

BONSPRI®

20 mg ofatumumab solution for injection (0,4 mL of 50 mg/mL solution)

Patient Information Leaflet

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BONSPRI® 20 mg solution for injection in pre-filled syringe

Ofatumumab

Read all of this leaflet carefully before you start using BONSPRI

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.**
- **BONSPRI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

1. What BONSPRI is and what it is used for
2. What you need to know before you use BONSPRI
3. How to use BONSPRI
4. Possible side effects
5. How to store BONSPRI
6. Contents of the pack and other information

1. What BONSPRI is and what it is used for

What BONSPRI is

BONSPRI contains the active substance ofatumumab. Ofatumumab belongs to a group of medicines called monoclonal antibodies.

What BONSPRI is used for

BONSPRI is used to treat adults with relapsing forms of multiple sclerosis (MS).

How BONSPRI works

BONSPRI works by attaching to a target called CD20 on the surface of B cells. B cells are a type of white blood cell which are part of the immune system and which play a role in multiple sclerosis.

BONSPRI targets and removes the B cells and thereby reduces the chance of having a relapse, relieves symptoms and slows down the progression of the disease.

2. What you need to know before you use BONSPRI

Do not use BONSPRI

- if you are allergic to ofatumumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Before starting BONSPRI

- Your doctor will check if you are at risk of hepatitis B infection by performing a blood test. If this shows that you have had hepatitis B or are a carrier of the hepatitis B virus, your doctor will refer you to a specialist. BONSPRI may cause the hepatitis B virus to become active again.
- Your doctor may check your immune system.
- If you have an infection, your doctor may decide that you cannot be given BONSPRI or may delay your treatment with BONSPRI until the infection is resolved.
- Your doctor will check if you need any vaccinations before you start your treatment with BONSPRI. If you need a type of vaccine called a live or live-attenuated vaccine, this should be given at least 4 weeks before you start BONSPRI treatment. Other types of vaccine should be given at least 2 weeks before you start BONSPRI treatment.

While using BONSPRI

Tell your doctor:

- if you have a general injection-related reaction or a local injection-site reaction. These are the most common side effects of BONSPRI treatment and are described in section 4. They usually occur in the 24 hours following injection of BONSPRI, in particular after the first injection, and the first injection should therefore be administered under the guidance of a healthcare professional.
- if you have an infection. 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. Infections could be serious and sometimes even life-threatening.
- if you plan to have any vaccinations. Your doctor will advise you on whether the vaccination you need is a live vaccine, a live-attenuated vaccine, or another type of vaccine. You should not be given live or live-attenuated vaccines during treatment with BONSPRI as this may result in infection. Other types of vaccine can be less effective if administered during treatment with BONSPRI.

Tell your doctor straight away if you get any of the following during your treatment with BONSPRI, because it could be serious:

- if you believe your multiple sclerosis is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms. This may indicate a rare brain disorder caused by infection called progressive multifocal leukoencephalopathy (PML).

Children and adolescents

Do not give this medicine to children and adolescents below 18 years of age because BONSPRI has not yet been studied in this age group.

Other medicines and BONSPRI

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

In particular, tell your doctor or pharmacist:

- if you are taking, have recently taken or might take 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. This is because these may have an added effect on the immune system.

- if you plan to have any vaccinations (see "Warnings and precautions" above).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnancy

You should avoid becoming pregnant while using BONSPRI and for 6 months after you stop using it.

If you do become pregnant during treatment or think you may be pregnant, tell your doctor straight away. Your doctor will discuss with you the potential risks of using BONSPRI during pregnancy. This is because BONSPRI can reduce the number of immune cells (B cells) in both the mother and the unborn baby.

If there is a possibility that you could become pregnant, you should use an effective birth control method during treatment and for 6 months after stopping BONSPRI. Ask your doctor about the available options.

Breastfeeding

BONSPRI can pass into breast milk. Talk to your doctor about the benefits and risks before breastfeeding your baby while using BONSPRI.

Vaccination of newborn babies

Ask your doctor or pharmacist for advice before vaccinating your newborn if you have used BONSPRI during your pregnancy (see “Warnings and precautions” above).

Driving and using machines

BONSPRI is unlikely to affect your ability to drive and use machines.

3. How to use BONSPRI

Do not share medicines prescribed for you with any other person.

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

How much BONSPRI to use and how often to use it

Do not exceed the dose prescribed by your doctor.

- The initial dose is 20 mg 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 20 mg 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

If you get the impression that the effect of BONSPRI is too strong or too weak, tell your doctor or pharmacist.

What time of day to use BONSPRI

You can use BONSPRI at any time of day (morning, afternoon or evening).

How to use BONSPRI

BONSPRI is given by subcutaneous injection (injection under your skin).

The first injection should be administered under the guidance of a healthcare professional.

BONSPRI pre-filled syringes are for single use only.

Instructions for use of BONSPRI pre-filled syringe

It is important that you read, understand, and follow these instructions for use before injecting

BONSPRI. Talk to your doctor, pharmacist or nurse 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 needlestick 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.
- Dispose of the used BONSPRI pre-filled syringe immediately after use. **Do not re-use a BONSPRI pre-filled syringe.**

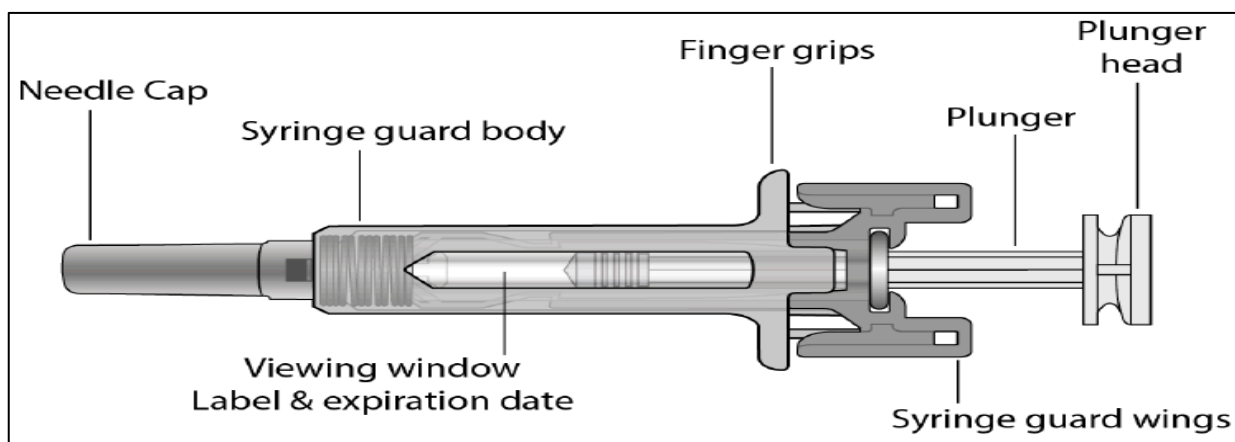
How should I store BONSPRI?

- Store the BONSPRI pre-filled syringe carton in a refrigerator between 2 °C and 8 °C.
- If necessary, BONSPRI may be stored unrefrigerated 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.
- 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.

Keep BONSPRI out of the sight and reach of children.

BONSPRI pre-filled syringe parts (see Picture A):

Picture A



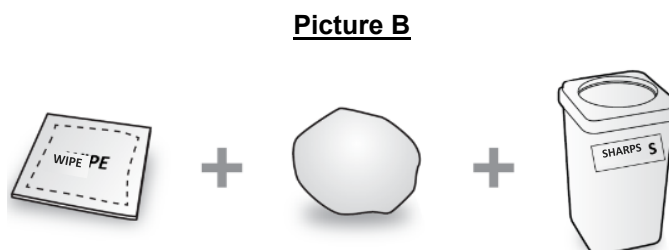
What you need for your injection:

Included in the carton:

- A new BONSPRI pre-filled syringe.

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

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



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.

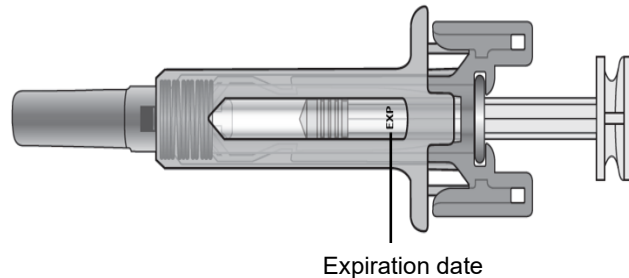
Step 4. Remove the pre-filled syringe from the outer carton and take it out of the blister by holding the syringe guard body.

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 expiry date has passed (**see Picture C**). Return the expired pre-filled syringe and the package it came into the pharmacy.

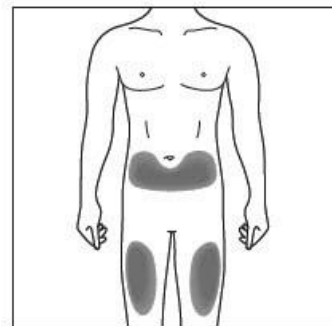
Picture C



Choose and clean the injection site

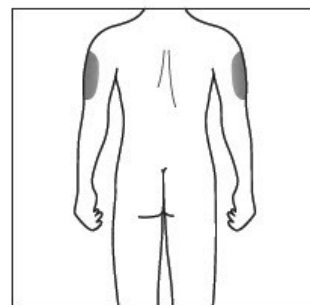
- Areas of your body that you may use as injection sites include:
 - the front of your thighs (**see Picture D**)
 - the lower stomach-area (abdomen), but not the area five cm around your navel (belly button) (**see Picture D**)
 - your upper outer arms, if a healthcare provider or caregiver is giving you the injection (**see Picture E**).
- Choose a different site each time you inject BONSAPRI.
- **Do not inject** into areas where the skin is tender, bruised, red, scaly, or hard. Avoid areas with scars or stretch marks.

Picture D



Picture E

(Caregiver and healthcare provider only)

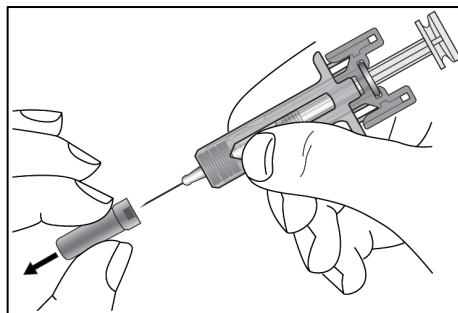


Step 8. Using a circular motion, clean the injection site with the alcohol wipe. Leave it to dry before injecting. Do not touch the cleaned area again before injecting.

Giving your injection

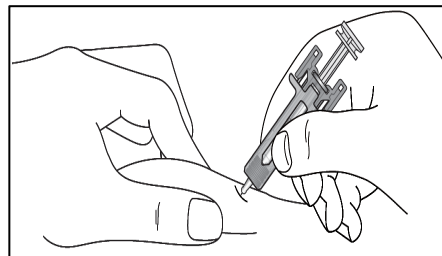
Step 9. Carefully remove the needle cap from the pre-filled syringe (**see Picture F**). Throw away the needle cap. You may see a drop of liquid at the end of the needle. This is normal.

Picture F



Picture G

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 Picture G**). Push the needle all the way in to make sure that you inject your full dose.



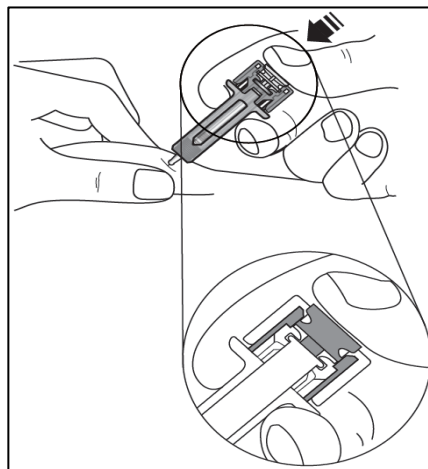
Step 11. Hold the pre-filled syringe finger grips as shown (see **Picture H**). Slowly press down on the plunger as far as it will go, so that the plunger head is completely between the syringe guard wings.

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

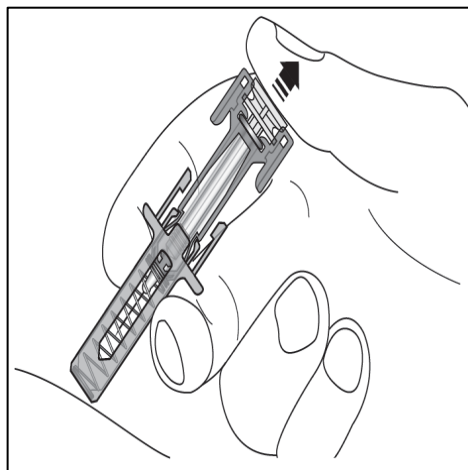
Step 13. **Slowly** release the plunger until the needle is covered (see **Picture I**), and then remove the syringe from the injection site.

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.

Picture H



Picture I

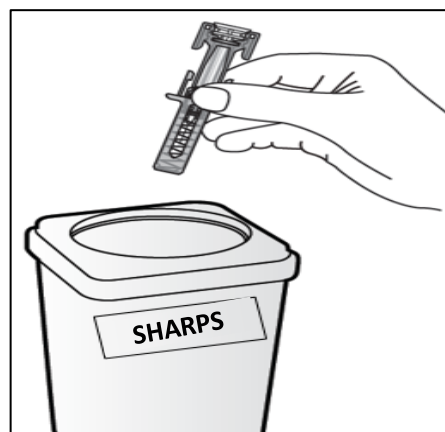


How should I dispose of used BONSPRI pre-filled syringe?

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 Picture J**).
- **Do not dispose of** your used pre-filled syringe in your household trash.
- Never try to reuse your pre-filled syringe.

Picture J



Keep the sharps container out of the reach of children.

How long to use BONSPRI

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 check your condition to determine whether the treatment is having the desired effect.

If you have questions about how long to use BONSPRI, talk to your doctor, pharmacist or nurse.

If you use more BONSPRI than you should

If you have injected too much BONSPRI, contact your doctor right away.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use BONSPRI

To get the full benefit of BONSPRI, it is important that you administer each injection when it is due.

If you realise that you have forgotten an injection of BONSPRI, inject yourself as soon as possible.

Do not wait until the next scheduled dose. The timing of future injections should then be calculated from the day you administered the missed injection and not based on the original schedule (see also “How much BONSPRI to use and how often to use it” above).

If you stop using BONSPRI

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

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

BONSPRI can have side effects.

Not all side effects reported for BONSPRI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BONSPRI, please consult your health care provider for advice.

The side effects of BONSPRI are listed below. Most are mild to moderate and will generally disappear after a few days to a few weeks of treatment. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse.

Very frequent side effects

- upper respiratory tract infection, with symptoms such as sore throat and runny nose
- injection-site reactions, such as redness, pain, itching and swelling at the injection site
- injection-related reactions, such as fever, headache, muscle pain, chills and tiredness
- decrease in the blood level of a specific protein called immunoglobulin M, which helps protect against infection

Frequent side effects

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BONSPRI.

5. How to store BONSPRI

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Keep the syringe(s) in the outer carton in order to protect from light. Store in a refrigerator (2 °C - 8 °C). Do not freeze.

If necessary, BONSPRI may be stored unrefrigerated 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.

Do not use this medicine if you notice that the solution contains visible particles or is cloudy.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What BONSPRI contains

- The active substance is ofatumumab. Each pre-filled syringe contains 20 mg ofatumumab.
- The other ingredients are L-arginine, sodium acetate trihydrate, sodium chloride, polysorbate 80, disodium edetate dihydrate, hydrochloric acid (for pH adjustment) and water for injections.

What BONSPRI looks like and contents of the pack

BONSPRI solution for injection is clear to slightly opalescent, and colourless to slightly brownish-yellow.

BONSPRI is available in unit packs containing 1 pre-filled syringe and in multipacks containing 3 (3 packs of 1) pre-filled syringes.

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

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