slowly, directing the needle toward the side of the vial to allow the liquid to run down the inside wall (injecting diluent directly onto the powder will cause excess foaming).
5. Make sure that the needle does not come into contact with the powder or the resulting solution.
6. After the diluent in the syringe has been completely injected into the Betaferon vial, withdraw the diluent syringe and needle and dispose of in the disposal unit.
7. Hold the vial between your thumb, forefinger and middle finger and gently rotate your hand to completely dissolve the white powder of Betaferon. **DO NOT SHAKE !**
8. Look closely at the solution (it should be clear).

NOTE: If the mixture contains particles or is discoloured, throw it away and start again.

#### Drawing up the required volume of the solution for injection (1.0 mL) into the orange capped injection syringe.

1. Remove the orange capped syringe from its wrapping. Remove the orange cap. Do not touch the needle.
2. Holding the Betaferon vial on a stable surface, slowly insert the needle through the stopper into the vial containing the reconstituted Betaferon.
3. Turn the vial upside down and hold the syringe with the needle pointing upward.

NOTE: Keep the needle tip in the liquid.

4. Pull back the plunger to withdraw liquid to the 100unit ( 1 mL) mark on the syringe.
5. Keep the vial upside down and hold the syringe with the needle pointing upward.
6. Tap the syringe gently until any air bubbles rise to the top of the barrel of the syringe.
7. Carefully push in the plunger to eject ONLY THE AIR through the needle.
8. Withdraw the needle from the vial. Make sure the needle does not touch any surface.
9. Throw away unused portion of the solution remaining in the vial.

NOTE: The injection should be administered immediately after mixing (if the injection is delayed, refrigerate the solution and inject it within 3 hours). Do not freeze.

#### Choosing and preparing the injection site and injecting the Betaferon solution (1.0 mL) subcutaneously (under the skin).

1. Choose an injection site (see enclosed medication record card with an injection site diagram); you may want to hold the syringe like a pencil or dart. Use a different site each day you inject:
  - Arms (upper back portion)
  - Abdomen (except around navel and waistline)
  - Buttocks
  - Thighs (front and sides except at groin and knee)

NOTE: Do not use any areas in which you feel lumps, firm knots, or pain. Do not use any area in which the skin is discoloured, depressed, scabbed or has broken open. Talk to your doctor or health care professional about anything you find.

2. Use an alcohol wipe to clean the skin at the injection site; let it air dry.
3. Throw away the wipe.
4. Take the syringe with the needle on it. . Make sure not to touch the needle.
5. Gently pinch the skin together around the site (to lift it up a bit).
6. Resting your wrist on the skin near the site, stick the needle straight into the skin at a 90 deg angle with a quick, firm motion.
7. Inject the drug by using a slow steady push (push the plunger all the way in until the syringe is empty).
8. Hold a swab on the injection site. Remove the needle from the skin.
9. Gently massage the injection site with a dry cotton ball or gauze.
10. Throw away the syringe and the needle in the disposal unit.

#### INJECTION SITE

##### Picking an injection site

Betaferon (Interferon beta-1b) therapy should be injected into subcutaneous (under the skin) tissue. The best areas for injection are loose and soft (flabby), away from joints and nerves.

Each therapy day you can choose an injection site from the ones identified in the diagrams. It's a good idea to know where your injection will be given before you prepare your syringe.

If there are any sites that are difficult for you to reach, you can ask your support person (or someone who has been trained to give injections) to help you.

##### Rotating injection sites

Changing sites each time helps prevent injection reactions: it gives the site time to "bounce back" from the last injection. Today's injection should not be given in the same areas as the last one. Keep a record of where and when you last gave yourself an injection. One way to do that is to note this information on the enclosed medication record card.

You may use a site again after waiting 1 week. If all areas become tender, talk to your doctor about choosing other injection sites.

#### OVERDOSE

If you are concerned that you have given yourself too much Betaferon, contact your doctor or the Poisons Information Centre (13 11 26) for recommendations on the management and treatment of overdose.

#### WHEN USING BETAFERON

##### Tell your doctor immediately if:

- You experience depression or suicide thoughts.
- If you experience symptoms like irregularity of your heart beats or fluid retention (swelling) in the lower parts of your body (eg ankles, legs) or shortness of breath, These may be symptoms of a disease of the heart muscle, which has been reported in rare cases during treatment with Betaferon.
- You think you may be pregnant. Betaferon use must be stopped immediately.
- You suffer from severe hypersensitivity reactions such as difficulty in breathing, hives, shock.

##### Tell your doctor if:

- You suffer from signs of frequent infections such as fever or sore throat
- You notice a yellowish change in the colour of your skin (jaundice)

#### SIDE EFFECTS

As with any other medicine, some side effects may occur, some more severe than others.

The most common side effects are:

- Flu-like symptoms (fever, chills, muscular pain, headache, tiredness, painful joints, a general feeling of being unwell, or sweating) These are usually worst at the start of treatment but become less of a problem over time. These flu-like symptoms occur much less often if paracetamol or ibuprofen is taken when the injection is given.
- Injection site reactions. These may be reduced by administration with an autoinjector. Please consult your doctor for further information.

Other relatively common side effects include:

- Redness, swelling, discolouration, pain, allergy, skin cell-death where the injection was given. These tend to be worst at the start of treatment and become less of a problem over time. If you experience multiple skin sores, very severe sores or breakage of the skin associated with swelling or drainage of fluid from the injection site you should discuss this with your doctor. It may be necessary to stop using Betaferon until these are healed.
- Rash, itchiness, urticaria (hives), skin discolouration, sweating.
- Nausea, vomiting, diarrhoea, constipation, abdominal pain.
- Dizziness, anxiety, nervousness.
- Infected sinus.
- Conjunctivitis.

##### Less common side effects include:

- Migraine.
- Palpitations.
- High blood pressure.
- Menstrual period upsets.

- Depression, emotional instability, convulsions (fits), suicide attempts, and confusion.
- Blood disorders.
- Muscle pain and stiffness.
- Muscle weakness
- Shortness of breath, wheeze.
- Chest pain.
- Pelvic pain
- Abnormal vision
- Back pain
- Fast heart beat

**In very rare cases the following side effects have occurred:**

- Disease of the heart muscle.
- When Betaferon has been given to patients who have a very rare disease where abnormal proteins are found in the blood there have been problems with small blood vessels leading to collapse and even death.
- Loss of scalp hair.
- Serious allergic reactions.
- Disturbances of the thyroid gland.
- Hepatitis, liver failure.
- Cystitis
- Breast pain
- joint pain
- Menorrhagia (heavy menstruation)
- Infection
- Insomnia
- Urinary disorders
- Anorexia
- Convulsion
- Changes in weight

The above lists provide information on the most serious and most common side effects which have been reported with Betaferon. Other side effects may occur. If side effects are severe or if you notice any other side effects please tell your doctor.

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## STORAGE

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Store Betaferon below 25 deg C before reconstitution. If, after reconstitution, you do not inject Betaferon at once, you can store the reconstituted solution in the refrigerator for up to 3 hours. However, once you have given the injection, you should throw any unused portion away.

Please note the expiry date on the pack. Do not use after this date or if the contents do not look right.

Store all drugs properly and keep them out of the reach of children.

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## WHERE TO GO FOR FURTHER INFORMATION

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Should you wish to discuss any aspect of Betaferon, you should contact your doctor or pharmacist.

### AUSTRALIAN REGISTRATION NUMBER

AUST R 83309

### DATE OF REVISION

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## SPONSOR

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