

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

BILDYOS (*bil-di-os*)

denosumab injection

This patient medication information is written for the person who will be taking **BILDYOS**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about BILDYOS, talk to a healthcare professional.

BILDYOS is a biosimilar biologic drug (biosimilar) to the reference biologic drug Prolia. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What BILDYOS is used for:

- Treatment of osteoporosis (thinning and weakening of the bone) in women after menopause who
 - have an increased risk for fractures or;
 - cannot use other osteoporosis medicines, or other osteoporosis medicines did not work well.
- to increase bone mass in men with osteoporosis at high risk for fracture.
- to increase bone mass and may reduce fractures that occur when medication to reduce testosterone levels are taken for the treatment of prostate cancer that has not spread to other parts of the body (nonmetastatic).
- to increase bone mass in women who are receiving certain treatments for breast cancer, which has not spread to other parts of the body (nonmetastatic) and at high risk of fracture.
- to increase bone mass to treat osteoporosis in both women and men at high risk for fracture related to the use of corticosteroid medicines, such as prednisone.
- to increase bone mass to prevent osteoporosis in both women and men at high risk for fracture related to starting corticosteroid medicines, such as prednisone.

How BILDYOS works:

BILDYOS works differently than other osteoporosis medications. It is a RANK ligand inhibitor. RANK ligand is a protein which activates the cells that break down bone (osteoclasts). BILDYOS blocks RANK ligand to stop the cells that break down bone. This action strengthens your bones by increasing bone mass and lowers the chance of breaking bones of the hip, spine, and nonspinal sites.

The ingredients in BILDYOS are:

Medicinal ingredient: denosumab

Non-medicinal ingredients: Acetic acid, polysorbate 20, sodium hydroxide, sorbitol, and water for injection. The prefilled syringe is not made with natural rubber latex. BILDYOS is citrate-free.

BILDYOS comes in the following dosage forms:

BILDYOS is a liquid for injection, available in vial and in prefilled syringe with safety guard.

Do not use BILDYOS if:

- you are allergic to denosumab or any other ingredient of BILDYOS. Allergic reactions (e.g., rash, hives, or in rare cases, swelling of the face, lips, tongue, throat, or trouble breathing) have been reported.
- you have low calcium levels in your blood (hypocalcemia).
- you are less than 18 years of age (see also **What BILDYOS is used for** above and **Other warnings you should know about** below).
- you are pregnant or breastfeeding.
- you are a woman before menopause [unless you have been diagnosed with breast cancer or are taking BILDYOS for the treatment or prevention of osteoporosis related to the use of corticosteroid medicines (see also **What BILDYOS is used for** above and **Other warnings you should know about** below)].
- you are currently taking other denosumab-containing medicinal products.
- you do not have access to a health professional or trained injector.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BILDYOS. Talk about any health conditions or problems you may have, including if you:

- have low blood calcium.
- cannot take daily calcium and vitamin D.
- had parathyroid or thyroid surgery (glands located in your neck).
- have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome).
- have kidney problems or are on kidney dialysis.
- have ever had an allergic reaction to BILDYOS.
- plan to have dental surgery or teeth removed.
- have a history of cancer.
- are pregnant or could become pregnant.

BILDYOS may interfere with normal bone and tooth development in fetuses, nursing babies, and children under 18 years of age. BILDYOS is not indicated for use in patients under 18 years of age.

Do not take BILDYOS if you are pregnant or could become pregnant as BILDYOS may harm your unborn baby. Your healthcare professional should do a pregnancy test before you start treatment with BILDYOS. You should use an effective method of birth control (contraception) during treatment with BILDYOS and for at least 5 months after your last dose of BILDYOS. If you become pregnant while taking BILDYOS, stop taking BILDYOS and tell your healthcare professional right away.

Nursing mothers should not take BILDYOS. It may also interfere with breastfeeding.

BILDYOS may lower levels of calcium in the blood. If you are prone to low calcium levels, your healthcare professional will monitor your blood, especially in the first few weeks after starting BILDYOS. Severe low blood calcium levels may lead to hospitalization, life-threatening events, and death. Low blood calcium should be treated before receiving BILDYOS. Symptoms of low blood calcium may include muscle spasms, twitches, cramps, numbness or tingling in hands, feet or around the mouth, and weakness. Some patients may not have any symptoms of low calcium. Tell your

healthcare professional if you have any of these symptoms. Tell your healthcare professional if you have or have had severe kidney problems as this may increase your risk of getting low blood calcium.

Tell your healthcare professional right away if you have symptoms of infection, including:

- Fever or chills
- Skin that looks red, swollen, hot or tender to touch
- Severe abdominal pain
- Frequent or urgent need to urinate or burning feeling when you urinate.

Tell your healthcare professional if you have any of the following symptoms of skin problems that do not go away or get worse:

- Redness
- Itching
- Rash
- Dry or leathery skin
- Open, crusted or peeling skin
- Blisters

After you start BILDYOS:

- Take good care of your teeth and gums, and see your dentist regularly.
- If you have a history of dental problems (such as poorly fitting dentures or gum disease), see your dentist before starting BILDYOS.
- Tell your dentist that you are taking BILDYOS, especially if you are having dental work.

A dental condition called osteonecrosis of the jaw (ONJ) which can cause tooth and jawbone loss has been reported in patients treated with denosumab. The risk of ONJ may increase with length of time on denosumab. Tell your healthcare professional and dentist immediately about any dental symptoms, including pain or unusual feeling in your teeth or gums, or any dental infections.

Some people have developed unusual fractures in their thigh bone. Contact your healthcare professional if you experience new or unusual pain in your hip, groin, or thigh.

After your treatment with BILDYOS is stopped, it is possible that broken bones in your spine may occur especially if you have a history of broken bones in the spine. Do not stop taking BILDYOS without first talking with your healthcare professional. If your BILDYOS treatment is stopped, discuss other available treatment options with your healthcare professional.

Other warnings you should know about:

- BILDYOS contains the medicine denosumab. If you are being treated with BILDYOS, you should not be taking other denosumab-containing medicinal products.
- There is an increased risk of skin infection (cellulitis) with BILDYOS therapy, most commonly on the leg. See a healthcare professional urgently if you develop swollen, red, hot or painful skin, with or without fever.
- You should take calcium and vitamin D supplements as recommended by your healthcare professional.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BILDYOS:

In a drug interaction study, denosumab did not interfere with the action of a drug called midazolam which is metabolized (broken down) by a certain liver enzyme called cytochrome P450 3A4. No drug interactions are expected with BILDYOS and other drugs metabolised by this enzyme in women with postmenopausal osteoporosis.

You should discuss with your healthcare professional any medications or vitamins or herbal products you are taking before using BILDYOS.

How to take BILDYOS:

BILDYOS is a clear to slightly opalescent, colourless to slightly yellow solution that may contain trace amounts of translucent to white proteinaceous particles. Do not use if the solution is cloudy or discoloured.

BILDYOS is administered as a single injection under the skin (subcutaneous) every 6 months. The injection can be in your upper arm, upper thigh, or abdomen. It can be given any time with or without food by a healthcare professional, by a trained injector, or a patient may self-inject if a healthcare professional determines that is appropriate.

Your prefilled syringe or vial may be left outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable. See instructions for injection.

Keep all medicines, including BILDYOS, away from children.

Do not share BILDYOS product with others, even if they have a similar disease.

Instructions for injection

IMPORTANT: TO HELP AVOID CONTAMINATION AND POSSIBLE INFECTION DUE TO INJECTION, PLEASE READ AND FOLLOW THESE INSTRUCTIONS CAREFULLY.

How to prepare for BILDYOS injection

BILDYOS is available as a liquid in vials. When you receive your BILDYOS, always check to see that:

- The name BILDYOS appears on the package and vial label.
- The expiration date on the vial label has not passed. Do not use a vial after the date on the label.
- The BILDYOS liquid in the vial is clear to slightly opalescent, colourless to slightly yellow. Do not use if the solution is cloudy or discoloured.

Only use disposable syringes and needles. Use the syringes only once and dispose of them as instructed by your healthcare professional.

Setting up for an injection

1. Find a clean flat working surface, such as a table.
2. Remove the vial of BILDYOS from the refrigerator. Allow BILDYOS to reach room temperature (this takes about 15 to 30 minutes). Vials should be used only once. **DO NOT SHAKE THE VIAL.** Shaking may damage BILDYOS. If the vial has been shaken vigorously, the solution may appear foamy and it should not be used.
3. Assemble the supplies you will need for an injection:
 - BILDYOS vial and sterile disposable syringe with a 27-gauge needle.
 - Two alcohol swabs and one cotton ball or gauze pad.
 - Sharps disposal container.
4. Clean your work surface thoroughly and wash your hands with soap and warm water.

Selecting and preparing the injection site

1. Choose an injection site. The recommended injection sites for BILDYOS are:
 - The outer area of your upper arms.
 - The abdomen, except for the two-inch (5 cm) area around your navel.
 - The top of your thighs.

How to prepare the dose of BILDYOS in vials

1. Take the cap off the vial. Clean the stopper with an alcohol swab.
2. Check the package containing the syringe. If the package has been opened or damaged, do not use that syringe. Dispose of that syringe in the sharps disposal container. If the syringe package is undamaged, open the package and remove the syringe.
3. Keep the vial on your flat working surface and insert the needle straight down through the rubber stopper. Do not put the needle through the rubber stopper more than once.
4. Push the plunger of the syringe down and inject the air from the syringe into the vial of BILDYOS. Keeping the needle inside the vial, turn the vial upside down. Make sure that the tip of the needle is in the BILDYOS liquid.
5. Keeping the vial upside down, slowly pull back on the plunger to fill the syringe with BILDYOS liquid. Withdraw the entire content of the vial.

6. Keeping the needle in the vial, turn the syringe needle up and check for air bubbles in the syringe. If there are air bubbles, gently tap the syringe with your fingers until the air bubbles rise to the top of the syringe. Then slowly push the plunger up to force the air bubbles out of the syringe.
7. Remove the syringe from the vial but **do not lay it down** or let the needle touch anything.

Injecting the dose of BILDYOS

1. Hold the syringe in the hand you will use to inject BILDYOS. With the other hand, clean the injection site with an alcohol swab. Use a circular motion from the inside to the outside of the injection site.
2. Pinch a fold of skin at the cleaned injection site.
3. Holding the syringe like a pencil, use a quick “dart-like” motion to insert the needle either straight up and down (90-degree angle) or at a slight angle (45 degrees) into the skin.
4. After the needle is inserted, let go of the skin. Inject the prescribed dose subcutaneously as directed by your healthcare professional.
5. When the syringe is empty, pull the needle out of the skin and place a cotton ball or gauze over the injection site and press for several seconds.
6. Use a syringe, needle and vial only once. **DO NOT** put the needle cover (the cap) back on the needle. Discard the vial with any remaining BILDYOS liquid.

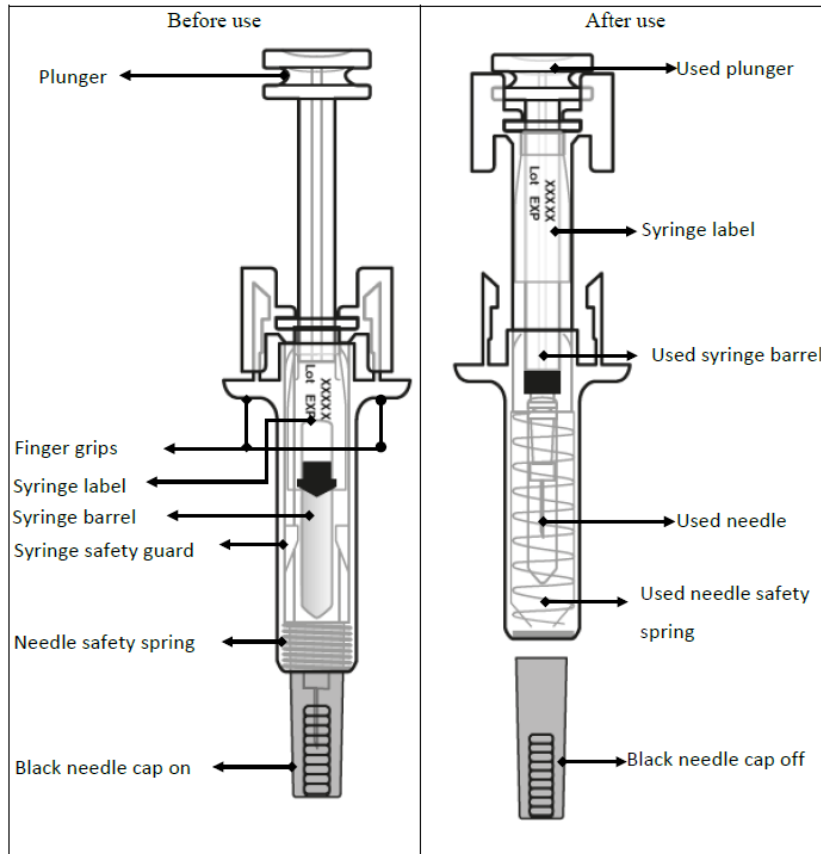
Disposal of syringes, needles and vials

You should always follow the instructions given by your healthcare professional on how to properly dispose of containers with used syringes, needles and vials. There may be special provincial or local laws for disposal of used needles and syringes.

- Place all used needles, needle covers, syringes, and vials (empty or unused contents) into a sharps disposal container given to you by your healthcare professional or in a hard-plastic container with a screw-on cap, or a metal container with a plastic lid, labelled “used syringes.” Do not use glass or clear plastic containers.
- When the container is full, tape around the cap or lid to make sure the cap or lid does not come off. Do not throw the container in the household trash. Do not recycle.
- Always keep the container out of the reach of children.

Instructions for injection

IMPORTANT: TO HELP AVOID CONTAMINATION AND POSSIBLE INFECTION DUE TO INJECTION, PLEASE READ AND FOLLOW THESE INSTRUCTIONS CAREFULLY.



Important:

Before you use BILDYOS prefilled syringe read this information:

- Administration should be performed by an individual who has been trained in injection techniques. It is important that you do not try to give yourself the injection unless you have received training from your healthcare professional.
- BILDYOS is for subcutaneous injection only (an injection into the tissue just under the skin).
- Make sure the name BILDYOS appears on the carton and prefilled syringe label.
- Check the carton and prefilled syringe label to make sure the dose strength is 60 mg.
- **Do not** use a syringe after the expiration date on the label.
- **Do not** shake the syringe.
- **Do not** remove the black needle cap from the prefilled syringe until you are ready to inject.
- **Do not** use the prefilled syringe if it has been dropped on a hard surface. If this happens, use a new prefilled syringe and call your healthcare professional.
- **Do not** attempt to activate the prefilled syringe prior to injection.
- **Do not** attempt to remove the clear prefilled syringe needle safety guard from the prefilled syringe.

Call your healthcare professional if you have any questions.

Step 1: Prepare to inject BILDYOS

A

Remove the prefilled syringe tray from the package and gather the supplies needed for your injection: (not included)

- alcohol wipes
- cotton ball or gauze
- adhesive bandage
- sharps disposal container

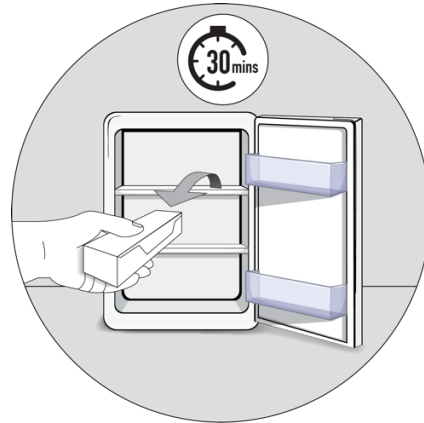


For a more comfortable injection, leave the prefilled syringe at room temperature for about 15-30 minutes before injecting.

Wash your hands thoroughly with soap and water.

Place the prefilled syringe and other supplies on a clean, well-lit work surface.

- ✘ **Do not** use the prefilled syringe if the carton is damaged.
- ✘ **Do not** try to warm the syringe by using a heat source such as hot water or microwave.
- ✘ **Do not** leave the prefilled syringe exposed to direct sunlight.
- ✘ **Do not** shake the prefilled syringe.

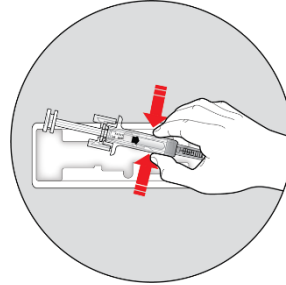


Keep the prefilled syringe out of the sight and reach of children.

B

Open the tray by peeling away the cover.

Remove the prefilled syringe from the tray by grabbing the needle safety guard as shown.



For safety reasons:

- ✗ **Do not** grasp the plunger.
- ✗ **Do not** grasp the black needle cap.

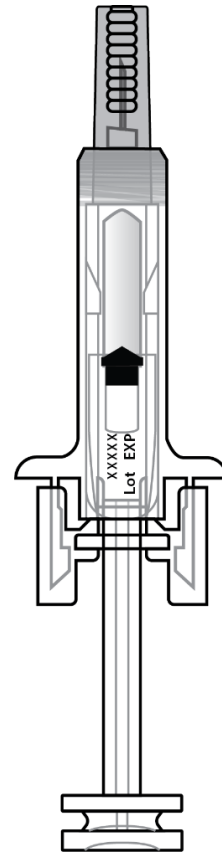
C

Inspect the medicine and prefilled syringe.

You may see air bubbles in the liquid, which is normal.

- ✗ **Do not** use the prefilled syringe if:
 - The medicine is cloudy or discoloured. Make sure the medicine is clear to slightly opalescent and colourless to slightly yellow.
 - Any part appears cracked or broken.
 - The black needle cap is missing or not securely attached.
 - The expiry date printed on the label has passed.

In all cases, call your healthcare professional.



Step 2: Get ready

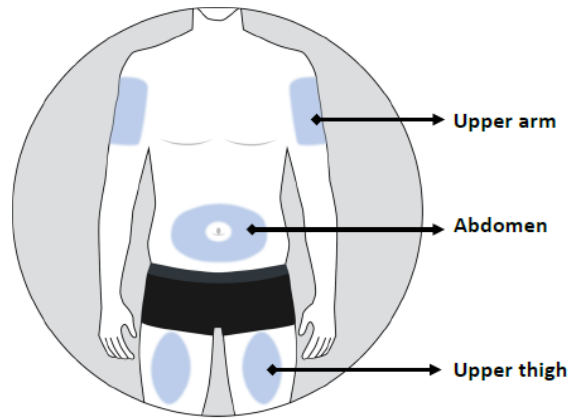
A

Prepare and clean your injection site.

You can use:

- Upper part of your thigh
- Stomach area (abdomen), except for a 5 cm area right around your belly button.
- Outer area of upper arm (only if someone else is giving you the injection).

Clean the injection site with an alcohol wipe. Let your skin dry.

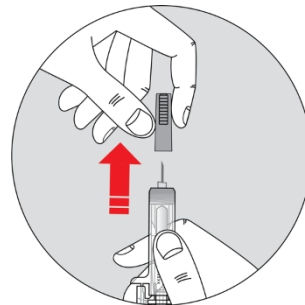


- ✗ **Do not** touch the injection site before injecting.

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

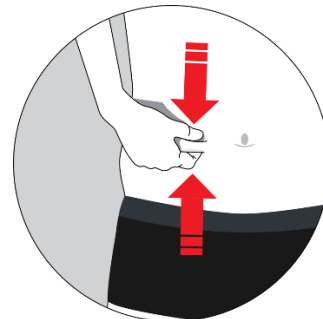
B

Carefully pull the black needle cap straight off and away from your body.



C

Pinch your injection site to create a firm surface.



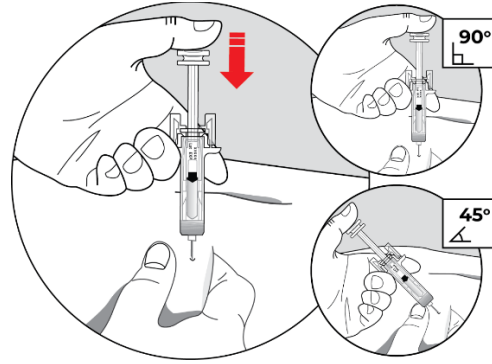
! It is important to keep the skin pinched when injecting.

Step 3: Inject

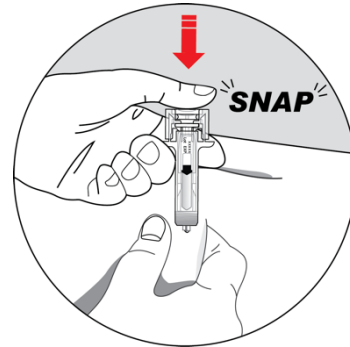
A

Continue to hold the pinch as you INSERT the needle into the skin at a **45- to 90-degree** angle.

- ✗ **Do not** touch the cleaned area of the skin.

**B**

Using slow and constant pressure, PUSH the plunger until you feel or hear a “snap”.

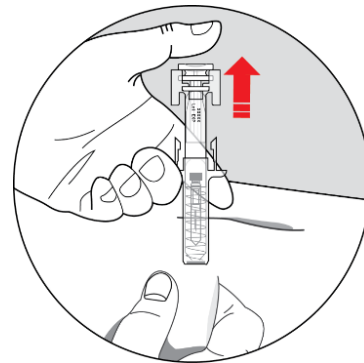


It is important to push down through the “snap” to deliver your full dose.

C

When done, RELEASE your thumb, then LIFT the syringe off of the skin.

After releasing the plunger, the prefilled syringe needle safety guard will safely cover the injection needle.



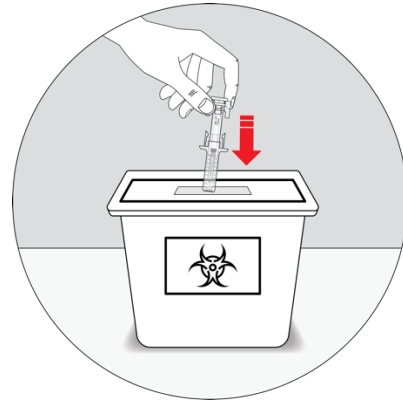
- ✗ **Do not** put the black needle cap back on used prefilled syringes.

Step 4: Finish

A

Discard the used prefilled syringe and other supplies in a sharps disposal container.

Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.



Keep the syringe and sharps disposal container out of sight and reach of children.

- ✘ **Do not** reuse the prefilled syringe.
- ✘ **Do not** recycle prefilled syringe or throw them into household waste.

B

Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site.

Apply an adhesive bandage if needed.

Usual dose:

The usual dose of BILDYOS is 60 mg administered once every 6 months. You should also take supplements of calcium and vitamin D.

Overdose:

If you think you, or a person you are caring for, have taken too much BILDYOS, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose, you should receive your next dose as soon as convenient. Schedule your next dose 6 months from the date of your last injection.

Possible side effects from using BILDYOS:

Like all medicines, BILDYOS can cause side effects, although not everybody gets them.

These are not all the possible side effects you may have when taking BILDYOS. If you experience any side effects not listed here, tell your healthcare professional.

Possible side effects include:

- Pain, sometimes severe, in the muscles, joints, arms, legs or back.
- Low blood calcium (hypocalcemia). Symptoms of low blood calcium may include muscle spasms, twitches, cramps, numbness or tingling in fingers, toes or around the mouth.
- Allergic reactions (eg, rash, hives, or in rare cases, swelling of the face, lips, tongue, throat, or trouble breathing).
- Allergic reaction that can damage blood vessels mainly in the skin (eg, purple or brownish-red spots, hives or skin sores)
- Severe allergic reaction (drug reaction with eosinophilia and systemic symptoms [DRESS] syndrome) with skin rash/blisters, fever and/or increase in a type of white blood cell (eosinophils) with possible organ damage, such as liver, kidney, or lung.
- Skin condition with itching, redness and/or dryness (eczema). Injection site reactions were uncommon.
- Rash that may occur on the skin or sores in the mouth (lichenoid drug eruption).
- Hair loss (alopecia).
- Skin infection with swollen, red area of skin, that feels hot and tender and may be accompanied by fever (cellulitis).
- Common cold (runny nose or sore throat).
- Broken bones in the spine after stopping BILDYOS (multiple vertebral fractures).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON (≥ 1%, in 1 to 10% of patients)			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Skin condition with itching, redness and/or dryness (eczema)	X		
UNCOMMON ($\geq 0.1\%$, $< 1\%$)			
Skin infection (mainly cellulitis) leading to hospitalization, erysipelas (serious and rapid skin infection commonly on the face or legs)		X	
Bladder infection, pancreatitis (inflamed pancreas causing severe stomach pains), and ear infection		X	
Broken bones in the spine after stopping BILDYOS treatment (multiple vertebral fractures)		X	
RARE ($\geq 0.01\%$, $< 0.1\%$)			
Low calcium levels in the blood (muscle spasms, twitches, cramps, numbness or tingling in hands, feet or around the mouth, and weakness)		X	
Endocarditis (inflammation of the inner lining of the heart)		X	X
Sore in mouth involving gums or jaw bones (osteonecrosis of the jaw)		X	X
Allergic reaction (feeling faint, trouble breathing/wheezing, throat tightness, swelling of face, lips or tongue, rash, hives)		X	X
Unusual thigh bone fractures (atypical femoral fracture)		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of the reach and sight of children.

When prescribed BILDYOS, you will likely need to fill your prescription at a pharmacy. Store BILDYOS in your refrigerator at 2°C to 8°C until your injection appointment with your health professional or trained injector. Do not freeze.

When removed from the refrigerator, BILDYOS must be kept at room temperature (up to 25°C) in the original carton and must be used within 30 days. If not used within 30 days, BILDYOS should be discarded.

Store in original carton in order to protect from light.

Do not use BILDYOS after the expiry date which is printed on the carton and label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required.

If you want more information about BILDYOS:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the Canadian distributor (Organon Canada Inc.) website www.organon.ca, or by calling 1-844-820-5468.

This leaflet was prepared by Shanghai Henlius Biotech, Inc.

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