

PRODUCT MONOGRAPH  
INCLUDING PATIENT MEDICATION INFORMATION

Pr **VALCYTE®**

Valganciclovir Film Coated Tablets  
450 mg (as valganciclovir hydrochloride)

Valganciclovir Powder for Oral Solution  
50 mg/mL when reconstituted (as valganciclovir hydrochloride)

Professed Standard  
Antiviral Agent

Hoffmann-La Roche Limited  
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Mississauga, Ontario, Canada  
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Date of Initial Authorization:  
MAY 03, 2002  
Date of Revision:  
SEP 10, 2021

Submission Control Number: 247484

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## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr VALCYTE®

#### valganciclovir hydrochloride tablets

Read this carefully before you start taking VALCYTE and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about VALCYTE.

#### Serious Warnings and Precautions

- **Blood problems:** VALCYTE can cause serious blood cell problems. These include reduced numbers of white blood cells, reduced numbers of red blood cells and reduced numbers of platelets. See “Serious side effects and what to do about them” table.
- **Cancer, Fertility and Birth Defects:** VALCYTE causes cancer in animals and may cause cancer in people. VALCYTE also has damaging effects on the reproductive system. In men, it may decrease the number of sperm in the semen and this may be complete and irreversible. In women, it may cause fertility problems. It may also cause birth defects. See “Other warnings you should know about”.

#### What is VALCYTE used for?

- VALCYTE is used to treat a disease called cytomegalovirus (CMV) retinitis in adults who have acquired immunodeficiency syndrome (AIDS).
- VALCYTE is also used to prevent CMV disease in adults who have received a solid organ transplant and are at risk of developing CMV disease.

#### How does VALCYTE work?

- VALCYTE is a prescription medicine that belongs to the family of drugs known as “antivirals”. It is used to treat infections caused by viruses.
- VALCYTE works by slowing the growth of the CMV virus.
- VALCYTE contains valganciclovir, which is the starting form of the medicine ganciclovir. This means the valganciclovir is changed to ganciclovir once it is absorbed into the body. Ganciclovir is the active part of the drug that actually slows the growth of CMV virus.
- Your doctor will let you know how long to take VALCYTE for and if it is working for you.

#### What are the ingredients in VALCYTE?

Medicinal ingredient: valganciclovir hydrochloride

Non-medicinal ingredients: crospovidone, microcrystalline cellulose, povidone K-30, and stearic acid powder. The film-coat applied to the tablets is Opadry® Pink, which contains hydroxypropyl methylcellulose, polyethylene glycol 400/macrogol, polysorbate 80, synthetic red iron oxide, and titanium dioxide.

**VALCYTE comes in the following dosage form:**

As a pink, film-coated tablet containing 450 mg valganciclovir (as valganciclovir hydrochloride).

**Do not use VALCYTE if you:**

- Are allergic to valganciclovir or to ganciclovir.
- Are allergic to any of the other ingredients in VALCYTE or to a component of the container.
- Are allergic to the antiviral medicine acyclovir or to valacyclovir, as a similar reaction can occur with VALCYTE.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VALCYTE. Talk about any health conditions or problems you may have, including if you:**

- Have kidney problems.
- Have liver problems.
- Are receiving hemodialysis since your dose of VALCYTE will need to be modified.
- Are receiving or have received radiation therapy.

**Other warnings you should know about:*****Blood problems:***

VALCYTE can cause serious blood cell problems. These include reduced numbers of certain white blood cells (granulocytopenia, neutropenia, or leukopenia), reduced numbers of red blood cells (anemia), and reduced numbers of platelets (thrombocytopenia). See “Serious Warnings and Precautions” box. If you have or had a history of blood problems or abnormal results on your blood tests, please talk to your healthcare professional before you take VALCYTE. VALCYTE may also cause blood creatinine elevation and abnormal liver function. Your doctor should recommend that you have blood tests done on a regular basis.

***Kidney problems:***

VALCYTE can cause an increase in serum creatinine (an indicator of kidney function). An increase in serum creatinine may indicate abnormal kidney function. Your doctor may have blood tests done on a regular basis to monitor your serum creatinine.

***Pregnancy and Birth Defects:***

Tell your doctor if you are pregnant or planning to become pregnant. VALCYTE may cause birth defects and should not be used during pregnancy. If you are a woman of child-bearing potential, then you should avoid pregnancy. You must use effective contraception during treatment and for 30 days after stopping treatment. Effective contraception includes a barrier method, such as a condom plus an additional method like birth control pills or an intrauterine device. If you are a male taking VALCYTE with a female partner, then you should use a barrier method (e.g. condom) during treatment and for 90 days after stopping treatment. This is because VALCYTE can cause birth defects.

***Breast-feeding:***

Tell your doctor if you are breast-feeding or planning to breast-feed. You should not take VALCYTE while breast-feeding. Women who are HIV positive should not breast-feed because HIV infection can be passed to the baby via the breast milk.

**Driving and using machines:**

Be careful when driving a car or using machines. VALCYTE and/or ganciclovir can cause seizures, dizziness, ataxia (unsteadiness) and confusion. You should not drive a car or use machines until you know how VALCYTE affects you.

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

**The following may interact with VALCYTE:**

- Drugs that treat AIDS such as such as zidovudine, didanosine, stavudine. These drugs may need to have their dose changed when taken with VALCYTE.
- Drugs that reduce your immune system such as cyclosporine, tacrolimus, mycophenolate mofetil.
- Drugs that treat cancer such as vincristine, vinblastine, doxorubicin, hydroxyurea.
- Drugs that fight infections such as trimethoprim/sulphonamides, dapsone, amphotericin B, flucytosine, pentamidine, pegylated interferons with ribavirin.
- Drugs that stop the growth of infections such as imipenem-cilastin. Seizures have occurred in patients taking imipenem-cilastin and ganciclovir. You may discuss different options with your doctor.
- Probenecid, a medicine used to treat gout. Taking probenecid and VALCYTE at the same time could increase the amount of ganciclovir in your blood to toxic levels.

**How to take VALCYTE:**

- Take VALCYTE exactly as your doctor has told you to.
- Do not skip any doses or take more than the recommended dose.
- Take VALCYTE with food.
- Do not break or crush VALCYTE tablets. Avoid contact with broken VALCYTE tablets on your skin, lips, in your nose or in your eyes. If contact occurs, wash your skin well with soap and water or rinse your eyes well with sterile or plain water if sterile water is not available.
- If you have kidney problems, your doctor might prescribe a lower dose.

**Usual dose:**Treatment of CMV Retinitis in Patients with AIDS

- The usual dosage for adults to get active CMV retinitis under control (induction therapy) is two 450 mg tablets twice a day for 21 days.
- The usual dosage for adults to help keep CMV retinitis under control (maintenance therapy) is two 450 mg tablets once a day.

Prevention of CMV Disease in Solid Organ Transplantation

- The usual dosage to prevent CMV in adults who received a solid organ transplant is two 450 mg tablets once a day. Treatment starts within 10 days of transplant and continues until 100 days after the transplant.

**Overdose:**

If you think you, or a person you are caring for, have taken too much VALCYTE, particularly accidental oral ingestion, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

- If you forget to take a dose of VALCYTE, take it as soon as possible, then just carry on with the regular times you take your medication. If you remember your missed dose close to the time for your next dose, do not take the missed dose. Do not take two doses of VALCYTE at the same time.
- Do not let your VALCYTE run out. The amount of virus in your blood may increase if your medicine is stopped, even for a short time.
- It may be a good idea to ask your doctor or pharmacist ahead of time what to do about missed doses.

**What are possible side effects from using VALCYTE?**

These are not all the possible side effects you may have when taking VALCYTE. If you experience any side effects not listed here, tell your healthcare professional.

**Side effects may include:**

- Diarrhea, nausea, vomiting
- Constipation
- Fever
- Headache
- Trembling
- Swelling of the legs
- Back pain
- Insomnia (sleeplessness)
- High blood pressure
- Dizziness, unsteadiness
- Confusion
- Increased potassium in the blood.

**Other side effects.** VALCYTE causes cancer in animals and may cause cancer in people.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>VERY COMMON</b>			
<b>Graft Rejection – Transplant tissue is destroyed by your immune system:</b> discomfort, feeling ill, pain or swelling in the area of the tissue, fever, flu-like symptoms.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Blood Problems – Reduced number of white blood cells:</b> chills, fever, fatigue, sore mouth, cough, redness, pain or swelling of any area of your body, pain or burning when you pass your urine.	✓		
<b>Blood Problems – Reduced number of red blood cells:</b> tiredness and weakness, paleness, shortness of breath.	✓		
<b>Blood Problems – Reduced number of platelets:</b> increased bruising and bleeding, fatigue, weakness.	✓		
<b>Seizures:</b> uncontrolled movements, loss of consciousness, staring, fits.		✓	
<b>UNCOMMON</b>			
<b>Kidney Problems:</b> decrease in amount of urine produced, lower back pain or side pain, swelling of feet or lower legs, pain or discomfort when urinating.	✓		
<b>Infertility in Men - Inability for a man to cause pregnancy:</b> not able to produce sperm, lower sperm count.	✓		

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.

#### Reporting 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.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

- Keep out of reach and sight of children.
- Store VALCYTE tablets in a clean dry area at room temperature (15-30°C).
- Keep container tightly closed.
- Do not use medication after the expiry date on the package.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**If you want more information about VALCYTE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.rochecanada.com](http://www.rochecanada.com)), or by calling 1-888-762-4388.

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Last Revised SEP 10, 2021

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Hoffmann-La Roche Limited  
Mississauga, ON L5N 5M8

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr VALCYTE®

#### valganciclovir hydrochloride oral solution

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#### Serious Warnings and Precautions

- **Blood problems:** VALCYTE can cause serious blood cell problems. These include reduced numbers of white blood cells, reduced numbers of red blood cells and reduced numbers of platelets. See “Serious side effects and what to do about them” table.
- **Cancer, Fertility and Birth Defects:** VALCYTE causes cancer in animals and may cause cancer in people. VALCYTE also has damaging effects on the reproductive system. In men, it may decrease the number of sperm in the semen and this may be complete and irreversible. In women, it may cause fertility problems. It may also cause birth defects. See “Other warnings you should know about”.

#### What is VALCYTE used for?

- VALCYTE is used to treat a disease called cytomegalovirus (CMV) retinitis in adults who have acquired immunodeficiency syndrome (AIDS).
- VALCYTE is also used to prevent CMV disease in adults who have received a solid organ transplant and are at risk of developing CMV disease.

#### How does VALCYTE work?

- VALCYTE is a prescription medicine that belongs to the family of drugs known as “antivirals”. It is used to treat infections caused by viruses.
- VALCYTE works by slowing the growth of the CMV virus.
- VALCYTE contains valganciclovir, which is the starting form of the medicine ganciclovir. This means the valganciclovir is changed to ganciclovir once it is absorbed into the body. Ganciclovir is the active part of the drug that actually slows the growth of CMV virus.
- Your doctor will let you know how long to take VALCYTE for and if it is working for you.

#### What are the ingredients in VALCYTE?

Medicinal ingredient: valganciclovir hydrochloride

Non-medicinal ingredients: povidone K30, fumaric acid, sodium benzoate, sodium saccharin, mannitol, tutti-frutti flavour (maltodextrins (maize), propylene glycol, arabic gum and natural identical flavouring substances mainly consisting of banana, pineapple, and peach flavour).

**VALCYTE comes in the following dosage form:**

As a powder for oral solution. The fruit-flavoured solution containing 50 mg/mL valganciclovir (as valganciclovir hydrochloride) will be prepared by your pharmacist.

**Do not use VALCYTE if you:**

- Are allergic to valganciclovir or to ganciclovir.
- Are allergic to any of the other ingredients in VALCYTE or to a component of the container.
- Are allergic to the antiviral medicine acyclovir or to valacyclovir, as a similar reaction can occur with VALCYTE.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VALCYTE. Talk about any health conditions or problems you may have, including if you:**

- Have kidney problems.
- Have liver problems.
- Are receiving hemodialysis since your dose of VALCYTE will need to be modified.
- Are receiving or have received radiation therapy.

**Other warnings you should know about:*****Blood problems:***

VALCYTE can cause serious blood cell problems. These include reduced numbers of certain white blood cells (granulocytopenia, neutropenia, or leukopenia), reduced numbers of red blood cells (anemia), and reduced numbers of platelets (thrombocytopenia). See “Serious Warnings and Precautions” box. If you have or had a history of blood problems or abnormal results on your blood tests, please talk to your healthcare professional before you take VALCYTE. VALCYTE may also cause blood creatinine elevation and abnormal liver function. Your doctor should recommend that you have blood tests done on a regular basis.

***Kidney problems:***

VALCYTE can cause an increase in serum creatinine (an indicator of kidney function). An increase in serum creatinine may indicate abnormal kidney function. Your doctor may have blood tests done on a regular basis to monitor your serum creatinine.

***Pregnancy and Birth Defects:***

Tell your doctor if you are pregnant or planning to become pregnant. VALCYTE may cause birth defects and should not be used during pregnancy. If you are a woman of child-bearing potential, then you should avoid pregnancy. You must use effective contraception during treatment and for 30 days after stopping treatment. Effective contraception includes a barrier method, such as a condom plus an additional method like birth control pills or an intrauterine device. If you are a male taking VALCYTE with a female partner, then you should use a barrier method (e.g. condom) during treatment and for 90 days after stopping treatment. This is because VALCYTE can cause birth defects.

***Breast-feeding:***

Tell your doctor if you are breast-feeding or planning to breast-feed. You should not take VALCYTE while breast-feeding. Women who are HIV positive should not breast-feed because HIV infection can be passed to the baby via the breast milk.

### **Driving and using machines:**

Be careful when driving a car or using machines. VALCYTE and/or ganciclovir can cause seizures, dizziness, ataxia (unsteadiness) and confusion. You should not drive a car or use machines until you know how VALCYTE affects you.

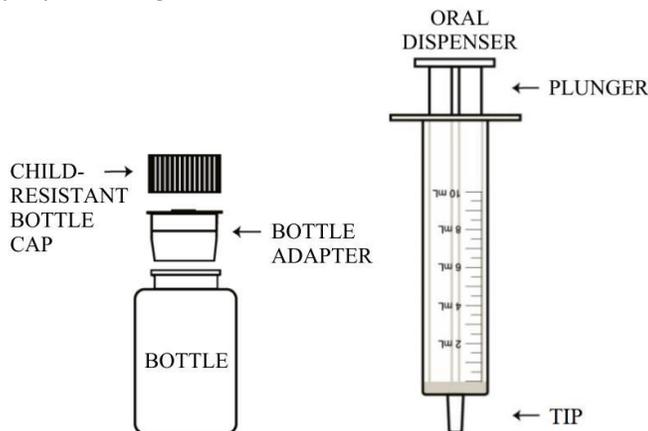
**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **The following may interact with VALCYTE:**

- Drugs that treat AIDS such as such as zidovudine, didanosine, stavudine. These drugs may need to have their dose changed when taken with VALCYTE.
- Drugs that reduce your immune system such as cyclosporine, tacrolimus, mycophenolate mofetil.
- Drugs that treat cancer such as vincristine, vinblastine, doxorubicin, hydroxyurea.
- Drugs that fight infections such as trimethoprim/sulphonamides, dapsone, amphotericin B, flucytosine, pentamidine, pegylated interferons with ribavirin.
- Drugs that stop the growth of infections such as imipenem-cilastin. Seizures have occurred in patients taking imipenem-cilastin and ganciclovir. You may discuss different options with your doctor.
- Probenecid, a medicine used to treat gout. Taking probenecid and VALCYTE at the same time could increase the amount of ganciclovir in your blood to toxic levels.

### **How to take VALCYTE:**

- Take VALCYTE exactly as your doctor has told you to.
- Do not skip any doses or take more than the recommended dose.
- Take VALCYTE with food.
- Be careful with handling the VALCYTE solution. Avoid getting the solution on your skin, lips, in your nose or in your eyes. If you happen to get the solution on your skin or lips, then wash the area well with soap and water. If you happen to get the solution in your eyes, rinse your eyes well with sterile water or plain tap water.
- If you have kidney problems, your doctor might prescribe a lower dose.
- If your doctor has prescribed VALCYTE oral solution, follow the directions below to ensure proper dosing:



1. With the child-resistant cap on the bottle, shake the bottle well for 5 seconds before each use.
2. To open the bottle, press downward firmly on the child-resistant cap and turn it counter-clockwise. **Do not throw away the child-resistant cap.**
3. Push the plunger down toward the tip of the oral dispenser. With the bottle in an upright position, insert the oral dispenser into the bottle adapter opening.
4. Turn the entire unit (bottle with attached oral dispenser) upside down.
5. Slowly pull out the plunger until the desired amount of solution is withdrawn into the oral dispenser (see figure).



6. Turn the entire unit right side up and slowly remove the oral dispenser from the bottle.
  7. Place the tip of the oral dispenser directly into mouth. Slowly push down the plunger until the oral dispenser is empty. Swallow the solution. Do not mix with any liquid prior to swallowing.
  8. Use the child-resistant cap to close the bottle. Return the bottle to the refrigerator (see Storage).
  9. After each use:  
Remove the plunger from the oral dispenser by pulling the plunger all the way out. Rinse the oral dispenser and plunger under running tap water and air dry before next use.
- It is important that you use the oral dispenser provided in the box to measure the amount of VALCYTE solution.
  - Each box contains two oral dispensers, in case one of them gets lost or damaged. Each oral dispenser is designed to measure up to a 10 mL amount of VALCYTE solution. Remember to take the amount of VALCYTE as prescribed by your doctor.
  - Reach out to your doctor or pharmacist if both oral dispensers become lost or damaged. They will tell you how to take your VALCYTE solution.

**Usual dose:**

Treatment of CMV Retinitis in Patients with AIDS

- The usual dosage for adults to get active CMV retinitis under control (induction therapy) is 18 mL of VALCYTE solution taken twice a day for 21 days. Use the oral dispenser provided and take two 9 mL amounts of the solution in the morning and two 9 mL amounts in the evening.
- The usual dosage for adults to help keep CMV retinitis under control (maintenance therapy) is 18 mL VALCYTE solution taken once a day. Use the oral dispenser provided and take two 9 mL amounts of solution once a day. You should try to take the solution at the same time each day.

## Prevention of CMV Disease in Solid Organ Transplantation

- The usual dosage to prevent CMV in adults who received a solid organ transplant is 18 mL VALCYTE solution taken once a day. Treatment starts within 10 days of transplant and continues until 100 days after the transplant. Use the oral dispenser provided and take two 9 mL amounts of solution once a day.

Patients with kidney problems: If your kidneys are not working properly, your doctor may instruct you to take a lower dose of VALCYTE solution each day. It is very important that you follow the dose prescribed by your doctor.

### **Overdose:**

If you think you, or a person you are caring for, have taken too much VALCYTE, particularly accidental oral ingestion, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### **Missed Dose:**

- If you forget to take a dose of VALCYTE, take it as soon as possible, then just carry on with the regular times you take your medication. If you remember your missed dose close to the time for your next dose, do not take the missed dose. Do not take two doses of VALCYTE at the same time.
- Do not let your VALCYTE run out. The amount of virus in your blood may increase if your medicine is stopped, even for a short time.
- It may be a good idea to ask your doctor or pharmacist ahead of time what to do about missed doses.

### **What are possible side effects from using VALCYTE?**

These are not all the possible side effects you may have when taking VALCYTE. If you experience any side effects not listed here, tell your healthcare professional.

#### **Side effects may include:**

- Diarrhea, nausea, vomiting
- Constipation
- Fever
- Headache
- Trembling
- Swelling of the legs
- Back pain
- Insomnia (sleeplessness)
- High blood pressure
- Dizziness, unsteadiness
- Confusion
- Increased potassium in the blood.

**Other side effects.** VALCYTE causes cancer in animals and may cause cancer in people.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>Graft Rejection – Transplant tissue is destroyed by your immune system:</b> discomfort, feeling ill, pain or swelling in the area of the tissue, fever, flu-like symptoms.		✓	
<b>COMMON</b>			
<b>Blood Problems – Reduced number of white blood cells:</b> chills, fever, fatigue, sore mouth, cough, redness, pain or swelling of any area of your body, pain or burning when you pass your urine.	✓		
<b>Blood Problems – Reduced number of red blood cells:</b> tiredness and weakness, paleness, shortness of breath.	✓		
<b>Blood Problems – Reduced number of platelets:</b> increased bruising and bleeding, fatigue, weakness.	✓		
<b>Seizures:</b> uncontrolled movements, loss of consciousness, staring, fits.		✓	
<b>UNCOMMON</b>			
<b>Kidney Problems:</b> decrease in amount of urine produced, lower back pain or side pain, swelling of feet or lower legs, pain or discomfort when urinating.	✓		
<b>Infertility in Men - Inability for a man to cause pregnancy:</b> not able to produce sperm, lower sperm count.	✓		

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.

### Reporting 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.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Keep out of reach and sight of children.
- Store VALCYTE oral solution in its original labelled container in a refrigerator at 2-8°C. The pharmacist will write the date of expiration on the bottle label.
- Keep the bottle tightly closed.
- Do not use medication after the expiry date on the package.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### If you want more information about VALCYTE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website ([www.rochecanada.com](http://www.rochecanada.com)), or by calling 1-888-762-4388.

This leaflet was prepared by Hoffmann-La Roche Limited.

Last Revised SEP 10, 2021

Oral dosing dispenser manufactured by B. Braun Melsungen AG, 34209 Melsungen, Germany.

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