READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

BRENZYS (pronounced) <BREN-ziss>

etanercept injection

Single-use Pre-filled Syringe

Read this carefully before you start taking **BRENZYS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BRENZYS**.

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

Serious Warnings and Precautions

- **Serious infections.** There have been cases where patients taking BRENZYS or other TNF-blocking agents have developed serious infections, including tuberculosis (TB) and infections caused by bacteria, viruses or fungi that have spread throughout their body. Some patients have died from these infections. In very rare cases, hepatitis B recurred in patients with previous hepatitis. If you tend to get infections easily or if you develop an infection while taking BRENZYS, you should tell your doctor right away.
- **Malignancies.** There have been cases, sometimes fatal, of unusual cancers in children and teenage patients who started using TNF-blocking agents, including etanercept, at less than 18 years of age.

What is BRENZYS used for?

BRENZYS is a medicine for treating people with moderate to severe forms of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA) and a type of disease called psoriatic (sore-ee-ah-tick) arthritis (PsA). BRENZYS is also for treating adults with a type of arthritis called ankylosing spondylitis (ank-e-low-sing spond-e-lie-tis (AS). BRENZYS is also for adults with moderate to severe psoriasis (sore-I-ah-sis) (PsO) and children with severe psoriasis (PsO). RA, JIA, PsA and AS are inflammatory diseases that affect the joints in your body. PsO is an inflammatory disease that affects the skin and can cause raised, thick, red and scaly patches ("psoriatic skin lesions") that can appear anywhere on the body. PsA is usually seen in patients with PsO and affects both the joints and the skin.

How does BRENZYS work?

BRENZYS is a type of protein called a tumour necrosis factor (TNF) blocker that blocks the action of a substance your body makes called TNF-alpha. TNF-alpha is made by your body's immune system. People with immune diseases like RA, JIA, PsA and PsO, as well as patients with AS, have too much TNF-alpha in their bodies, which can cause inflammation and lead to painful, swollen joints and raised thick, red, scaly patches ("psoriatic skin lesions") that can appear anywhere on the body. BRENZYS can reduce the amount of TNF in the body to normal levels, helping to treat joint damage. In patients with inflammatory arthritis, BRENZYS may be effective in reducing signs and symptoms of inflammatory arthritis (such as pain, morning

stiffness and fatigue), may help improve your ability to do simple daily activities (such as dressing, walking and climbing stairs), and may help prevent damage to your bones and joints. In patients with psoriatic skin conditions, BRENZYS may be effective in clearing skin and improving quality of life (such as personal relationships, work and daily activities, and treatment satisfaction).

When can I expect to see results from taking BRENZYS?

Improvement may be seen as early as 1 week after starting etanercept in adults and within 2 weeks in children with JIA and 4 weeks with PsO. In clinical trials, full effect was usually seen by 3 months in both adults and children and was sustained with continued treatment.

In clinical trials with PsA, one quarter of patients saw improvement in their joint symptoms within 1 month, one half of patients saw improvement within 3 months, and three quarters of patients saw improvement within 9 months of treatment with etanercept.

During the PsA clinical trials, approximately 2% of patients treated with etanercept stopped taking etanercept due to side effects and up to 5% of etanercept-treated patients stopped taking etanercept due to lack of improvement.

What are the ingredients in BRENZYS?

Medicinal ingredients: etanercept

Non-medicinal ingredients: Sodium chloride, Sodium phosphate and Sucrose

BRENZYS comes in the following dosage forms:

BRENZYS single-use pre-filled syringes are available as a 50 mg dosage strength (0.98 mL of a 50 mg/mL solution of etanercept, minimum deliverable volume of 0.94 mL).

BRENZYS single-use pre-filled auto-injectors are available as a 50 mg dosage strength (0.98 mL of a 50 mg/mL solution of etanercept, minimum deliverable volume of 0.93 mL).

Do not use BRENZYS if you:

- have ever had an allergic reaction to BRENZYS or any of the ingredients in BRENZYS.
- have an infection that has spread through your body (sepsis).

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

- have an infection. This could put you at risk for serious side effects from BRENZYS.
- have symptoms of an infection such as fever, sweats or chills, cough or flu-like symptoms, shortness of breath, blood in your phlegm, weight loss, muscle aches, warm, red, or painful areas on your skin, sores on your body, diarrhea or stomach pain, burning when you urinate or urinate more often than normal, and feel very tired.
- have a history of infections that keep coming back or other conditions — like diabetes, HIV, or a weak immune system — that might increase your risk of infections.
- have tuberculosis (TB), or have been in close contact with someone who has or has had TB. You will need to be evaluated for TB. Your doctor should test you for TB before starting BRENZYS.
- were born in, lived in, or traveled to countries where there is a risk for getting TB. Ask your doctor if you are not sure.

- live in, have lived in or have traveled to, areas where there is a greater risk for certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become more severe if you take BRENZYS. If you don't know if you have lived in an area where these infections are common, ask your doctor.
- have or have had hepatitis B.
- have or have had persistent numbness, tingling and muscle weakness or a disease such as multiple sclerosis, Guillain- Barré or a Guillain-Barré -like syndrome, which causes inflammation of the nervous system, either in the brain and spinal cord or nerves going to your hands and feet.
- have been newly diagnosed or are being treated for congestive heart failure.
- are scheduled to have major surgery.
- have recently received or are scheduled to receive a vaccine. All vaccines should be brought up-to-date before starting BRENZYS. Patients taking BRENZYS should not receive live vaccines.
- use the medication Kineret® (anakinra), Orencia® (abatacept) or cyclophosphamide (see "**The following may interact with BRENZYS:**" below).
- have been around someone with varicella zoster (chicken pox, shingles).

Know the medicines you take. Keep a list of them to show your doctor and pharmacist each time you get a new medicine.

Your doctor should monitor you closely for signs and symptoms of TB during treatment with BRENZYS even if you have tested negative for TB. If you develop any of the symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor.

If you are not sure or have any questions about any of this information, ask your doctor.

Other warnings you should know about:

All medicines have side effects. Medicines, like BRENZYS, that affect your immune system can cause serious side effects. The possible serious side effects include:

- **Nervous system diseases.** There have been rare cases of disorders that affect the nervous system of people taking BRENZYS or other TNF blockers, such as multiple sclerosis, seizures or inflammation of the nerves of the eyes. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling throughout your body, problems with your vision, weakness in your arms and/or legs, and dizziness.
- **Blood problems.** In some patients the body may fail to produce enough of the blood cells that can help your body fight infections or help you to stop bleeding. This can lead to death. If you develop a fever that doesn't go away, bruise or bleed very easily or look very pale or feel faint, call your doctor right away. Your doctor may decide to stop treatment. Some people have also had symptoms that resemble lupus (rash on your face and arms that gets worse in the sun) that may go away when you stop taking BRENZYS.
- **Heart problems.** You should also tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on BRENZYS, or may want to monitor you more closely. Symptoms include shortness of breath or swelling of your ankles and feet.
- **Allergic reactions.** Some patients have had allergic reactions to BRENZYS. If you develop

a severe rash, swollen face or difficulty breathing while taking BRENZYS, call your doctor right away.

- **Malignancies.** Patients with inflammatory diseases including RA, AS or PsO, particularly those with highly active disease, may be at higher risk for lymphoma (a type of cancer). For children and adults taking TNF-blocker medicines including BRENZYS, the chances of getting lymphoma or other cancers may increase. Whether treatment with BRENZYS might influence the development and course of malignancies in adults is unknown.
- **Liver problems (autoimmune hepatitis).** Liver problems can happen in people who use TNF blocker medicines, including BRENZYS. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms: feel very tired, skin or eyes look yellow, poor appetite or vomiting, pain on the right side of your stomach (abdomen). These symptoms may occur several months after starting and even after BRENZYS has been stopped.
- **Psoriasis.** Some people using BRENZYS developed new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps which may be filled with pus. Your doctor may decide to stop your treatment with BRENZYS.
- **Serious infections.** BRENZYS can lower the ability of your immune system to fight infections. So, taking BRENZYS can make you more prone to getting infections or make any infection that you may have worse. Some people have serious infections while taking BRENZYS including infections that spread through the body such as tuberculosis (TB), legionellosis (usually a bacterial pneumonia), and listeriosis (usually from contaminated food). Other infections caused by viruses, fungi, bacteria or parasites may occur. Some people have died from these infections.

Can I take BRENZYS if I am pregnant or breastfeeding?

The safe use of BRENZYS has not been established in pregnant women.

You should tell your doctor if you are pregnant, become pregnant or are thinking about becoming pregnant. If you took BRENZYS during pregnancy, talk to your doctor prior to administration of live vaccines to your infant.

BRENZYS can pass into breast milk. BRENZYS has not been studied in nursing mothers, and therefore its effects on nursing babies are not known. Talk to your healthcare provider about the best way to feed your baby while taking BRENZYS.

If you are not sure or have any questions about any of this information, ask your doctor.

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 BRENZYS:

It is important that you tell your doctor about any other medicines (for example, high blood pressure medicine) you are taking for other conditions before you start taking etanercept. You should also tell your doctor about any over-the-counter drugs, herbal medicines and vitamin and mineral supplements you are taking.

<u>General Information about BRENZYS</u>

Medicines are sometimes prescribed for purposes not mentioned in the Patient Medication Information leaflet. **Do NOT** use BRENZYS for a condition for which it was not prescribed. **Do NOT** give BRENZYS to other people, even if they have the same condition.

Can I take BRENZYS if I am taking other medicines for my RA, JIA, PsA, AS or other conditions?

In adults, BRENZYS can be used in combination with methotrexate. However, little is known of the interaction of etanercept with methotrexate and other drugs in children with JIA.

Taking BRENZYS with Kineret® (anakinra) is not recommended because this may increase your risk of getting a serious infection.

Taking BRENZYS with Orencia® (abatacept) is not recommended because this may increase your risk for serious side effects.

Taking BRENZYS with cyclophosphamide (used to treat cancer or immune diseases) is not recommended. You may have a higher chance for getting certain cancers when taking BRENZYS with cyclophosphamide.

If you have diabetes and are taking medication to control your diabetes, your doctor may decide you need less anti-diabetic medicine while taking BRENZYS.

How to take BRENZYS:

BRENZYS is administered by an injection under the skin.

You may continue to use other medicines that help treat your condition while taking BRENZYS, such as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

Usual dose:

If you have RA, PsA or AS, the recommended dose of BRENZYS for adults is 50 mg per week given as one injection using a 50 mg single-use prefilled syringe.

If you have PsO, the recommended starting dose of BRENZYS for adult patients is a 50 mg dose twice a week (3 or 4 days apart) for 3 months. After 3 months, your doctor will tell you to reduce your dose to 50 mg once per week using one 50 mg single-use pre-filled syringe.

The recommended dose of BRENZYS for children with JIA or PsO is based on the child's body weight. Your child's doctor will tell you the correct amount of BRENZYS your child should take and will prescribe an appropriate strength of etanercept. BRENZYS is available for treatment of children and adolescents weighing 63 kg (138 pounds) or more.

BRENZYS should be given by, or under the supervision of, a responsible adult.

Make sure you have been shown how to inject BRENZYS before you do it yourself. Someone you know can also help you with your injection. Remember to take this medicine just as your doctor has told you and do not miss any doses.

Overdose:

If you accidentally inject BRENZYS more frequently than instructed, talk to a doctor or pharmacist immediately.

If you think you have taken too much BRENZYS, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use BRENZYS, inject your dose as soon as you remember. Then, take your next dose at your regular(ly) scheduled time. In case you are not sure when to inject BRENZYS, call your healthcare provider.

Detailed instructions on how to inject BRENZYS are provided in "Instructions for Use". Do not mix the BRENZYS solution with any other medicine.

To help you remember, it may be helpful to write in a diary which day(s) of the week BRENZYS should be used.

What are possible side effects from using BRENZYS?

Like all medicines, BRENZYS can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

What are the common side effects?

In studies comparing etanercept to placebo (inactive injection), side effects that occurred more frequently in patients treated with etanercept were:

- Reactions where the injection was given. These reactions are usually mild and include redness, swelling, itching, or bruising. These usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away or gets worse, call your doctor.
- Upper respiratory infections (sinus infections)
- Headaches

These are not all the possible side effects you may feel when taking BRENZYS. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

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	
VERY COMMON Injection site reactions		✓	
COMMON Upper respiratory tract infections (sinus infections)		✓	
Headaches	✓		
UNCOMMON Serious infections		✓	✓
Tuberculosis		✓	
Nerve disorders		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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 reach and sight of children.

The BRENZYS pre-filled syringe should be refrigerated at 2°C to 8°C. **Do NOT freeze BRENZYS**. Refrigerated BRENZYS remains stable until the expiration date printed on the syringe.

BRENZYS may be transferred to room temperature storage (up to 27°C). Upon removal from the refrigerator, it must be used within 60 days. Protect from direct sunlight, sources of heat, and humidity until ready to use.

If you want more information about BRENZYS:

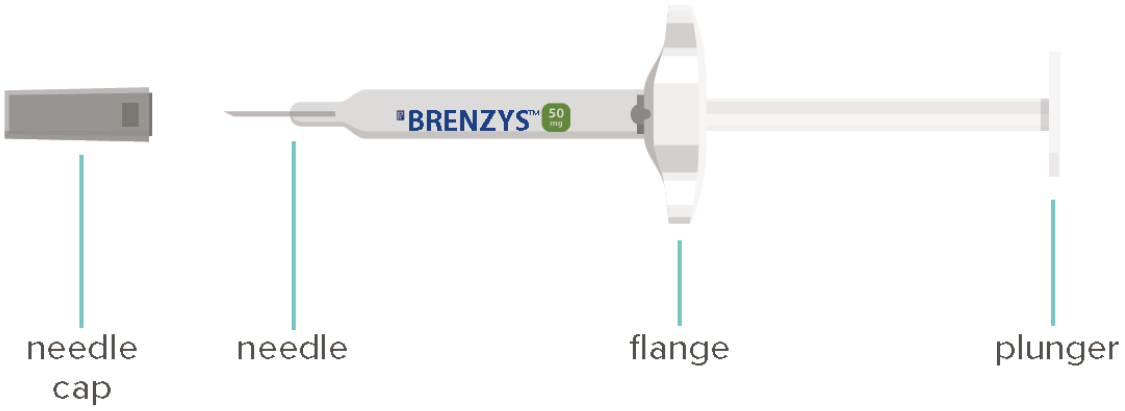
- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); the Canadian distributor (Organon Canada Inc.)'s website www.organon.ca, or by calling 1-844-820-5468.

This information is current up to the last revision date shown below, but more current information may be available from the manufacturer.

Instructions for Use:

The following instructions are for preparing and giving a dose of BRENZYS using a single-use pre-filled syringe.

Your pre-filled syringe:

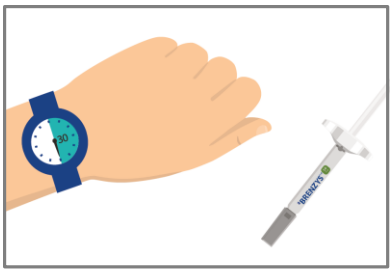


Step 1: Gather supplies

- Place your syringe and unopened alcohol swabs on a clean, dry surface.
- Remember to wash your hands.
- Don't uncap.

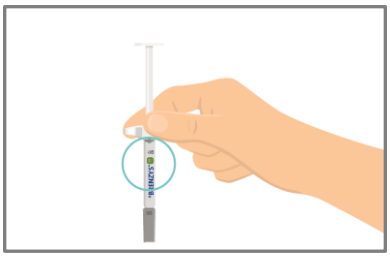
Step 2: Wait 30 minutes

- Wait approximately 30 minutes for your syringe to warm-up to room temperature, which helps reduce your pain during injection.
- Don't remove the cap just yet.



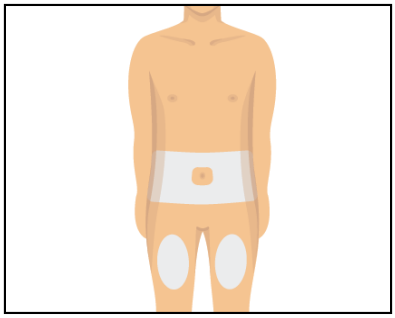
Step 3: Inspect medicine & date

- Always make sure your medicine hasn't expired.
- The medicine should be clear and colorless, and may contain small particles.
- You may see an air bubble, and that's okay.
- Don't remove the cap just yet.



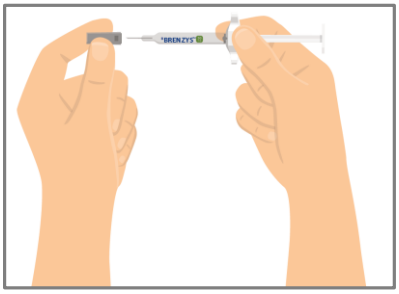
Step 4: Choose site & clean skin

- Choose an injection site on your body.
- Your abdomen or thighs are best.
- Wipe your skin at the injection site with an alcohol swab.
- Avoid skin that's sore, bruised, scarred, scaly or has red patches.



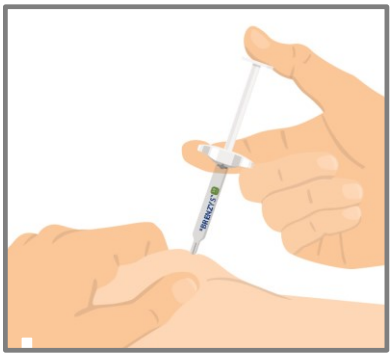
Step 5: Remove syringe cap

- Carefully remove the needle cap.



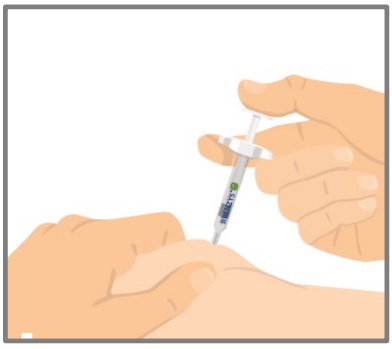
Step 6: Pinch skin & insert needle

- Gently pinch your skin, and carefully insert the needle.



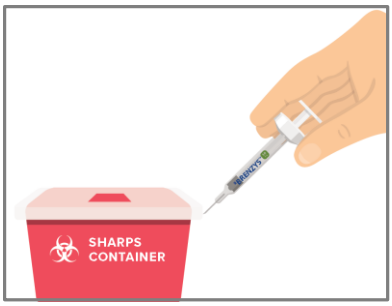
Step 7: Push plunger all the way

- Hold the syringe steady and press the plunger all the way down.



Step 8: Remove syringe & dispose

- Pull the syringe away from your skin and dispose of it in a sharps container.
- Don’t recap or reuse your needle.



This leaflet was prepared by Samsung Bioepis Co., Ltd.

Last Revised: March 17, 2022

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- have a history of infections that keep coming back or other conditions — like diabetes, HIV, or a weak immune system — that might increase your risk of infections.
- have tuberculosis (TB), or have been in close contact with someone who has or has had TB. You will need to be evaluated for TB. Your doctor should test you for TB before starting BRENZYS.
- were born in, lived in, or traveled to countries where there is a risk for getting TB. Ask your doctor if you are not sure.

- live in, have lived in or have traveled to, areas where there is a greater risk for certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become more severe if you take BRENZYS. If you don't know if you have lived in an area where these infections are common, ask your doctor.
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- have or have had persistent numbness, tingling and muscle weakness or a disease such as multiple sclerosis, Guillain- Barré or a Guillain-Barré -like syndrome, which causes inflammation of the nervous system, either in the brain and spinal cord or nerves going to your hands and feet.
- have been newly diagnosed or are being treated for congestive heart failure.
- are scheduled to have major surgery.
- have recently received or are scheduled to receive a vaccine. All vaccines should be brought up-to-date before starting BRENZYS. Patients taking BRENZYS should not receive live vaccines.
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- **Allergic reactions.** Some patients have had allergic reactions to BRENZYS. If you develop

a severe rash, swollen face or difficulty breathing while taking BRENZYS, call your doctor right away.

- **Malignancies.** Patients with inflammatory diseases including RA, AS or PsO, particularly those with highly active disease, may be at higher risk for lymphoma (a type of cancer). For children and adults taking TNF-blocker medicines including BRENZYS, the chances of getting lymphoma or other cancers may increase. Whether treatment with BRENZYS might influence the development and course of malignancies in adults is unknown.
- **Liver problems (autoimmune hepatitis).** Liver problems can happen in people who use TNF blocker medicines, including BRENZYS. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms: feel very tired, skin or eyes look yellow, poor appetite or vomiting, pain on the right side of your stomach (abdomen). These symptoms may occur several months after starting and even after BRENZYS has been stopped.
- **Psoriasis.** Some people using BRENZYS developed new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps which may be filled with pus. Your doctor may decide to stop your treatment with BRENZYS.
- **Serious infections.** BRENZYS can lower the ability of your immune system to fight infections. So, taking BRENZYS can make you more prone to getting infections or make any infection that you may have worse. Some people have serious infections while taking BRENZYS including infections that spread through the body such as tuberculosis (TB), legionellosis (usually a bacterial pneumonia), and listeriosis (usually from contaminated food). Other infections caused by viruses, fungi, bacteria or parasites may occur. Some people have died from these infections.

Can I take BRENZYS if I am pregnant or breastfeeding?

The safe use of BRENZYS has not been established in pregnant women.

You should tell your doctor if you are pregnant, become pregnant or are thinking about becoming pregnant. If you took BRENZYS during pregnancy, talk to your doctor prior to administration of live vaccines to your infant.

BRENZYS can pass into breast milk. BRENZYS has not been studied in nursing mothers, and therefore its effects on nursing babies are not known. Talk to your healthcare provider about the best way to feed your baby while taking BRENZYS.

If you are not sure or have any questions about any of this information, ask your doctor.

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 BRENZYS:

It is important that you tell your doctor about any other medicines (for example, high blood pressure medicine) you are taking for other conditions before you start taking etanercept. You should also tell your doctor about any over-the-counter drugs, herbal medicines and vitamin and mineral supplements you are taking.

<u>General Information about BRENZYS</u>

Medicines are sometimes prescribed for purposes not mentioned in the Patient Medication Information leaflet. **Do NOT** use BRENZYS for a condition for which it was not prescribed. **Do NOT** give BRENZYS to other people, even if they have the same condition.

Can I take BRENZYS if I am taking other medicines for my RA, JIA, PsA, AS or other conditions?

In adults, BRENZYS can be used in combination with methotrexate. However, little is known of the interaction of etanercept with methotrexate and other drugs in children with JIA.

Taking BRENZYS with Kineret® (anakinra) is not recommended because this may increase your risk of getting a serious infection.

Taking BRENZYS with Orencia® (abatacept) is not recommended because this may increase your risk for serious side effects.

Taking BRENZYS with cyclophosphamide (used to treat cancer or immune diseases) is not recommended. You may have a higher chance for getting certain cancers when taking BRENZYS with cyclophosphamide.

If you have diabetes and are taking medication to control your diabetes, your doctor may decide you need less anti-diabetic medicine while taking BRENZYS.

How to take BRENZYS:

BRENZYS is administered by an injection under the skin.

You may continue to use other medicines that help treat your condition while taking BRENZYS, such as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

Usual dose:

If you have RA, PsA or AS, the recommended dose of BRENZYS for adults is 50 mg per week. given as one injection using a 50 mg single-use pre-filled auto-injector.

If you have PsO, the recommended starting dose of BRENZYS for adult patients is a 50 mg dose twice a week (3 or 4 days apart) for 3 months. After 3 months, your doctor will tell you to reduce your dose to 50 mg once per week using one 50 mg single-use pre-filled auto-injector.

The recommended dose of BRENZYS for children with JIA or PsO is based on the child's body weight. Your child's doctor will tell you the correct amount of BRENZYS your child should take and will prescribe an appropriate strength of etanercept. BRENZYS is available for treatment of children and adolescents weighing 63 kg (138 pounds) or more.

BRENZYS should be given by, or under the supervision of, a responsible adult.

Make sure you have been shown how to inject BRENZYS before you do it yourself. Someone you know can also help you with your injection. Remember to take this medicine just as your doctor has told you and do not miss any doses.

Overdose:

If you accidentally inject BRENZYS more frequently than instructed, talk to a doctor or pharmacist immediately.

If you think you have taken too much BRENZYS, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use BRENZYS, inject your dose as soon as you remember. Then, take your next dose at your regular(ly) scheduled time. In case you are not sure when to inject BRENZYS, call your healthcare provider.

Detailed instructions on how to inject BRENZYS are provided in "Instructions for Use". Do not mix the BRENZYS solution with any other medicine.

To help you remember, it may be helpful to write in a diary which day(s) of the week BRENZYS should be used.

What are possible side effects from using BRENZYS?

Like all medicines, BRENZYS can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

What are the common side effects?

In studies comparing etanercept to placebo (inactive injection), side effects that occurred more frequently in patients treated with etanercept were:

- Reactions where the injection was given. These reactions are usually mild and include redness, swelling, itching, or bruising. These usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away or gets worse, call your doctor.
- Upper respiratory infections (sinus infections)
- Headaches

These are not all the possible side effects you may feel when taking BRENZYS. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

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	
VERY COMMON Injection site reactions		✓	
COMMON Upper respiratory tract infections (sinus infections)		✓	
Headaches	✓		
UNCOMMON Serious infections		✓	✓
Tuberculosis		✓	
Nerve disorders		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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 reach and sight of children.

The BRENZYS pre-filled auto-injector should be refrigerated at 2°C to 8°C. **Do NOT freeze BRENZYS**. Refrigerated BRENZYS remains stable until the expiration date printed on the auto-injector.

BRENZYS may be transferred to room temperature storage (up to 27°C). Upon removal from the refrigerator, it must be used within 60 days. Protect from direct sunlight, sources of heat, and humidity until ready to use.

If you want more information about BRENZYS:

- 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 (http://hc-sc.gc.ca/index-eng.php); the Canadian distributor (Organon Canada Inc.)'s website www.organon.ca, or by calling 1-844-820-5468.

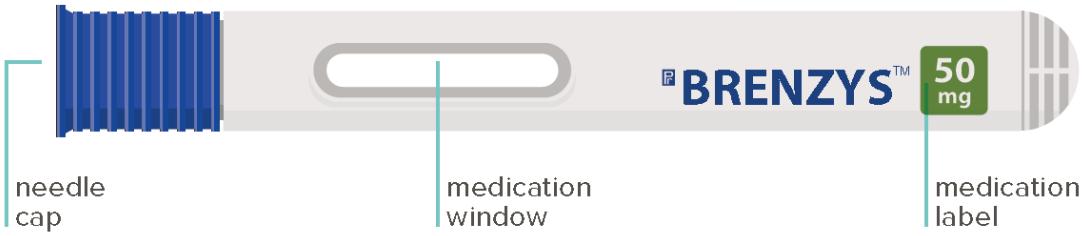
This information is current up to the last revision date shown below, but more current information may be available from the manufacturer.

Instructions for Use:

The following instructions are for preparing and giving a dose of BRENZYS using a single-use pre-filled auto-injector.

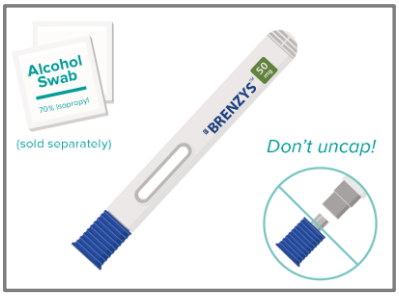
Your pre-filled auto-injector:

- There is no button on your auto-injector.
- The needle is hidden behind a shield, under the cap.
- When you push the shield onto your skin, the injection will start automatically.



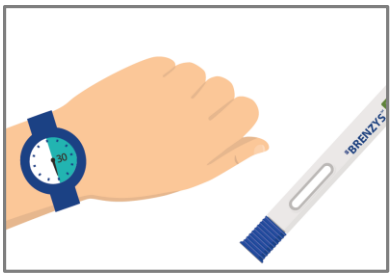
Step 1: Gather supplies

- Place your auto-injector and unopened alcohol swabs on a clean, dry surface.
- Remember to wash your hands.
- Don't uncap.



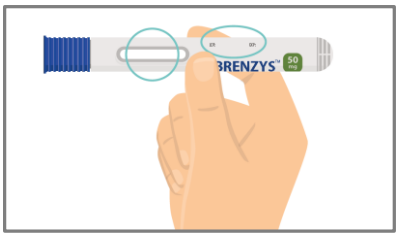
Step 2: Wait 30 minutes

- Wait approximately 30 minutes for your auto-injector to warm-up to room temperature, which helps reduce your pain during injection.
- Don't remove the cap just yet.



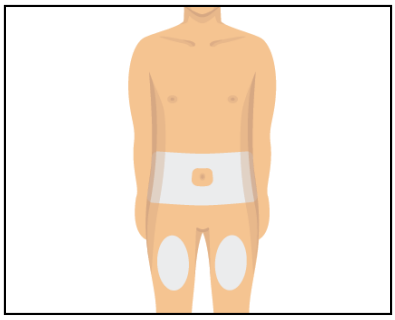
Step 3: Inspect medicine & date

- Always make sure your medicine hasn't expired.
- The medicine should be clear and colorless, and may contain small particles.
- You may see an air bubble, and that's okay.
- Don't remove the cap just yet.



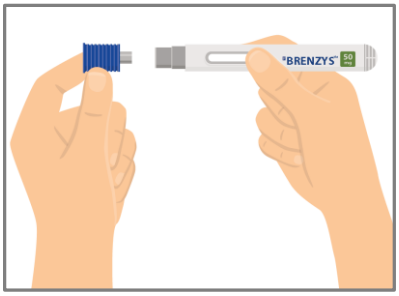
Step 4: Choose site & clean skin

- Choose an injection site on your body.
- Your abdomen or thighs are best.
- Wipe your skin at the injection site with an alcohol swab.
- Avoid skin that's sore, bruised, scarred, scaly or has red patches.



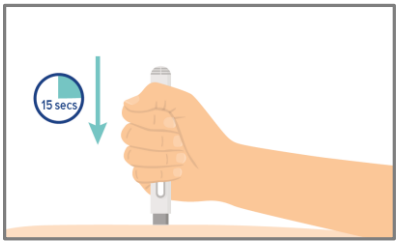
Step 5: Remove the blue needle cap

- Carefully remove the blue needle cap with a metal center from the auto-injector.



Step 6: Place gray needle shield, press down and hold 15 seconds

- Place the gray needle shield straight on your skin, and push the entire auto-injector down firmly to start the injection.
- When you push down, the injection starts.
- You may hear a click.



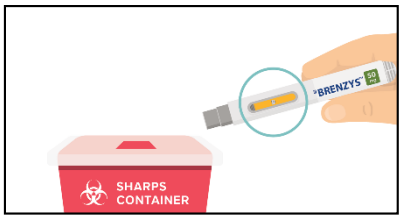
Step 7: After 15 seconds, remove auto-injector

- Hold the auto-injector against your skin.
- After 15 seconds, remove the auto-injector from the injection site.
- You may hear a second click.

Step 8: Confirm completion & dispose auto-injector

- Confirm that the medication window is yellow.
- Discard your auto-injector in a sharps container.

- If the window isn't yellow, you may not have received your full dose.
- Note: As per illustration a small grey band may still be visible.



This leaflet was prepared by Samsung Bioepis Co., Ltd.

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