Patient Support Program

PfizerFlex

Experienced, Dedicated Team

Getting in touch with your treatment



A guide for using VELSIPITY









Welcome to your ulcerative colitis (UC) treatment with VELSIPITY.

Along with the support you receive from your healthcare team, you can turn to your experienced PfizerFlex support team for information and advice about your new plan.

This booklet is a great resource for you to learn more about your VELSIPITY treatment, and so is your PfizerFlex Care Coach, who is a qualified nurse.

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 assist you in discovering new strategies for helping manage your UC.

VELSIPITY is used to treat adult patients with moderately to severely active ulcerative colitis (UC). It is used when a patient's ulcerative colitis is still active after other treatments have not worked or were not tolerated.

VELSIPITY is pronounced vel-SIP-it-ee.

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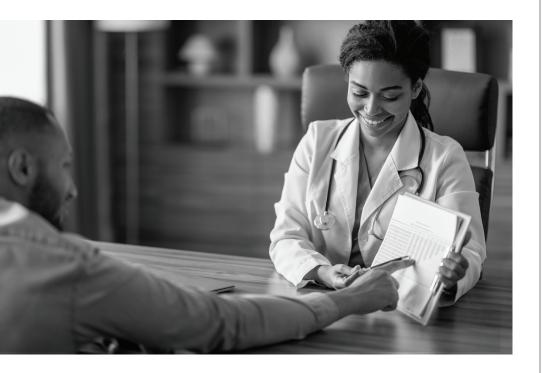
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The VELSIPITY Patient Information leaflet can be found in the pocket of this booklet.

Basic facts about UC

UC typically affects the colon (large intestine), including the rectum and anus. It is a chronic (lifelong) condition that is marked by inflammation and ulceration of the innermost lining of the colon, called the mucosa. UC involves periods of active symptoms and then other periods of remission.

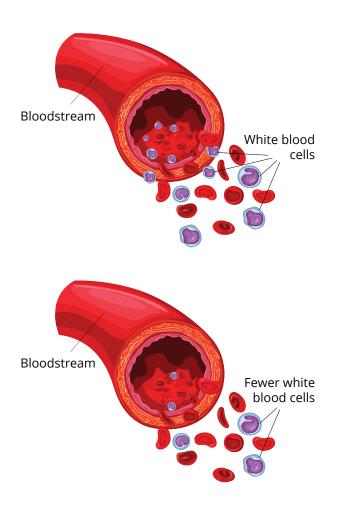
Canada has one of the highest rates of UC in the world, with over 100,000 people currently living with it.



VELSIPITY is used to treat adult patients with moderately to severely active ulcerative colitis (UC). It is used when a patient's ulcerative colitis is still active after other treatments have not worked or were not tolerated.

How it works

VELSIPITY helps reduce inflammation in the gut. It works by stopping certain white blood cells from reaching the lining of the gut.



Before taking VELSIPITY

- Your healthcare professional will check your heart using a test called an electrocardiogram (ECG) to check if you have any heart problems. This may be facilitated through the PfizerFlex Patient Support Program.
- Before and while you are taking VELSIPITY, your healthcare professional may check your ability to breathe. They will also perform various blood tests and will interpret the results.
- You should tell your healthcare professional if you have an infection. You must not take VELSIPITY if you have a severe active infection or an active chronic infection.
- You should also tell your healthcare professional if you have cancer. You must not take VELSIPITY if you have cancer. Before you start taking VELSIPITY or soon after you start taking it, your healthcare professional may examine your skin.
- You must not take VELSIPITY if you are pregnant or are planning to become pregnant. This is because VELSIPITY can harm an unborn baby. Your healthcare professional will explain the pregnancy risks to you before you start taking VELSIPITY.
- Do not take VELSIPITY if you are breastfeeding. This is because VELSIPITY may pass into breast milk.

How to take it

Usual adult dose



VELSIPITY is a 2 mg tablet taken once daily. To help you remember to take your medicine, you should take it at the same time each day.



You can take VELSIPITY with or without food. Swallow tablets whole with water. Do not split, crush, or chew the tablets.

Always take VELSIPITY exactly as your doctor tells you.

Some things to remember when taking VELSIPITY

- You must use effective contraception while taking VELSIPITY and for at least 6 days after you stop taking it. Ask your doctor about effective birth control methods.
 - If you do become pregnant while taking VELSIPITY, tell your doctor immediately. This is because VELSIPITY can harm an unborn baby. You should also talk to them about participating in the pregnancy exposure registry for women who take VELSIPITY while they are pregnant. The purpose of this registry is to collect information about the health of you and your baby. You can call 1-800-616-3791 for more information.
- Your skin may be looked at by your healthcare professional from time to time to look for any skin lesions or moles, especially if you have risk factors for cancer. If you find a mole, contact your healthcare professional right away so that they can look at it.
 Limit how much time you spend in the sun by wearing clothes that protect your skin and by using sunscreen with a high protection factor (also known as SPF).
- Tell your doctor if you are taking, have recently taken, or might take any other medicines including any drugs, vitamins, minerals, natural supplements or alternative medicines. This is because VELSIPITY can affect the way some other medicines work. Also, some other medicines can affect the way VELSIPITY works.
- VELSIPITY lowers the number of white blood cells in your blood.
 This can increase your risk of getting an infection, including serious infections. Your healthcare professional may test your white blood cell levels before you start taking VELSIPTY. Call your doctor right away if you have an infection while taking VELSIPITY or 5 weeks after you stop taking VELSIPITY. Your healthcare professional might stop or pause your treatment with VELSIPITY if you get an infection.
- Cases of progressive multifocal leukoencephalopathy (PML) and posterior reversible encephalopathy syndrome (PRES) have been reported with medicines similar to VELSIPITY. PML is a serious viral brain infection that may lead to severe disability or death. Symptoms of PML include vision problems, weakness in the arms or legs that gets worse, clumsiness, lack of coordination, memory loss or confusion, problems speaking and personality changes. If you get

any of these symptoms, talk to your healthcare professional straight away. Symptoms of PRES include sudden severe headache, feeling nauseous or throwing up, confusion, drowsiness, personality change, paralysis, abnormal speech, convulsions and vision changes. In case you experience any of these symptoms, your healthcare professional should urgently examine how your brain is functioning. If untreated, PRES may result in a stroke or bleeding in the brain. If your healthcare professional thinks you might have PML or PRES, they will examine you further and may stop your treatment with VELSIPITY.

- VELSIPITY may cause your heart rate to decrease, or the impulse of your heartbeat to decrease. Talk to your healthcare professional if you get any symptoms of bradycardia (slow heart rate). These include: dizziness, tiredness, confusion, fainting, feeling lightheaded, feeling like your heart is beating slowly or skipping beats, shortness of breath, or chest pain. You might also experience a slow heart rate and not have any symptoms. Your healthcare professional might also check your blood pressure while you are taking VELSIPITY. This is because VELSIPITY can increase your blood pressure.
 - If you think you, or a person you are caring for, have taken too much VELSIPITY, contact a healthcare provider, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.
 - If you miss a dose of VELSIPITY, take it as soon as you remember on that day. If you forget to take VELSIPITY for the whole day, skip the missed dose and take the next scheduled dose the following day. Do not take a double dose to make up for a forgotten dose. Contact your healthcare professional to discuss how to restart taking VELSIPITY if you miss a dose for more than 2 days in a row within your first week of taking it, or if you miss a dose for more than 7 days in a row at any point.

Store your VELSIPITY

between 15°C and 30°C, and keep out of sight and reach of children.



Exploring your PfizerFlex Program

Focused on you

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

Support for every step of your treatment plan

Live support, available from our dedicated team and your Care Coach (nurse), 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



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 UC 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 options
- Help you begin your treatment with VELSIPITY
- 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–a registered nurse–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).

Lifestyle tips for UC

Think healthy

Fight stress

Stress can increase the risk of a relapse in UC. That's why it's important to recognize stress and anxiety triggers and minimize them. Do you get overwhelmed when you have a lot of errands? You may need to manage your time a little differently. Are you a night owl? Don't force yourself to accomplish your chores first thing in the morning.

The truth is, everyone gets stressed. Luckily, there are many ways to deal with it.

Be active

Being active eases pain, improves mood and lowers stress. Try to pick activities that are easy on your joints, like yoga or Tai Chi.



Try meditating

Calm your mind to improve your mood and reduce stress – it can be as simple as deep breathing.



Be good to yourself

Treat yourself better by getting enough rest and stopping bad habits like smoking.



Get support

If you think it will help you, join a support group. Either way, be sure to continue talking openly to your healthcare team and your family and friends.



Stay positive

Stay realistic with the goals you set, and make sure to be patient with yourself.





Be prepared

• Carry a healthy snack to avoid giving in to trigger foods when you get hungry.



- Know where the bathrooms are when you're out.
 - Check out the GoHere Washroom Locator App, developed by Crohn's and Colitis Canada. This app helps you map out washrooms along a route and locate the closest one. It is free and available on iPhone and Android.

Work healthy

Many people diagnosed with UC are of working age and are affected by their condition, regardless of the type of work they do.



Be open

Because of the sensitive nature of your symptoms, you may not want to share your UC diagnosis with your employer. You are not obliged to do so if you do not want to, but in many cases, employers and colleagues can be very supportive. They may even offer reasonable adjustments to ease your day.

Consider scheduling a private conversation with your manager or your company's human resources department if you decide to share your condition. Bringing printed information about UC will help – just remember to only share information that you feel comfortable discussing.



Work smart

Explain what kind of changes you would like to make and how they may help you at work. These could include a desk or office near the bathrooms, a flexible schedule or even permission to work from home.

Additional resources

Here are some certified websites that may be useful. Please note that this is not a complete list of the available resources you may find.

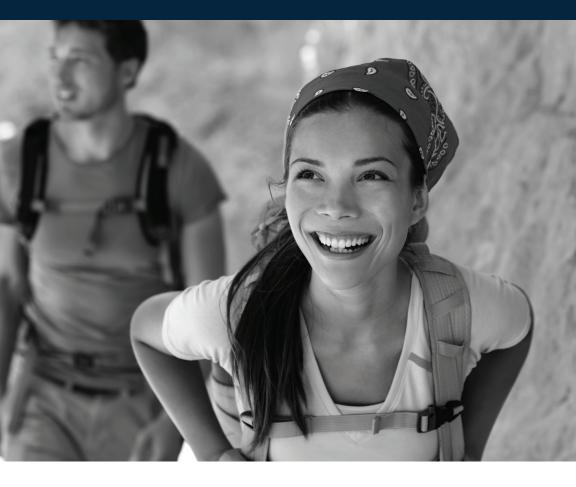
These websites include:

- Crohn's and Colitis Canada –
 crohnsandcolitis.ca
- Canadian Digestive Health
 Foundation –
 cdhf.ca



- American Society of Colon and Rectal Surgeons –
 fascrs.org
- Crohn's and Colitis –
 crohnsandcolitis.com
- IMAGINE Strategy for Patient-Oriented Research (SPOR) network – imaginespor.com

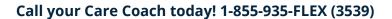




Additional Lifestyle Support

As a VELSIPITY patient, you may receive access to the lyfeMD App, a nutrition and lifestyle app available to help you manage your UC through healthy changes. Contact your Care Coach for more information.





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Glossary of UC terms

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).

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.



Notes		

Possible side effects

These are not all the possible side effects you may have when taking VELSIPITY. See the Patient Information leaflet in the pocket of this booklet for more information. If you experience any side effects not listed here, tell your doctor. The side effects of VELSIPITY include:

- High level of cholesterol in the blood
- Headache
- Nausea
- Infection
- Lymphopenia (decreased white blood cells)
- Urinary tract infection
- Slow heartbeat (bradycardia)
- High blood pressure (hypertension)

- Feeling dizzy
- Vision problems (macular oedema)
- Irregular heartbeat
- Breathing problems
- · Liver problems
- Posterior reversible encephalopathy syndrome
- Progressive multifocal leukoencephalopathy
- · Skin cancer

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VELSIPITY.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional. Speak to your healthcare team for more information and consult your Patient Information leaflet.

If you develop any signs or symptoms of infection, contact your doctor.

FAQs

What should I do if I experience 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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Can I take VELSIPITY if I am pregnant or planning to have a baby?

Do not take this medication if you are pregnant or are planning to become pregnant. This is because VELSIPITY can harm an unborn baby.

Can I take VELSIPITY if I am breastfeeding or plan to breastfeed?

Do not take this medication if you are breastfeeding or intend to breastfeed.

1-855-935-FLEX (3539)

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





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