

## Crohn's disease

(13-17 years, severe disease | ≥18 years, moderate to severe disease)

Patient Support Program

# PfizerFlex

Experienced, Dedicated Team

## Ulcerative colitis

(≥5 years, moderate to severe disease)

# Getting in touch with your treatment



## A guide for using ABRILADA



[abrilada.ca](http://abrilada.ca)



# Welcome

to your PfizerFlex  
Patient Support Program for  
**ABRILADA**

**Welcome to your or your child's treatment with ABRILADA for Crohn's disease (CD) or ulcerative colitis (UC).** Along with the support you receive from your healthcare team, you can turn to your experienced PfizerFlex support team for information and advice to help you with your new plan.

**This booklet is a great resource** for you to learn more about your ABRILADA treatment, and so is your PfizerFlex Care Coach.

Keep in mind as you read this booklet that both resources may provide more information if you choose to explore all the lifestyle recommendations and tools the PfizerFlex program has to offer, to help you discover new strategies for helping manage your or your child's CD or your UC.

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# ABRILADA basics

## Why did your doctor choose ABRILADA?

Your doctor has prescribed ABRILADA for you or your child because of your condition, your age and your treatment history:

- **Crohn's disease (CD)** for adults and children aged 13 to 17 (who weigh 40 kg or more) who did not respond well enough to other treatments.
- **Ulcerative colitis (UC)** for adults and children aged 5 to 17 who did not respond well enough to other treatments.

## What type of medicine is ABRILADA?

ABRILADA is a biosimilar biologic drug, and is part of a class of medications called biologic response modifiers.

## What is a biosimilar?

A biosimilar is a biologic drug product that is authorized based on its likeness to a reference biologic drug product already authorized for sale in Canada.

ABRILADA is a biosimilar of the reference biologic drug Humira®.

# How ABRILADA works

Your immune system works to protect your body from bacteria, viruses and other foreign agents. In Crohn's disease (CD) or ulcerative colitis (UC), the immune system mistakenly recognizes the body as foreign and attacks healthy body cells.



When you have CD or UC, your immune system overproduces a substance called TNF-alpha (which stands for tumour necrosis factor alpha). The extra TNF-alpha can attack normal healthy body tissues and cause inflammation, especially in the digestive tract.



The way ABRILADA works is by binding to TNF-alpha and decreasing the inflammation process of CD and UC. However, ABRILADA can also lower the body's ability to fight infections, and taking it can make you more prone to getting infections, or make any infection worse.

# How to take ABRILADA












## How to administer to yourself or your child

ABRILADA is administered by injection under the skin—also called a subcutaneous injection.























View the instructional video:



## What is the usual dose for Crohn's disease?

	Induction period (first 4 weeks)		Maintenance period (after 4 weeks)
<b>For adults</b> with moderate to severe Crohn's disease	 OR  <b>1<sup>st</sup> dose</b> (Day 1/Week 0) <b>160 mg</b> <ul style="list-style-type: none"> <li>• 4 x 40 mg injections in one day, or</li> <li>• 2 x 40 mg injections per day over two days</li> </ul>	 OR  <b>2<sup>nd</sup> dose</b> (Week 2) <b>80 mg</b> <ul style="list-style-type: none"> <li>• 2 x 40 mg injections in one day</li> </ul>	 OR  <b>3<sup>rd</sup> dose</b> (Week 4) and beyond <b>40 mg</b> every other week
<b>For children</b> aged 13 to 17 years weighing 40 kg or more with severe Crohn's disease	 OR  <b>160 mg</b> <ul style="list-style-type: none"> <li>• 4 x 40 mg injections in one day, or</li> <li>• 2 x 40 mg injections per day over two days</li> </ul>	 OR  <b>80 mg</b> <ul style="list-style-type: none"> <li>• 2 x 40 mg injections in one day</li> </ul>	 <b>20 mg</b> every other week (depending on your child's response, the doctor may increase the dose to 40 mg every other week [given as one injection])

## What is the usual dose for ulcerative colitis?

	Induction period (first 4 weeks)		Maintenance period (after 4 weeks)
<b>For adults</b> with Ulcerative Colitis	 OR  <b>1<sup>st</sup> dose</b> (Day 1/Week 0) <b>160 mg</b> <ul style="list-style-type: none"> <li>• 4 x 40 mg injections in one day, or</li> <li>• 2 x 40 mg injections per day over two days</li> </ul>	 OR  <b>2<sup>nd</sup> dose</b> (Week 2) <b>80 mg</b> <ul style="list-style-type: none"> <li>• 2 x 40 mg injections in one day</li> </ul>	 OR  <b>3<sup>rd</sup> dose</b> (Week 4) and beyond <b>40 mg</b> every other week
<b>For children</b> aged 5 to 17 years with moderate to severe Ulcerative Colitis Weighing less than 40 kg	 OR  <b>80 mg</b> <ul style="list-style-type: none"> <li>• 2 x 40 mg injections in one day</li> </ul>	 OR  <b>40 mg</b> <ul style="list-style-type: none"> <li>• 1 x 40 mg injections in one day, or</li> </ul>  <b>40 mg</b> <ul style="list-style-type: none"> <li>• 2 x 20 mg injections in one day</li> </ul>	 OR  <b>40 mg</b> every other week, or  <b>20 mg</b> every week
<b>For children</b> aged 5 to 17 years with moderate to severe Ulcerative Colitis Weighing 40 kg or more	 OR  <b>160 mg</b> <ul style="list-style-type: none"> <li>• 4 x 40 mg injections in one day, or</li> <li>• 2 x 40 mg injections per day over two days</li> </ul>	 OR  <b>80 mg</b> <ul style="list-style-type: none"> <li>• 2 x 40 mg injections in one day</li> </ul>	 OR  <b>80 mg</b> every other week, or  OR  <b>40 mg</b> every week

## What if you or your child miss a dose?

If you/your child forget an injection, you/your child should inject the missed dose of ABRILADA as soon as you/your child remember. Then administer the next dose on the originally scheduled date.

# What formats does ABRILADA come in?

There are 2 different injection formats for ABRILADA:

**Note:** Do not try to inject ABRILADA yourself until you have read and understood the Instructions for Use.



## Prefilled Pen

40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)

\* The syringe plunger stopper and needle cover are not made with natural rubber latex.



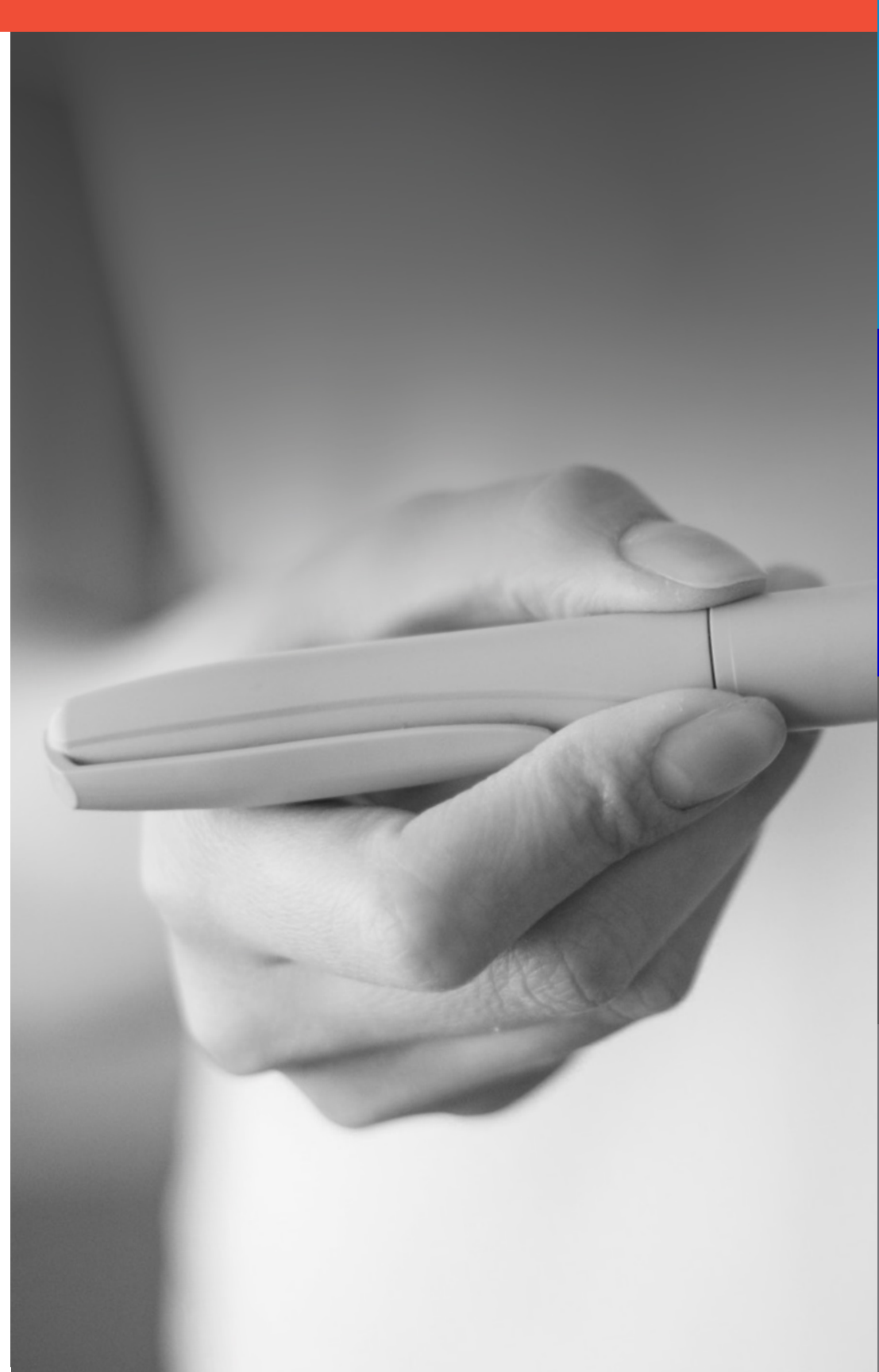
## Prefilled Syringe

Single dose, 1 mL prefilled glass syringe containing either:

- 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL) or
- 20 mg adalimumab dissolved in 0.4 mL sterile solution (50 mg/mL) or
- 10 mg adalimumab dissolved in 0.2 mL sterile solution (50 mg/mL)

\* The syringe plunger stopper and needle cover are not made with natural rubber latex.

Full injection instructions for the prefilled pen and the prefilled syringe are available in the Patient Medication Information leaflet contained in your product package, as well as online at [abrilada.ca](http://abrilada.ca).







# What should you tell your doctor before starting treatment?

To help avoid side effects and ensure proper use, talk to your/your child's healthcare professional before you/your child take ABRILADA. Talk about any health conditions or problems you/your child may have, including any infections, nervous system disorders, heart failure, major surgery, immunizations, concomitant medications, pregnancy and/or breastfeeding. Consult the Patient Medication Information leaflet for additional information.

Before starting, during and after treatment with ABRILADA, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test.

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

**The following may interact with ABRILADA**  
You/your child should not take ABRILADA with:

- Other TNF blockers such as Enbrel<sup>®</sup>, Remicade<sup>®</sup>, Cimzia<sup>®</sup> or Simponi<sup>®</sup>
- Abatacept (Orencia<sup>®</sup>)
- Anakinra (Kineret<sup>®</sup>)

**If you have questions, ask your/your child's doctor.**

# Possible side effects

These are not all the possible side effects you may feel when taking ABRILADA. See the Patient Medication Information leaflet in your product package for more information. If you experience any side effects not listed here, contact your healthcare professional.

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

**Tell your/your child's doctor **immediately** if you/your child experience any of the following:**

- Severe rash, hives or other signs of allergic reaction
- Swollen face, hands, feet
- Trouble breathing, swallowing
- Sudden weight gain; this is possibly indicative of new or worsening heart failure
- Bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets

**Tell the doctor **as soon as possible** if you/your child notice any of the following:**

- Signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- Feeling weak or tired
- Coughing
- Tingling
- Numbness
- Double vision
- Arm or leg weakness
- Arm or leg pain, swelling or redness
- Bump or open sore that does not heal
- Alopecia (loss of hair)
- Red scaly patches or raised bumps that are filled with pus; this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection
- Changes in the colour of the skin
- Changes in the colour of your/your child's urine (dark or red)
- Worsening of the appearance of a scar
- Night sweats
- Weight loss
- Pain in the abdomen or chest





# Exploring your PfizerFlex Program

## Focused on you

Welcome to the PfizerFlex Program! Designed with patients like you in mind, the program gives you access to important treatment information and assistance to support you in getting the most out of your ABRILADA treatment plan.

### Support for every step of your treatment plan

Live support, available from our dedicated team and your Care Coach, for questions about the program or treatment



Reimbursement expertise to help you find and secure coverage for your treatment plan



Experienced team members to help you access your medication as quickly as possible



Access to a reliable injection clinic network, staffed by qualified healthcare professionals



Practical tools to help you navigate your treatment plan







## Coaches who care

**Your individual PfizerFlex Care Coach** is a nurse and an important member of your support team. The PfizerFlex Program has a lot of personalized support and advice to offer, and your PfizerFlex Care Coach will be the one who guides you through this process.

Your PfizerFlex Care Coach will:

- Assist you in exploring your financial assistance options
- Help you begin your treatment with ABRILADA
- Help empower you to understand and manage elements of your treatment plan



### Meeting Your PfizerFlex Care Coach

Within one business day of enrolment, you'll receive a phone call from a PfizerFlex Care Coach to help you discover how the PfizerFlex Program can best support you.

**For more information or to reach your Care Coach, call [1-855-935-FLEX \(3539\)](tel:1-855-935-FLEX).**

# Managing your medication

## Taking advantage of your support teams

It is essential in any treatment to follow your prescription and to let your healthcare professional know what other medications you are taking prior to starting a new treatment.

**Your healthcare team** can help answer important questions you may have, including:

1. What are my most problematic symptoms?
2. Why should I take this medication?
3. What else do I need to do?
4. Why is it important for me to do this?

**Your treatment support team** can help you manage your treatment day to day, and discuss and help you with any of your concerns.

It can also be helpful to discuss the possible treatment outcomes you wish to achieve, which ones are most important to you and why.



## Medication reminders

If you miss your dose of ABRILADA, inject the missed dose as soon as you remember, and take the next dose as planned at the next scheduled time. Do not take a double dose to make up for a forgotten dose. There are many ways to remind yourself to take your medication—here are some useful tips:



Try to take it around activities that you do daily, like brushing your teeth or eating a meal



Use a reminder card or sticky notes



Set an alarm on your cell phone to remind you when it's time



Ask a family member or friend to remind you

 Medisafe



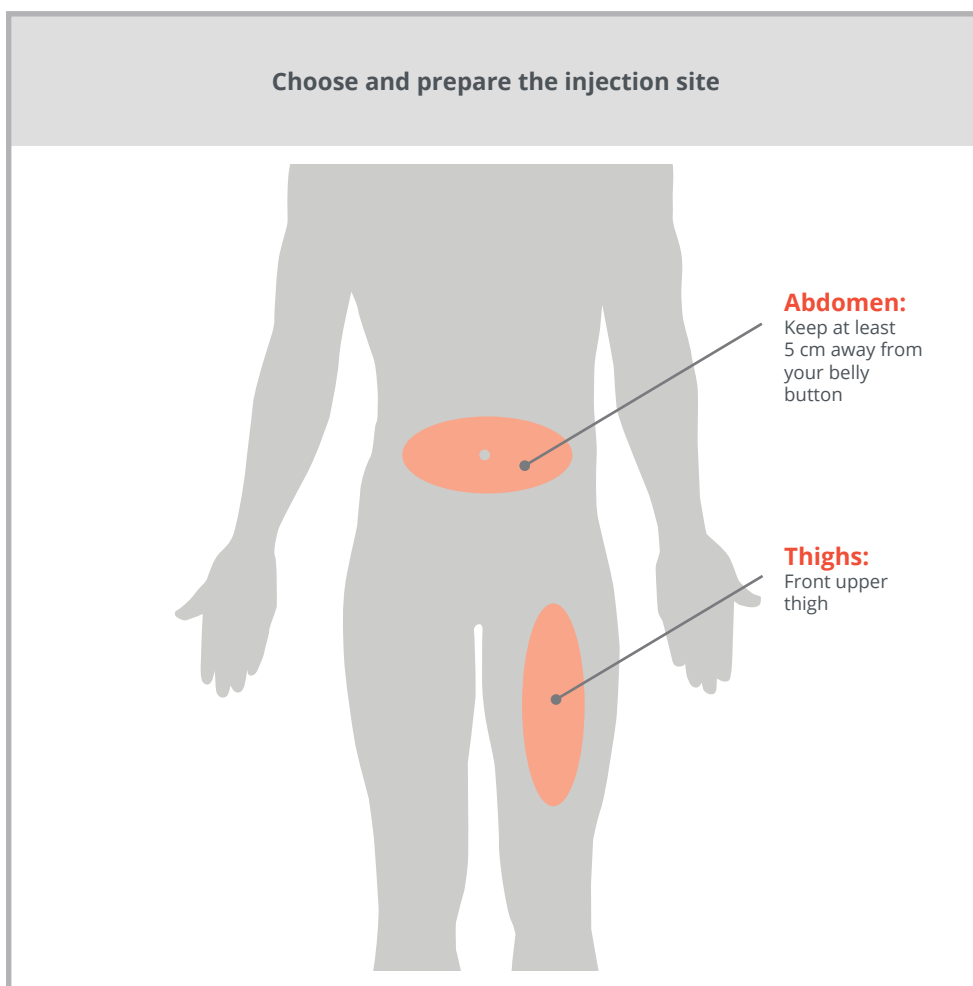
A virtual injection reminder can help you keep track of your medicines. Try Medisafe®, a user-friendly app that reminds you to take your medication at the right time. Medisafe is available on Google Play and the App Store®.

These apps are for reference and not endorsed by Pfizer. Google Play and the Google Play logo are trademarks of Google LLC.

**Remember, always take your medicine exactly as directed by your healthcare provider. Know when to take it, how often and for how long. Know what to do if you miss a dose, and under what conditions you should stop taking it. If you don't know, ask!**

# Injection site location tracker

Use the following table to keep track of when and where you administer your ABRILADA injection. **Choose a different site each time you give an injection.** Do not inject into bony areas or areas on the skin that are bruised, red, sore (tender) or hard. Avoid injecting into areas with scars or stretch marks.



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

**You should discuss any side effects you are experiencing while taking ABRILADA with your doctor or healthcare professional. For complete safety information, please consult the Patient Medication Information leaflet contained in your product package.**

Location of injection	Date of injection

# Basic facts about Crohn's disease

## What is Crohn's disease?

Crohn's disease is a chronic condition where part of the lining of the digestive system becomes inflamed, most commonly the last part of the small intestine and the bowel (colon).

Crohn's disease is slightly more frequent in women than in men. It can start at any age, but is most likely to develop in people between the ages of 15 and 30.

## What are the symptoms?

Symptoms of Crohn's disease may vary in severity, ranging from moderate to severe.

### Common symptoms:

- Diarrhea
- Vomiting
- Abdominal pain and cramping
- Tiredness
- Nausea
- Weight loss



Crohn's disease usually starts with repeated bouts of symptoms (called flares) lasting weeks or months, which are followed by periods when the condition improves (called remission).

## What causes it?

It is not known what causes Crohn's disease, but it is believed to involve your genes—genes contain the blueprint for each individual's specific traits—and immune system.

## How is the immune system involved?

The immune system is designed to attack foreign substances, such as viruses, bacteria or other pathogens.

In Crohn's disease, while the immune system tries to fight off invading foreign substances, an abnormal immune response also causes the immune system to mistake food, harmless bacteria and other materials in the intestine for foreign substances, and to attack the cells in the digestive tract.

## Does family history matter?

Genetic factors are likely to be involved because having family members with Crohn's disease increases your risk of developing the condition.

## Are there any environmental factors?

Environmental factors include where you live, what you eat and whether you smoke. People who live in an urban area or in an industrial country are more likely to develop Crohn's disease. People living in northern climates also seem to be at greater risk.

Smoking is one of the main risk factors. Smokers are more likely to develop Crohn's disease than non-smokers. A diet high in fat or refined foods has also been shown to play a role in Crohn's disease.



# Basic facts about ulcerative colitis

## What is ulcerative colitis?

Ulcerative colitis is a long-term chronic condition causing inflammation and ulcers in the lining of the large intestine (colon), most commonly the last part of the colon and the rectum.

Ulcerative colitis is slightly more common in men. It can start at any age, but is most likely to develop in people between the ages of 15 and 30.

## What are the symptoms?

Ulcerative colitis is an unpredictable condition where symptoms can suddenly flare up at random and then disappear for months or years at a time (called remission). People can experience symptoms varying in severity, ranging from moderate to severe flare-ups.

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### Common symptoms of moderate to severe ulcerative colitis:

- Severe and bloody diarrhea
  - Abdominal pain and cramping
- 



## What causes it?

It is not known what causes ulcerative colitis, but it is believed to involve your genes—genes contain the blueprint for each individual's specific traits—and immune system.

## How is the immune system involved?

It is thought that ulcerative colitis is an autoimmune condition where the body's own immune system mistakes food, harmless bacteria and other materials in the intestine for foreign substances, and attacks the tissues in the colon. When this happens, the tissues in the colon become inflamed. This inflammation may cause painful sores, or ulcers, to develop. These may bleed and produce mucus and pus. It is unclear why the immune system starts making these mistakes, but it may be triggered by environmental factors.

## Does family history matter?

People with a sibling or parent who has ulcerative colitis have a higher risk of developing ulcerative colitis.

# Additional resources

In addition to the various resources offered by **abrilada.ca**, you can also find links to other certified websites that may be useful. Please note that this is not a complete list of the available resources you may find.

These websites include:

- Crohn's and Colitis Canada – [crohnsandcolitis.ca](http://crohnsandcolitis.ca)
- Canadian Digestive Health Foundation – [cdhf.ca](http://cdhf.ca)
- Crohn's and Colitis Foundation – [crohnscolitisfoundation.org](http://crohnscolitisfoundation.org)
- American Society of Colon and Rectal Surgeons – [fascrs.org](http://fascrs.org)
- Crohn's and Colitis – [crohnsandcolitis.com](http://crohnsandcolitis.com)
- IMAGINE Strategy for Patient-Oriented Research (SPOR) Network – [imaginespor.com](http://imaginespor.com)

Apps can modernize the way you track your treatment plan. Some of these apps are free and available on Google Play and/or the App Store®.

Check out some of these apps:

- Gali Health
- Colitis Tracker
- myColitis
- MyGiHealth GI Symptom Tracker

These apps are for reference and not endorsed by Pfizer. Google Play and the Google Play logo are trademarks of Google LLC.



As an ABRILADA patient, you may receive access to the **Lyfe<sup>MD</sup> App**, a nutrition and lifestyle app available to help you manage your condition through healthy changes. Contact your Care Coach for more information.

Pfizer accepts no responsibility for the content of the sites that are not owned and operated by Pfizer.

# Glossary

**Autoimmune disease** – a type of disease where the immune system makes antibodies that turn against the *self* and attack the healthy body tissue by mistake.

**Bowel** – another name for the intestine. The small and large bowels are the small and large intestines, respectively.

**Chronic illness** – an illness that lasts a long time. Usually, it develops slowly and is rarely cured completely.

**Colon** – the large bowel (large intestine).

**Crohn's disease (CD)** – a chronic disorder that causes inflammation of any area of the gastrointestinal tract from the mouth to the anus, although it most commonly affects the small intestine and/or colon. The symptoms and complications of CD differ, depending on what part of the intestinal tract is inflamed.

**Gastroenterologist** – a healthcare professional who specializes in the diagnosis and treatment of diseases of the digestive system.

**Gastrointestinal tract** – collectively refers to the mouth, esophagus, stomach, small and large intestines and anus.

**Immune (system or reaction)** – is made up of cells, organs and tissues that work together to protect the body against infections and some other kinds of diseases. The immune system identifies, attacks and destroys germs and antigens. This is called an immune reaction.

**Inflammation** – an immune response. Redness, heat, pain and swelling are all signs of inflammation.

**Intestine** – a long organ in the abdomen that completes the process of digestion, consisting of the small and large intestines (bowels). The large intestine is wider and shorter than the small one and is divided into the cecum, colon and rectum. Its function is to reabsorb water and to form feces.

**Rectum** – the lowest portion of the large intestine that connects to the anus.

**Ulcerative colitis (UC)** – a chronic disease of the colon characterized by inflammation and ulcers on the lining of the colon. The inflammation causes the colon to empty frequently. Affected organs can include the rectum and the entire colon.

## A STEP-BY-STEP VIDEO GUIDE

on using the ABRILADA  
**single-dose prefilled pen**  
 for subcutaneous injection



## 1-855-935-FLEX (3539)

For more information or to contact your Care Coach  
 (Monday–Friday, 8:00 AM–8:00 PM EST)

A network of clinics located across Canada and staffed by qualified  
 healthcare professionals specially trained in the administration  
 of ABRILADA.\*

Providing you with treatment support from the first prescription  
 to your last injection.

Visit [abrilada.ca](http://abrilada.ca).

\* The PfizerFlex Patient Support Program will work with you to find the most convenient location for  
 your treatment, if you choose not to self-administer your ABRILADA.



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Patient Support Program

**PfizerFlex**

Experienced, Dedicated Team

