

Using the ABRILADA Pen

A STEP-BY-STEP GUIDE



Not actual size.

SELECTED SAFETY INFORMATION

What is the most important information I should know about ABRILADA?

You should discuss the potential benefits and risks of ABRILADA with your doctor. ABRILADA is a tumor necrosis factor (TNF) blocker medicine that can lower the ability of your immune system to fight infections. You should not start taking ABRILADA if you have any kind of infection unless your doctor says it is okay.

- Serious infections have happened in people taking adalimumab products. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections. Your doctor should test you for TB before starting ABRILADA, and check you closely for signs and symptoms of TB during treatment with ABRILADA, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.
- Cancer. For children and adults taking TNF blockers, including ABRILADA, the chance of getting lymphoma or other cancers may increase. There have been cases of unusual cancers in children, teenagers, and young adults using TNF blockers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. If using TNF blockers including ABRILADA, your chance of getting two types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life-threatening if treated; tell your doctor if you have a bump or open sore that doesn't heal.

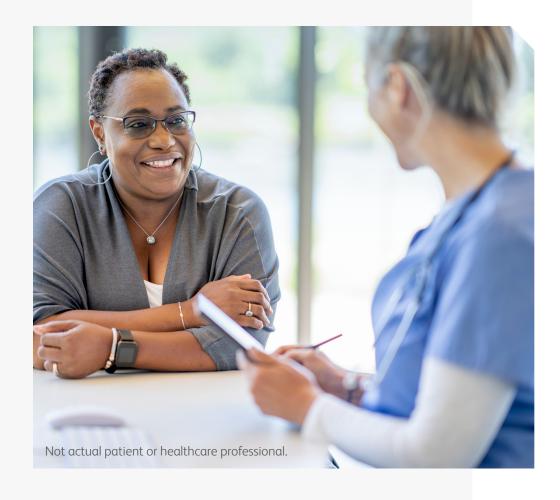
Please see additional Selected Safety Information throughout, and <u>Full Prescribing Information</u>, <u>including BOXED WARNING</u>, <u>Medication Guide</u>, and <u>Instructions for Use</u>, available at ABRILADA.com.





TABLE OF CONTENTS

Introduction	3
Important Information about the ABRILADA Pen	4
Key features of the ABRILADA Pen	5
How to use the ABRILADA Pen	6
Traveling with ABRILADA Pens	2
Tips on how to use the ABRILADA Pen	3







Introduction

ABRILADA is a prescription medication that patients and caregivers can inject using the ABRILADA pen.

Whether you are a caregiver administering an ABRILADA injection to a patient, or a patient self-injecting, you should have been shown the correct way to use the ABRILADA pen by your healthcare professional. This step-by-step guide is intended to be a refresher on how to use the ABRILADA pen, and is not intended to be relied on independently.

Do not attempt to inject with the ABRILADA pen until you have been shown how to do so by a healthcare professional and have reviewed the Instructions for Use.

If you have questions about injecting ABRILADA, the information in the Instructions for Use and this guide are here to help. By closely reviewing and following the simple steps inside, you can start to feel more confident about using the ABRILADA pen as a part of your treatment plan.

USES

ABRILADA is a prescription medicine used:

- To reduce the signs and symptoms of:
 - Moderate to severe rheumatoid arthritis (RA) in adults. ABRILADA can be used alone, with methotrexate, or with certain other medicines. ABRILADA may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - Moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children 2 years of age and older. ABRILADA can be used alone or with methotrexate.
 - **Psoriatic arthritis (PsA) in adults.** ABRILADA can be used alone or with certain other medicines. ABRILADA may prevent further damage to your bones and joints and may help your ability to perform daily activities.
 - Ankylosing spondylitis (AS) in adults.
 - Moderate to severe hidradenitis suppurativa (HS) in adults.
- To treat moderate to severe Crohn's disease (CD) in adults and children 6 years of age and older.
- To treat moderate to severe ulcerative colitis (UC) in adults. It is not known if adalimumab products are effective in people who stopped responding to or could not tolerate anti-TNF medicines.
- To treat moderate to severe chronic plaque psoriasis (Ps) in adults who are ready for systemic therapy or phototherapy, and are under the care of a doctor who will decide if other systemic therapies are less appropriate.
- To treat non-infectious intermediate (middle part of the eye), posterior (back of the eye), and panuveitis (all parts of the eye) in adults.

You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985 (U.S. only). If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit http://fda.gov/MedWatch or call 1-800-FDA-1088.

SELECTED SAFETY INFORMATION

What should I tell my doctor BEFORE starting ABRILADA?

Tell your doctor about all of your health conditions, including if you:

- Have an infection, are being treated for infection, or have symptoms of an infection
- Get a lot of infections or infections that keep coming back



IMPORTANT INFORMATION ABOUT THE ABRILADA PEN

KEEP THIS BOOKLET. It contains step-by-step instructions on how to prepare and give an injection with the ABRILADA pen.

- Store the ABRILADA pen in the refrigerator at 36°F to 46°F (2°C to 8°C)
- Store the ABRILADA pen in its original carton until use to protect it from light
- Do not freeze ABRILADA. Do not use ABRILADA if frozen, even if it has been thawed
- Refrigerated ABRILADA may be used until the expiration date printed on the ABRILADA carton or pen. Do not use ABRILADA after the expiration date
- If needed, for example when you are traveling, you may also store ABRILADA at room temperature up to 86°F (30°C) for up to 30 days. Store ABRILADA in the original carton until use to protect it from light
- Throw away ABRILADA if it has been kept at room temperature and not been used within 30 days
- Record the date you first remove ABRILADA from the refrigerator in the spaces provided on the ABRILADA pen carton
- Do not store ABRILADA in extreme heat or cold
- Do not use the pen if the liquid is cloudy, discolored, or has flakes or particles in it

Keep ABRILADA, injection supplies, and all other medicines out of the reach of children.

ABRILADA for injection comes in a disposable (throwaway) single-use pen that contains a single dose of medicine. Please be sure to dispose the pen in a US Food and Drug Administration (FDA) cleared puncture-resistant sharps disposal container for pen disposal. If you do not have a sharps container, you may use a household container that is made of a heavy-duty plastic, can be closed with a tight-fitting and puncture-resistant lid without sharps being able to come out, upright and stable during use, leak-resistant, and properly labeled to warn of hazardous waste inside the container.

ABRILADA for injection can be given by a patient, caregiver or healthcare professional. Do not try to inject ABRILADA yourself until you receive education from your healthcare professional and read and understand the Instructions for Use. If your healthcare professional decides that you or a caregiver may be able to give your injections of ABRILADA at home, you should receive training on the right way to prepare and inject ABRILADA. It is important that you read, understand, and follow the <u>Instructions for Use</u> to help you inject ABRILADA the right way.

It is important to talk to your healthcare professional to be sure you understand your ABRILADA dosing instructions. To help you remember when to inject ABRILADA, you can mark your calendar ahead of time. Pfizer has also developed a mobile app, All in 1, that can help you track your injections. To download the app, please visit the app store on your mobile device. Call your healthcare professional if you or your caregiver have any questions about the right way to inject ABRILADA.

SELECTED SAFETY INFORMATION

What should I tell my doctor BEFORE starting ABRILADA? (continued)

Tell your doctor about all of your health conditions, including if you: (continued)

- Have diabetes
- Have TB or have been in close contact with someone with TB, or were born in, lived in, or traveled where there is more risk for getting TB
- Live or have lived in an area (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections, such as histoplasmosis, coccidioidomycosis, or blastomycosis. These infections may happen or become more severe if you use ABRILADA. Ask your doctor if you are unsure if you have lived in these areas

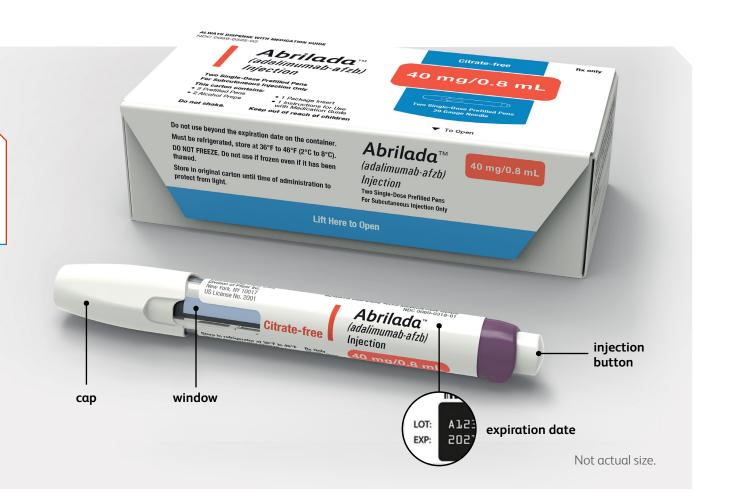


Key features of the ABRILADA Pen

Each ABRILADA pen can only be used once. Each pen delivers a predetermined dose of medicine. ABRILADA pens are packaged in cartons that also contain alcohol swabs.

The following pages describe how to give an injection using the ABRILADA pen in a few simple steps. Make sure you read the <u>Instructions for Use</u> carefully and in full. You should have received education from your healthcare professional on how to inject ABRILADA before doing it yourself.

<u>DO NOT</u> try to administer ABRILADA until you are sure how to use the ABRILADA pen. Talk to your doctor, nurse, or pharmacist if you or your caregiver have any questions about the correct way to inject ABRILADA.





The single-dose pen, which facilitates injection of ABRILADA, received the Arthritis Foundation's Ease of Use Certification. Products receiving this certification have been independently tested and proven easier to use for people with arthritis and inflammatory joint pain.

Learn more at arthritis.org/easeofuse.

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SELECTED SAFETY INFORMATION

What should I tell my doctor BEFORE starting ABRILADA? (continued)

Tell your doctor about all of your health conditions, including if you: (continued)

- Have or have had hepatitis B
- Are scheduled for major surgery
- Have or have had cancer
- Have numbness or tingling or a nervous system disease such as multiple sclerosis or Guillain-Barré syndrome



How to use the ABRILADA Pen

STEP 1

Supplies you need

Ensure you have the items below for each injection of ABRILADA. **Find a clean, flat surface and place the items onto it.**



1 ABRILADA Pen [included inside the carton]



1 alcohol swab

[included inside the carton]



1 cotton ball or gauze pad

[not included in the carton]



1 puncture-resistant sharps disposal container

[not included in the carton; please see step 10 for more information]

Items above not actual size.

SELECTED SAFETY INFORMATION

What should I tell my doctor BEFORE starting ABRILADA? (continued)

Tell your doctor about all of your health conditions, including if you: (continued)

- Have or had heart failure
- Have recently received or are scheduled to receive a vaccine. ABRILADA patients may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting ABRILADA
- Are allergic to any ABRILADA ingredients
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed
- Have a baby and you were using ABRILADA during your pregnancy. Tell your baby's doctor before your baby receives any vaccines

STEP 2

Getting ready

- Remove the ABRILADA carton from the refrigerator
- Make sure the name ABRILADA appears on the carton and pen label
- Take out one ABRILADA pen and the alcohol swab from the carton
 - Keep the pen out of direct sunlight
 - Put the original carton with any unused pens back into the refrigerator

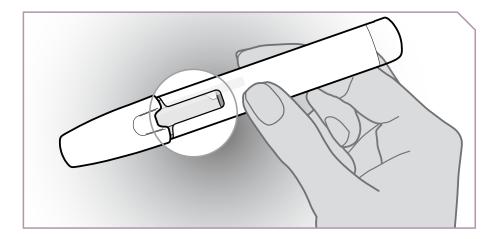
DO NOT USE YOUR PEN IF:

- X your pen or the carton containing the pen has been dropped
- X it has been frozen or thawed
- X it has been kept in direct sunlight
- X it appears to be damaged
- X the seals on a new carton are broken
- X it has been out of the refrigerator for more than 30 days
- X the expiration date has passed
- X the liquid is cloudy, discolored, or has flakes or particles
- You can leave your pen at room temperature for 15 to 30 minutes before your injection which may reduce stinging or discomfort
- **DO NOT** warm ABRILADA in any other way (for example, do not warm it in a microwave or in hot water)
- **DO NOT** shake the pen. Shaking can damage the medicine
- Wash your hands with soap and water, and dry completely
- **DO NOT** remove the cap until you are ready to inject

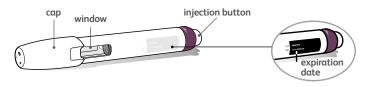




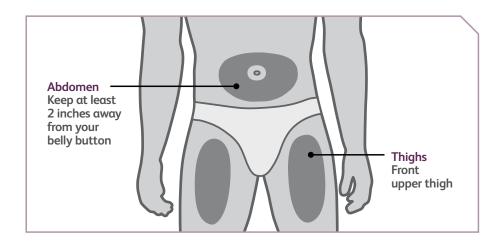
STEP 3 Check the medicine and expiration date



- Look carefully at the medicine in the window
- Make sure the medicine in the pen is clear and colorless to very light brown and free from flakes or particles
- It is normal to see one or more air bubbles in the window
- Check the expiration date on the pen label. The location of the expiration date on the pen label is shown below. **DO NOT** use the pen if the expiration date has passed



STEP 4 Choose and prepare the injection site



- Choose a different injection site each time you give an injection:
 - Only use the front of your thighs or your lower abdomen (belly) as shown. If you choose your abdomen, do not use the area 2 inches around your belly button (navel)
 - Each new injection should be given at least one inch from a site you used before
- **DO NOT** inject into bony areas or areas on your skin that are bruised, red, sore (tender) or hard. Avoid injecting into areas with scars or stretch marks
 - If you have psoriasis, do not inject directly into any raised, thick, red, or scaly skin patches or lesions on your skin
- **DO NOT** inject through your clothes
- Wipe the injection site with the alcohol swab
- Allow the injection site to dry. **DO NOT** fan or blow on the clean area
- **DO NOT** touch this area again before giving the injection

If you have any questions about your medicine, please contact your healthcare professional or pharmacist.

SELECTED SAFETY INFORMATION

What should I tell my doctor BEFORE starting ABRILADA? (continued)

Tell your doctor about all of your health conditions, including if you: (continued)

Also tell your doctor about all the medicines you take. You should not take ABRILADA with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

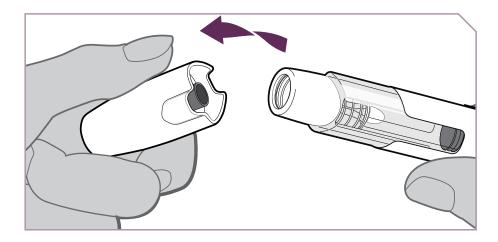
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STEP 5

Remove the cap

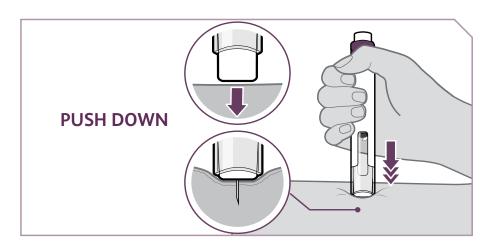


- Twist and pull off the cap
- Throw the cap away into a sharps disposal container. You will not need it again

Note: A needle cover stays inside the cap after cap removal.

STEP 6

Insert the needle



• Push your pen firmly against the skin at 90 degrees, as shown in the diagram **Keep your pen pushed against the skin until Step 9.**

Note: The needle goes into the skin as you push your pen down. You will only be able to press down the injection button in Step 7 when you are pushing down firmly enough.

IMPORTANT: Handle your pen with care to avoid an accidental needle stick injury.

SELECTED SAFETY INFORMATION

What should I watch for AFTER starting ABRILADA?

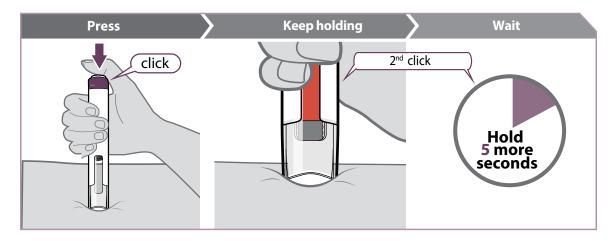
ABRILADA can cause serious side effects, including:

- Serious infections. These include TB and infections caused by viruses, fungi, or bacteria. Symptoms related to TB include a cough, low-grade fever, weight loss, or loss of body fat and muscle.
- **Hepatitis B infection in carriers of the virus.** Symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.



STEP 7

Inject the medicine



- Press the injection button all the way down and you will hear a click. The click means the start of the injection
- **Keep holding** your pen firmly against the skin while the orange bar moves across the window. You will hear a second click
- Wait for at least 5 more seconds after the second click to make sure you get the full dose of medicine

Note: If you cannot press down the injection button, it may be because you are not pushing the pen down firmly enough at the injection site.

See the Question and Answer section in the <u>Instructions for Use</u> for more information on what to do if the injection button does not press down.

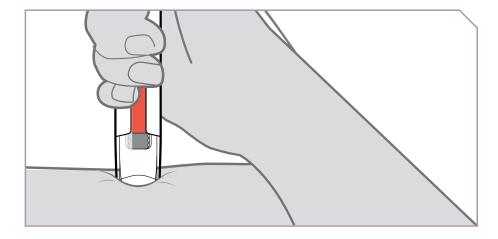
SELECTED SAFETY INFORMATION

What should I watch for AFTER starting ABRILADA? (continued)

- Allergic reactions. Symptoms of a serious allergic reaction include hives, trouble breathing, and swelling of your face, eyes, lips, or mouth.
- Nervous system problems. Signs and symptoms include numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- Blood problems (decreased blood cells that help fight infections or stop bleeding). Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.



STEP 8 Check the window

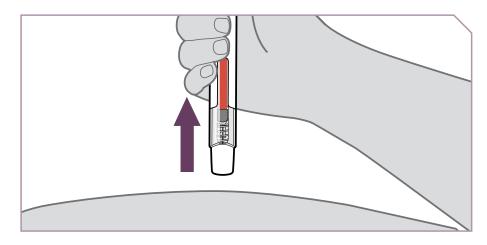


• You should see an orange bar in the window

<u>DO NOT</u> remove your pen until you have waited at least 5 seconds after the second click and until the orange bar completely fills the window.

STEP 9

Remove the pen



• Remove your pen from the skin

Note: After you remove your pen from the skin, the needle will be automatically covered.

- If the window has not turned orange, this means you have not received a full dose. Call your healthcare professional or pharmacist right away
- **DO NOT** inject another dose

SELECTED SAFETY INFORMATION

What should I watch for AFTER starting ABRILADA? (continued)

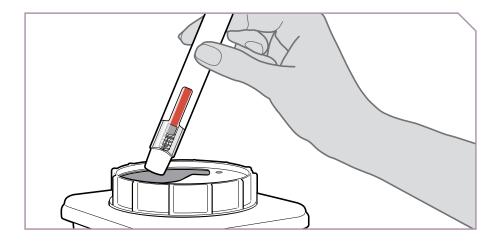
- Heart failure (new or worsening). Symptoms include shortness of breath, swelling of your ankles or feet, and sudden weight gain.
- Immune reactions including a lupus-like syndrome. Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or rash on your cheeks or arms that gets worse in the sun.
- **Liver problems.** Symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of your stomach (abdomen). These problems can lead to liver failure and death.





STEP 10

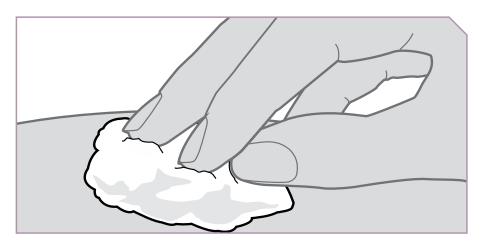
Dispose of the used pen



- Put your used pen in an FDA-cleared sharps disposal container right away after use. <u>DO NOT</u> throw away (dispose of) loose pens in your household trash
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:
 - made of heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid that does not allow sharps to come out,
 - upright and stable during use,
 - leak-resistant, and
 - is properly labeled to warn of hazardous waste inside the container

STEP 11

After the injection



- Look closely at your injection site. If there is blood, use a clean cotton ball or gauze pad to press lightly on the injection area for a few seconds
- **DO NOT** rub the injection site

Note: Store any unused pens in the refrigerator in the original carton.

SELECTED SAFETY INFORMATION

What should I watch for AFTER starting ABRILADA? (continued)

• **Psoriasis** (new or worsening). Symptoms include red scaly patches or raised bumps that are filled with pus.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Common side effects of ABRILADA include injection site reactions (pain, redness, rash, swelling, itching, or bruising), upper respiratory infections (including sinus infections), headaches, and rash. These are not all of the possible side effects with ABRILADA. Tell your doctor if you have any side effect that bothers you or that does not go away.

Please see additional Selected Safety Information throughout, and <u>Full Prescribing Information</u>, <u>including BOXED WARNING</u>, <u>Medication Guide</u>, and <u>Instructions for Use</u>, available at ABRILADA.com.





Traveling with ABRILADA Pens

You should keep cartons of ABRILADA pens in the refrigerator between 36°F to 46°F (2°C to 8°C).



When traveling, you may store the pen at room temperature, up to 86°F (30°C), for up to 30 days. **Store the ABRILADA pen in the original carton until use to protect it from light**. Remember to throw away the ABRILADA pen if it has been kept at room temperature and not been used within 30 days. For this reason, you should record the date you first remove ABRILADA from the refrigerator in the spaces provided on the ABRILADA pen carton.

Additional supplies to pack:

- Gauze or cotton balls
- Sharps disposal container



When traveling involves flying, pack your medication in your carry-on luggage to ensure ABRILADA is stored properly and you can easily access it at security checkpoints or during your flight. Additional considerations include:

- Inform the TSA officer of your medication(s) and separate them from other belongings before screening begins. Labeling these items may help facilitate the screening process
- If requested, carefully remove medically necessary items from your carry-on bag for screening (as these items will be screened separately from your other belongings)
- For more information, visit www.tsa.gov/travel/special-procedures

SELECTED SAFETY INFORMATION

Remember, tell your doctor right away if you have an infection or symptoms of an infection, including:

- Fever, sweats, or chills
- Muscle aches
- Cough
- Shortness of breath
- Blood in phlegm
- Weight loss

- Warm, red, or painful skin or sores on your body
- Diarrhea or stomach pain
- Burning when you urinate
- Urinating more often than normal
- Feeling very tired

ABRILADA is given by injection under the skin.

This is the most important information to know about ABRILADA. For more information, talk to your healthcare professional.

Please see additional Selected Safety Information throughout, and <u>Full Prescribing Information</u>, <u>including BOXED WARNING</u>, <u>Medication Guide</u>, and <u>Instructions for Use</u>, available at <u>ABRILADA.com</u>.





Tips on how to use the ABRILADA Pen



- Wash your hands with soap and water, and dry them completely before starting
- Check that the pen you are using has not expired. If the expiration date has passed, discard the pen into a sharps container
- Check that the medicine is clear, colorless to very light brown, and free from flakes or particles
- For a more comfortable injection, allow the pen to come to room temperature, away from direct sunlight
- Each pen can only be used once; do not remove the cap until you are ready to inject
- Dispose of pens, including caps, into a sharps container only
- Contact your healthcare professional if you have any questions about injecting ABRILADA

To learn more about ABRILADA, go to Abrilada.com

SELECTED SAFETY INFORMATION

What is the most important information I should know about ABRILADA?

You should discuss the potential benefits and risks of ABRILADA with your doctor. ABRILADA is a tumor necrosis factor (TNF) blocker medicine that can lower the ability of your immune system to fight infections. You should not start taking ABRILADA if you have any kind of infection unless your doctor says it is okay.

• Serious infections have happened in people taking adalimumab products. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections. Your doctor should test you for TB before starting ABRILADA, and check you closely for signs and symptoms of TB during treatment with ABRILADA, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.

Please see additional Selected Safety Information throughout, and Full Prescribing Information, including BOXED WARNING, Medication Guide, and Instructions for Use, available at ABRILADA.com.

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