

PAEDIATRIC

Patient reminder card

ABRILADA[®] adalimumab (40 mg/0.8ml solution for injection in pre-filled syringe & pre-filled syringe)

Information for you and health care professionals involved in your child's medical care or treatment.

Not all possible side effects are listed on this card. Please read the Abrilada package leaflet or talk with your child's doctor for more information about side effects.

If you have any questions, speak to your child's healthcare giver about your child's treatment.

This card contains select important safety information that you need to know before and during your child's treatment with Abrilada

- Keep this card with you at all times and for 70 days after your child's last injection of Abrilada
- Show this card to any doctor or health care professional that your child sees
- Record information about any tuberculosis tests or treatment your child has had on the back of this card

Introduction

Abrilada is a medicine that is intended to treat Rheumatoid Arthritis, Juvenile idiopathic arthritis, Axial spondyloarthritis, Psoriatic arthritis, Psoriasis, Paediatric plaque psoriasis, Hidradenitis suppurativa, Adult & Pediatric Crohn's Disease, Adult & Pediatric Ulcerative colitis, Adult and pediatric uveitis.

While Abrilada can be effective in treating these diseases, some people can have one or more side effects. It is important to talk to your child's doctor about the possible benefits and possible side effects of taking Abrilada. These can be different for each person.

- The purpose of this card is to tell you about some of the possible side effects of Abrilada
- Some of the serious side effects that could occur include infections, cancer, and nervous system problems
- These are not all of the possible side effects of Abrilada

Before Abrilada Treatment

Tell your child's doctor about any health problems your child has and any medicines your child takes. This will help you and your child's doctor decide if Abrilada is right for your child.

Tell your child's doctor if your child:

- Has an infection or has symptoms of an infection (such as fever, feeling tired)
- Has tuberculosis or has been in close contact with someone with tuberculosis
- Has or has had cancer
- Has any numbness or tingling or has a problem that affects your child's nervous system, such as multiple sclerosis

Your child's doctor should check him or her for signs and symptoms of tuberculosis before starting Abrilada. Your child may need to be treated for tuberculosis before he or she starts Abrilada.

Vaccinations

- Your child's doctor may suggest certain vaccinations for your child before they start Abrilada. Live vaccines should not be administered to your child while taking Abrilada. If you receive Abrilada while you are pregnant, it is important that you inform the baby's doctor before the baby receives any vaccine.

During Abrilada Treatment

To make sure that Abrilada is working properly and safely for your child, you should check in with his or her doctor regularly to discuss how your child is doing. Tell your doctor right away about any changes in your child's condition.

Keep your child's doctor informed about how Abrilada is working for your child.

- It is important to call your child's doctor right away about any unusual symptoms your child may have. This will help make sure your child gets the right care. It will also lower the chance of a side effect becoming worse
- Many side effects, including infections, can be managed if you tell your child's doctor right away.
- If your child gets a side effect, your child's doctor will decide if your child should continue or stop his or her Abrilada treatment. It is important to talk with your child's doctor to find out what is right for your child
- Since side effects can happen after your child's last dose of Abrilada, tell your child's doctor about any problems that your child may have up to 70 days after your child's last injection of Abrilada.

Tell your child's doctor about:

- Any new medical conditions that your child has
- New medicines your child is taking
- Any surgery or operation that is planned for your child

Some people taking Abrilada may get serious side effects, including:

Infections

• Abrilada helps people with certain inflammatory diseases. It does this by blocking a part of the immune system. However, this part of the immune system also helps fight infection. This means Abrilada can make your child more likely to get infections or make any infection that your child may have worse. This includes infections such as colds or more serious infections like tuberculosis.

Cancer

- If your child takes Abrilada, the risk of getting certain types of cancer may increase

Nervous system problems

- Some people have developed new or worsening nervous system problems with Abrilada. This includes multiple sclerosis

Please read the Abrilada package leaflet for more information. These are not all of the possible side effects that may occur during treatment with Abrilada.

Call your child's doctor or get medical care right away if your child has any of the following symptoms of these possible serious side effects:

Infections

- Fever, chills, sweating, feeling unwell or more tired than normal, feeling or being sick (such as vomiting), diarrhea, stomach pain, loss of appetite or weight loss, cough or coughing up blood or mucus, shortness of breath, problems urinating, skin sores, muscle aches

Nervous system problems

- Numbness or tingling, vision changes, muscle weakness, dizziness
- Tell your child's doctor about any unusual symptoms that your child may have during treatment with Abrilada. These are not all of the possible symptoms of these side effects.

Information for you and healthcare professionals involved in your child's medical care or treatment.

Tuberculosis (TB) Tests and Treatment

Mark this box if your child has ever been tested for TB:

- YES** (Check with your doctor if you do not know)

Mark this box if your child has ever had any test that was positive for TB:

- YES** (Check with your doctor if you do not know)

Mark this box if your child has ever taken any pills to treat or prevent TB:

- YES** (Check with your doctor if you do not know)

Please read the Abrilada package leaflet for more information.

If you have any other questions, talk to your child's doctor or another healthcare professional

Your child's name: _____

Your child's doctor's name (who prescribed Abrilada): _____

Your child's doctor's phone number: _____

Indication: _____

Date of your child's first Abrilada injection: _____

Dose of your child's Abrilada injection: _____

Date of your child's last Abrilada injection (if no longer taking Abrilada) _____

Please fill out information for your child and healthcare professionals involved in your child's medical care or treatment

To report side effects:

SFDA National Pharmacovigilance Center (NPC):

SFDA call center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa>

Pharmacovigilance Department in the company

- E-mail: SAU.AEReporting@pfizer.com

For extra copies of patient reminder card, please send an email with your contact details and the required amount to SAU.AEReporting@Pfizer.com



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