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

- Always keep this card with you/your child and for 70 days after your child's last injection of Adalicip.
- Show this card to any doctor or healthcare professional that is involved in your child's treatment.
- Record information about any tuberculosis tests or treatment your child has had in the space provided.

This information card is produced by:

## Cipla Australia Ptv Ltd.

Level 1/132 - 136 Albert Road, South Melbourne VIC 3205

Email: drugsafety@cipla.com

Phone: 1800-569-074

Date of preparation: October 2023



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 child's 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 child's doctor if you do not know)

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

YES (Check with your child's doctor if you do not know)

Please read the Adalicip consumer medicines information (CMI) for more information. If you have any other questions, talk to your child's doctor or another healthcare professional.



SCAN THE QR CODE to view the CMI online

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

Your child's doctor's name (who prescribed Adalicip):

Your child's name:

Your child's doctor's phone number:

Indication:

Date of your child's first Adalicip injection:

Dose of your child's Adalicip injection:

Date of your child's last Adalicip injection (if no longer taking Adalicip):

PAEDIATRIC

Patient Reminder Card

## **Adalicip**<sup>®</sup>

(adalimumab)

A biosimilar to Humira®1

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

Not all possible side effects are listed on this card.

Please read the Adalicip consumer medicines information (CMI) or talk with your child's doctor for more information about side effects.

Approved by TGA: October 2023. AU-ADA-2300003. Version 01/ADA/001/10.23 (AUS)

Reference: 1. ADALICIP (Adalimumab) Approved
Product Information

### Introduction

Adalicip is a medicine that is intended to treat certain diseases that affect a part of the immune system. While Adalicip 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 Adalicip. These can be different for each person.

- The purpose of this card is to tell you about some of the possible side effects of Adalicip.
- 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 Adalicip.

## **Before Adalicip Treatment**

Tell your child's doctor about any health problems your child has and any medication your child is currently on. This will help you and your child's doctor decide if Adalicip 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, wounds, feeling tired, dental problems).
- Has, or has previously had, 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 for signs and symptoms of tuberculosis before starting Adalicip. Your child may need to be treated for tuberculosis before they start Adalicip.

## **Vaccinations**

 Your child's doctor may suggest certain vaccinations for your child before they start Adalicip. Live vaccines should not be administered to your child while taking Adalicip. If your child receives Adalicip while pregnant, it is important that you inform the doctor before the baby receives any vaccine. The baby should not receive a "live vaccine", such as BCG (used to prevent tuberculosis) within 5 months following your last Adalicip injection during pregnancy.

## **During Adalicip Treatment**

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

## Keep your child's doctor informed about how Adalicip is working for your child

- It is important to contact 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 treatment with Adalicip.
  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 Adalicip, tell your child's doctor about any problems that your child may have up to 70 days after your child's last injection of Adalicip.

## Tell your 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.
- · If your child falls pregnant.

## Some people taking Adalicip may get serious side effects, including:

Infections: Adalicip 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 Adalicip 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 Adalicip, the risk of getting certain types of cancer may increase.

**Nervous system problems:** Some people have developed new or worsening nervous system problems with Adalicip. This includes multiple sclerosis.

Please read the Adalicip consumer medicines information (CMI) for more information. These are not all of the possible side effects that may occur during treatment with Adalicip.

# 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, unusual sweating, feeling unwell or more tired than normal, feeling or being sick (such as nausea or vomiting), diarrhoea, stomach pain, loss of appetite or weight loss, cough or coughing up blood or mucus, shortness of breath, problems urinating, skin sores, wounds, muscle aches, dental problems

#### Cancer

Night sweats, swelling of the lymph nodes (swollen glands) in the neck, armpits, groin or other areas, weight loss, new skin lesions or change in skin lesions (such as moles or freckles) your child already has, severe itchiness that cannot be explained.

## Nervous system problems

Numbness or tingling, vision changes, muscle weakness, unexplained dizziness.

Tell your child's doctor about any unusual symptoms that your child may have during treatment with Adalicip. These are not all the possible symptoms of these side effects.

