BONSPRI®

Ofatumumab (20 mg) Solution for Injection in pre-filled syringe

What is in this leaflet

What Bonspri is used for

Bonspri is used for the treatment of adult with relapsing forms of multiple sclerosis includes relapsing-remitting disease, and active secondary progressive disease.

Multiple sclerosis (MS) is a long-term condition that affects the central nervous system (CNS), particularly how the brain and spinal cord work. In MS, the immune system (the body's defense system) works incorrectly: inflammation destroys the protective sheath (called myelin) around the nerves in the CNS and stops the nerves from working properly. This process is called demyelination.
People with relapsing MS experience repeated attacks of nervous system symptoms that reflect inflammation within the CNS. These attacks are typically called relapses or flare ups. Symptoms vary from patient to patient but typically involve problems with walking or balance, weakness, numbness, vision problems (double vision and blurring), poor coordination and bladder problems. The symptoms of a relapse may disappear completely when the relapse is over but some problems may remain. Patients accumulate disability as a result of incomplete recovery from acute relapses and/or gradual disease progression.

How Bonspri works

The active substance in Bonspri, ofatumumab is a type of protein called a monoclonal antibody designed to recognize and attach to a target called CD20 on the surface of certain types of white blood cells which are part of the immune system (so called B-cells).

Once an abnormal response by the body's immune system is triggered, these white blood cells play a role in multiple sclerosis by attacking the sheaths around the nerves in the brain and spinal cord, causing inflammation and damage. By targeting and removing the B-cells, Bonspri helps to reduce their activity and thereby reduces the chance of having a relapse, relieves symptoms and slows down the progression of the disease.
In controlled clinical studies in patients with relapsing forms of MS, Bonspri cut down significantly the number of attacks, significantly prolonged the time without relapses and slowed down the progression of the disease. The average number of relapses in patients treated with Bonspri was a little bit more than half in comparison to patients treated with another MS medicine teriflunomide. Bonspri significantly reduced the blood levels of a biological indicator (so called neurofilament light chain). Increased levels in the blood of this indicator is associated with damage of brain cells.

If you have any questions about how Bonspri works or why this medicine has been prescribed for you, ask your doctor, your pharmacist or your healthcare provider.

Before you use Bonspri

- Before you start to use it

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

Do not use Bonspri

If you are allergic to Bonspri as confirmed by your doctor.

Warnings and precautions

Before initiation of treatment with Bonspri

Talk with your doctor before initiation of treatment with Bonspri:

- **Your doctor will check if you are at risk of hepatitis B infection** before initiation of treatment with Bonspri. All patients will have a blood test and patients who have had hepatitis B or are carriers of the hepatitis B virus will be referred to a specialized doctor. Bonspri may cause the hepatitis B virus to become active again.
- **Before you start treatment with Bonspri,** your doctor may check your immune system.
- **If you have an infection** before initiation of treatment with Bonspri, your doctor may decide that you cannot receive Bonspri or may delay your treatment with

Bonspri until the infection is resolved.

- **If you plan to receive a vaccine,** you should receive your vaccines at least 4 weeks prior to starting Bonspri for live or live-attenuated vaccines and at least 2 weeks prior to starting Bonspri for the other vaccines. You should not receive certain types of vaccines (live or live-attenuated vaccines) during treatment with Bonspri. For the other vaccines, they can be less effective if administered during treatment with Bonspri.

- Taking other medicines (interactions with other medicinal products including vaccines or biologics)

Before you take Bonspri, tell your doctor or pharmacist if you are taking any of the following medicines:

- **Medicines that suppress or modulate the immune system including other medicines used to treat MS** such as ocrelizumab, cladribine, fingolimod, natalizumab, teriflunomide, mitoxantrone, or dimethyl fumarate ~~d~~due to a possible added effect on the immune system.
- **Vaccines.** If you need to receive a vaccine, seek your doctor's advice first. During treatment with Bonspri, administration of some vaccines containing live virus (live-attenuated vaccines for example BCG for tuberculosis or vaccines against yellow fever) may result in infection (see section Before you use Bonspri- Before you start to use it).

Children and adolescents (below 18 years)

Bonspri has not been studied in patients below 18 years.

Older people (65 years or above)

You can use Bonspri if you are aged 65 years or over at the same dose as younger adults.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will discuss with you the potential risks of taking Bonspri during pregnancy. This is because Bonspri can reduce immune cells (B-cells) in the mother and unborn baby.

Talk with your doctor before breast-feeding while you use Bonspri. Bonspri can pass into breast milk in small amounts. Ask and discuss with your doctor about the benefits and the risks of breast-feeding your baby while you use Bonspri.

Talk with your doctor before vaccinating your newborn.

Ask your doctor or pharmacist for advice before vaccinating your newborn, if you have used Bonspri during your pregnancy (see section taking other medicines-vaccines)

Females of child-bearing potential

You should avoid becoming pregnant while taking Bonspri and for 6 months after you stop taking it. Bonspri may harm your unborn baby. Female patients who might become pregnant should use effective birth control methods during treatment and for 6 months after stopping Bonspri. Ask your doctor about options of effective birth control.

If you become pregnant or think you are pregnant, tell your doctor right away. You and your doctor will decide what is best for you and your baby.

How to use Bonspri

Bonspri is given by subcutaneous injection (injection under the skin). See Instruction for Use at the end of this leaflet for the details.

- How much to use

- The initial dosing is 20mg Bonspri administered by subcutaneous injection at weeks 0, 1 and 2. There is no injection at week 3.
- Starting at week 4 and then every month, the recommended dose is 20mg Bonspri administered by subcutaneous injection.

Dosage regimen with subcutaneous injection of Bonspri

Time	Dose
Week 0 (beginning of treatment)	20 mg
Week 1	20 mg
Week 2	20 mg
Week 4	20 mg
Every month (starting from week 4)	20 mg

- When to use it

You can use Bonspri at any time (morning, afternoon, evening) for the scheduled dose.

- How long to use it

Continue using Bonspri every month for as long as your doctor tells you.

This is a long-term treatment, possibly lasting for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you have questions about how long to use Bonspri, talk to your doctor or your pharmacist or healthcare provider.

- If you forget to use it

If an injection of Bonspri is missed, it should be administered as soon as possible. Do not wait until the next scheduled dose. The treatment interval as recommended should be maintained for the following doses. To get the full benefit of Bonspri, it is important that you receive each subcutaneous injection when it is due.

- If you use too much (overdose)

If you have used too much Bonspri at one time, or if you have used a first dose of Bonspri by mistake, contact your doctor right away.

While you are using it

- Things you must do

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose prescribed by your doctor.

After the initiation of treatment with Bonspri

Tell your doctor during your treatment with Bonspri:

- **If you have injection-related reactions or injection site reactions.** Injection-related reactions (general) and injection site reactions (local) are the most common side effects of Bonspri treatment (see Side Effects for the list). They generally occur after the first subcutaneous injection of Bonspri and up to 24 hours after the injection. The first subcutaneous injection should take place under the guidance of a healthcare professional.
- **if you have an infection.** Any infection that you already have may get worse. Infections could be serious and sometimes life-threatening.
- **if you have a lowered immune response** (due to a disease or medicines that suppress the immune system, see "Taking other medicines"). You may get infections more easily or an infection you already have may get worse. This is because the immune cells that Bonspri targets also help to fight infection.

Tell your doctor immediately, if you get any of the following symptoms or diseases **during your treatment** with Bonspri, because it could be serious:

- if you have rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue or throat, chest tightness, feeling faint. If any of these signs and symptoms become worse or you have new severe signs of reactions after subsequent injections, which could be a sign of allergic reaction.
- if you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms, because these may be the symptoms of a rare brain disorder caused by infection and called progressive multifocal leukoencephalopathy (PML).

-Things you must not do

Do not exceed the recommended dose prescribed by your doctor.

Do not stop using Bonspri or change your dose without talking with your doctor.

Some side effects can be related to having low level of B-cells in your blood. After you stop Bonspri your blood B-cells count will gradually increase to normal levels. This can take several months. During this time some side effects described in this leaflet may still occur.

- Things to be careful of

See Warnings and precautions and Things you must do after initiating treatment.

Side effects

As with all medicines, patients treated with Bonspri may experience side effects, although not everybody gets them.

Side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacists or healthcare provider.

Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Very common: *may affect more than 1 in 10 people*

- Upper respiratory tract infection with symptoms such as sore throat and runny nose
- Injection site reactions (local) such as redness, pain, itching and swelling at the injection site
- Injection-related reactions (general) such as fever, headache, muscle pain, chills and tiredness.

Common: *may affect up to 1 in every 10 people*

- Decrease in a specific protein in the blood (immunoglobulins M) which help protect against infection.

Not known: *frequency cannot be estimated from the available data*

- Allergic reactions

- Liver damage: Possible signs and symptoms of liver damage may include yellowing of the skin and eyes, nausea, vomiting, unusual darkening of the urine, feeling tired or weak.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Bonspri

- Storage

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date, which is stated on the carton.
- Store between 2 to 8°C. Keep in the original package.
- If necessary, Bonspri can be left out of the refrigerator for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, Bonspri can then be returned to the refrigerator for a maximum of 7 days.

- Disposal

Ask your pharmacist how to dispose of medicines you no longer use.

Product Description

- What it looks like

Bonspri is supplied as 20mg/0.4mL pre-filled syringe.

The single-use solution for injection is sterile, preservative-free, clear to slightly opalescent, and colorless to slightly brownish-yellow.

- Ingredients

- Active ingredient:
Ofatumumab
- Inactive ingredients
L-arginine, sodium acetate trihydrate, sodium chloride, polysorbate 80, disodium edetate dihydrate, hydrochloric acid and water for injection.

Instructions for Use of Bonspri

Be sure that you read, understand, and follow these "Instructions for Use" before injecting Bonspri. Talk to your healthcare provider if you have any questions before you use Bonspri for the first time.

Remember:

- **Do not use** the Bonspri pre-filled syringe if either the seal on the outer carton or the seal of the blister is broken. Keep the Bonspri pre-filled syringe in the sealed carton until you are ready to use it.
- **Do not shake** the Bonspri pre-filled syringe.
- The pre-filled syringe has a needle guard that will be activated to cover the needle after the injection is finished. The needle guard will help to prevent needle stick injuries to anyone who handles the pre-filled syringe after injection.
- Do not remove the needle cap until just before you give the injection.
- Avoid touching the syringe guard wings before use. Touching them may cause the needle guard to be activated too early.
- Do not use if the pre-filled syringe has been dropped onto a hard surface or dropped after removing the needle cap.
- Throw away (dispose of) the used Bonspri pre-filled syringe right away after use. **Do not re-use a Bonspri pre-filled syringe**. See "**How should I dispose of used Bonspri pre-filled syringe?**" at the end of these "Instructions for Use".

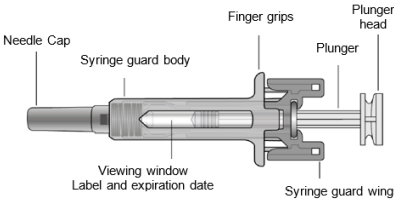
How should I store Bonspri?

- Store your carton of the Bonspri pre-filled syringe in a refrigerator, 2°C to 8°C.
- Keep the Bonspri pre-filled syringe in the original carton until ready to use to protect from light.
- **Do not freeze** the Bonspri pre-filled syringe.
- If necessary, Bonspri pre-filled syringe can be left out of the refrigerator for a single period of up to 7 days at room temperature (not above 30°C). If not used during this period, Bonspri pre-filled syringe can then be returned to the refrigerator for a maximum of 7 days.

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

Bonspri pre-filled syringe parts (see Figure A):

Figure A



What you need for your injection:

Included in the carton:
A new Bonspri pre-filled syringe.

Not included in the carton (**see Figure B**):

- 1 alcohol wipe
- 1 cotton ball or gauze
- Sharps disposal container

See "**How should I dispose of used Bonspri pre-filled syringes?**" at the end of these "Instructions for Use".

Figure B

Prepare the Bonspri pre-filled syringe

Step 1. Find a clean, well-lit, flat work surface.

Step 2. Take the carton containing the Bonspri pre-filled syringe out of the refrigerator and leave it **unopened** on your work surface for about 15 to 30 minutes so that it reaches room temperature.

Step 3. Wash your hands well with soap and water.

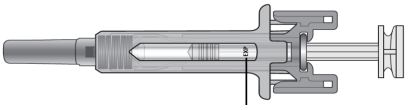
Step 4. Remove the pre-filled syringe from the outer carton and take it out of the blister by holding the syringe guard body.

Step 5. Look through the viewing window on the pre-filled syringe. The liquid inside should be clear to slightly cloudy. You may see a small air bubble in the liquid, which is normal. **Do not use** the pre-filled syringe if the liquid contains visible particles or is cloudy.

Step 6. **Do not use** the pre-filled syringe if it is broken. Return the pre-filled syringe and the package it came in to the pharmacy.

Step 7. **Do not use** the pre-filled syringe if the expiration date has passed (**see Figure C**). Return the expired pre-filled syringe and the package it came in to the pharmacy.

Figure C



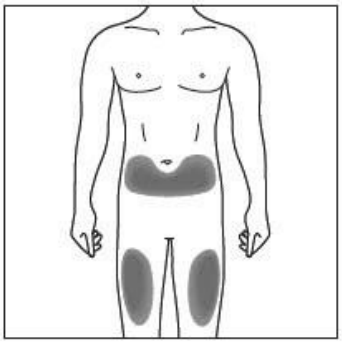
Choose and clean the injection site

•Areas of your body that you may use as injection sites include:

•the front of your thighs (**see Figure D)**

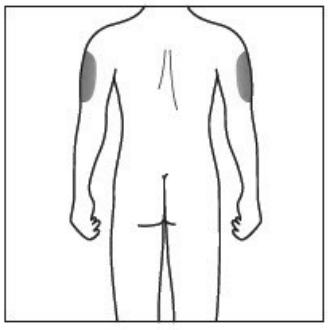
•the lower stomach-area (abdomen), but not the area five cm (2 inches) around your navel (belly button) (**see Figure D)**

Figure D



•your upper outer arms, if a healthcare provider or caregiver is giving you the injection (**see Figure E**).

Figure E
(Caregiver and healthcare provider only)



•Choose a different site each time you inject Bonspri.

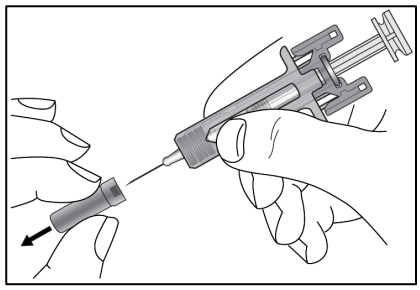
•**Do not inject** into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

Step 8. Using a circular motion, clean the injection site with the alcohol wipe. Leave it to dry before injecting. Do not touch the cleaned area again before injecting.

Giving your injection

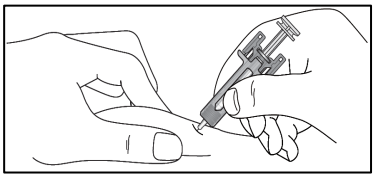
Step 9. Carefully remove the needle cap from the pre-filled syringe (see **Figure F**). Throw away the needle cap. You may see a drop of liquid at the end of the needle. This is normal.

Figure F



Step 10. With one hand, gently pinch the skin at the injection site. With your other hand insert the needle into your skin as shown (see **Figure G**). Push the needle all the way in to make sure that you inject your full dose.

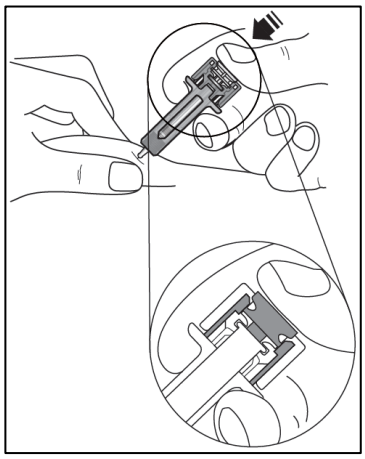
Figure G



Step 11. Hold the pre-filled syringe finger grips as shown (see **Figure H**). Slowly press down on the plunger as far as it will go, so that the plunger head is completely between the syringe guard wings.

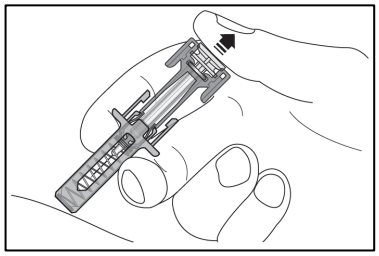
Step 12. Continue to press fully on the plunger for an additional 5 seconds. Hold the syringe in place for the full 5 seconds.

Figure H



Step 13. **Slowly** release the plunger until the needle is covered (see **Figure I**), and then remove the syringe from the injection site.
Step 14. There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

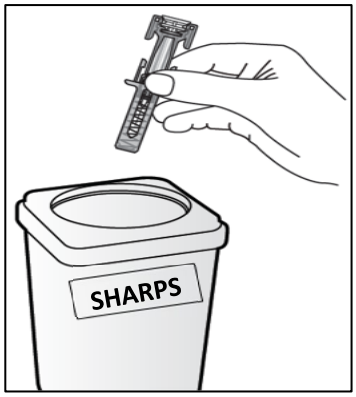
Figure I



How should I dispose of used Bonspri pre-filled syringe?
Step 15. Dispose of your used pre-filled syringe:
•Dispose of the used pre-filled syringe in a sharps disposal container (i.e. a puncture-resistant closable container, or similar) (see **Figure J**).
•**Do not throw away (dispose of)** your used pre-filled syringe in your household trash.
•Never try to reuse your pre-filled syringe.

Keep the sharps container out of the reach of children.

Figure J



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