PRODUCT MONOGRAPH

PrVALCYTE®

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
7070 Mississauga Road
Mississauga, Ontario
L5N 5M8
www.rochecanada.com

Date of Revision:
December 05, 2017

Submission Control No: 208920

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PART III: CONSUMER INFORMATION

PrVALCYTE®
valganciclovir hydrochloride
Tablets

This leaflet is part III of a three-part "Product Monograph" published when VALCYTE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VALCYTE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- VALCYTE is a prescription medication that belongs to the family of drugs known as "antivirals".
- VALCYTE is used to treat cytomegalovirus (CMV) retinitis in adults who have acquired immunodeficiency syndrome (AIDS).
- VALCYTE is also used to prevent cytomegalovirus (CMV) disease in adults who have received a solid organ transplant and are at risk of developing CMV disease.

What it does:

- VALCYTE works by slowing the growth of CMV virus, the virus that causes CMV retinitis as well as CMV infection at other sites in the body. For most people with CMV retinitis, VALCYTE prevents CMV from progressing (spreading) into healthy cells as quickly as it would without treatment, thereby protecting eyesight from damage due to CMV disease.
- VALCYTE does not cure CMV retinitis, and some people may experience progression of retinitis during or following treatment with VALCYTE. Therefore, you must follow your doctor's advice and have your eyes checked regularly.
- For most patients who have received a solid organ transplant, VALCYTE prevents the occurrence of CMV disease up to 6 months after the transplant.
- VALCYTE is a prodrug of ganciclovir. This means it 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.

When it should not be used:

Do not take VALCYTE if you have ever had a serious reaction to valganciclovir, ganciclovir (as VALCYTE or ganciclovir capsules or CYTOVENE®IV).

Do not take if you have had sensitivity reactions with acyclovir or its pro-drug valacyclovir as a similar reaction can occur with VALCYTE.

Do not take VALCYTE if you have any reaction to any of the non-medicinal ingredients (see "What the non-medicial ingredients are").

What the medicinal ingredient is:

valganciclovir hydrochloride.

What the non-medicinal ingredients are:

VALCYTE tablets contain the following 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.

What dosage forms it comes in:

VALCYTE is available as a pink 450 mg valganciclovir film-coated tablet (as valganciclovir hydrochloride).

VALCYTE is also available as a powder for oral solution. The solution will be prepared by your pharmacist and will be a fruit-flavoured liquid containing 50 mg/ml valganciclovir (as valganciclovir hydrochloride).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

• Serious blood problems can occur such as low numbers of white blood cells, red blood cells or platelets. (See Side Effects and What to Do About Them)

• Tumours have been found in laboratory animals receiving this drug, although at this time there is no similar information from human studies. The drug also has damaging effects on the reproductive system. When used in men, it may decrease the number of sperm in the semen and this may be complete and irreversible. In women, not only may there be suppression of fertility, but pregnancy during treatment is likely to lead to the birth of a malformed child.

BEFORE you use VALCYTE talk to your doctor or pharmacist if:

- you have ever had a bad reaction to VALCYTE

(valganciclovir) or any of the inactive ingredients shown above.
- you have ever had a bad reaction to ganciclovir, acyclovir or valacyclovir.
- you are allergic to other medicines, food and dyes.
- you are taking ANY other medicines (prescription or nonprescription) including herbal or natural products.
- you have any other illnesses/diseases, including a history of liver or kidney disease.
- you are receiving hemodialysis as dosage adjustment is required.
- you have blood problems or have abnormal results on your blood tests.
- you are breast-feeding or planning to breast feed. You should not take Valcyte while breastfeeding. Women who are HIV positive should not breast feed because HIV infection can be passed to the baby via the breast milk.

Pregnancy:
Tell your doctor if you are pregnant or planning to become pregnant.

Valcyte may cause birth defects in humans and should not be used during pregnancy.

If you are a woman of child-bearing potential then you should:
• avoid pregnancy
• use effective contraception during treatment and for 30 days after stopping treatment
• effective contraception includes:
    • a barrier method (e.g. condom) and
    • an additional method (e.g. birth control pills, intrauterine device)

If you are a male taking Valcyte, whose partner is female, then you should:
    • use a barrier method (e.g. condom) during treatment and for 90 days after stopping treatment , unless it is certain that the female partner is not at risk of becoming pregnant.

This information will help your doctor and you decide whether you should use VALCYTE and what extra care may need to be taken while you are on the medication. You should always consult your doctor or pharmacist before using other medications while on VALCYTE.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all medications that you are taking, including those you buy over the counter and herbal or natural products. VALCYTE may change the effect of other medications.

Tell your doctor if you are taking any of the following drugs:

- that reduce your immunity such as cyclosporine, tacrolimus, mycophenolate mofetil
- that act against tumours such as vincristine, vinblastine, doxorubicin, hydroxyurea
- that fight infections such as trimethoprim/sulphonamides, dapsone, amphotericin B, flucytosine, pentamidine
- pegylated interferons with ribavirin

The following drugs may need to have their dose changed when taken with VALCYTE:

- Videx® (didanosine, ddI)
- Retrovir® (zidovudine, ZDV, AZT)
- Benuryl™ (probenecid)

Imipenem-cilastin - talk to your doctor if you are taking imipenem-cilastin. Seizures have occurred in patients taking imipenem-cilastin and ganciclovir. You may discuss different options with your doctor.

PROPER USE OF THIS MEDICATION

Dosing Considerations:
- Your doctor has prescribed VALCYTE after carefully studying your case. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours. Do not give your VALCYTE to anyone else.
- To make sure that your therapy is as effective as possible, take your VALCYTE exactly as your doctor prescribes it. 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, mucous membranes or 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.

Usual Dose:
Treatment of CMV Retinitis in Patients with HIV
- 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 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 starting within 10 days of transplant and continuing until 100 days after the transplant.

Overdose:

In case of drug overdose or suspected drug overdose, particularly accidental oral ingestion, contact a healthcare practitioner (e.g. doctor), hospital emergency department, or regional poison control centre, 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. Two doses of VALCYTE should not be taken 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VALCYTE.

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). VALCYTE may also cause blood creatinine elevation, increased potassium in the blood, 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.

Common side effects. VALCYTE can cause other side effects. In studies, the most common side effects with the use of VALCYTE (although not necessarily related to VALCYTE) were diarrhea, nausea, vomiting, fever, headache, trembling, graft rejection, swelling of the legs, constipation, back pain, insomnia (sleeplessness), high blood pressure.

Other side effects. Seizures, dizziness, ataxia (unsteadiness) and/or confusion have also been reported with the use of VALCYTE. If they occur, these side effects may affect a person's ability to drive a car or operate machinery.

Although there is no supporting information from clinical trials in humans, animal studies indicate that VALCYTE may cause cancer and infertility in humans.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Call your doctor or pharmacist
		Only if severe	In all cases	
Common	**Blood Problems** **-Reduced number of white blood cells** Symptoms of infection of the gums, throat, upper airways and skin include: chills, fever (over 100°F or 38°C), sore mouth, cough, redness, pain or swelling of any area of your body, or pain or burning when you pass your urine. **-Reduced number of red blood cells** Symptoms: tiredness and weakness. **-Reduced number of platelets** Symptoms: increased bruising and bleeding.	✓		
Uncommon	**Kidney Problems** **-Increase in serum creatinine** Symptoms: decreased urine output, lower back pain or side pain, or swelling of feet or lower legs.	✓		

This is not a complete list of side effects. For any unexpected effects while taking VALCYTE, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep out of the 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

REMINDER: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at: www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388.

This leaflet was prepared by Hoffmann-La Roche Limited.

Last revised December 05, 2017

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Hoffmann-La Roche Limited
Mississauga, Ontario L5N 5M8

PART III: CONSUMER INFORMATION

PrVALCYTE®
valganciclovir hydrochloride
Oral Solution

This leaflet is part III of a three-part "Product Monograph" published when VALCYTE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VALCYTE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- VALCYTE is a prescription medication that belongs to the family of drugs known as "antivirals".
- VALCYTE is used to treat cytomegalovirus (CMV) retinitis in adults who have acquired immunodeficiency syndrome (AIDS).
- VALCYTE is also used to prevent cytomegalovirus (CMV) disease in adults who have received a solid organ transplant and are at risk of developing CMV disease.

What it does:

- VALCYTE works by slowing the growth of CMV virus, the virus that causes CMV retinitis as well as CMV infection at other sites in the body. For most people with CMV retinitis, VALCYTE prevents CMV from progressing (spreading) into healthy cells as quickly as it would without treatment, thereby protecting eyesight from damage due to CMV disease.
- VALCYTE does not cure CMV retinitis, and some people may experience progression of retinitis during or following treatment with VALCYTE. Therefore, you must follow your doctor's advice and have your eyes checked regularly.
- For most patients who have received a solid organ transplant, VALCYTE prevents the occurrence of CMV disease up to 6 months after the transplant.
- VALCYTE is a prodrug of ganciclovir. This means it 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.

When it should not be used:

Do not take VALCYTE if you have ever had a serious reaction to valganciclovir, ganciclovir (as VALCYTE or ganciclovir capsules or CYTOVENE®IV).

Do not take if you have had sensitivity reactions with acyclovir or its pro-drug valacyclovir as a similar reaction can occur with VALCYTE.

Do not take VALCYTE if you have any reaction to any of the non-medicinal ingredients (see "What the non-medicial ingredients are").

What the medicinal ingredient is:

valganciclovir hydrochloride.

What the non-medicinal ingredients are:

VALCYTE powder for oral solution contains the following 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).

What dosage forms it comes in:

VALCYTE is available as a powder for oral solution. The solution will be prepared by your pharmacist and will be a fruit-flavoured liquid containing 50mg/ml valganciclovir (as valganciclovir hydrochloride).

VALCYTE is also available as a pink 450 mg valganciclovir film-coated tablet (as valganciclovir hydrochloride).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

• Serious blood problems can occur such as low numbers of white blood cells, red blood cells or platelets. (See Side Effects and What to Do About Them)

• Tumours have been found in laboratory animals receiving this drug, although at this time there is no similar information from human studies. The drug also has damaging effects on the reproductive system. When used in men, it may decrease the number of sperm in the semen and this may be complete and irreversible. In women, not only may there be suppression of fertility, but pregnancy during treatment is likely to lead to the birth of a malformed child.

BEFORE you use VALCYTE talk to your doctor or pharmacist if:

- you have ever had a bad reaction to VALCYTE (valganciclovir) or any of the inactive ingredients shown above.
- you have ever had a bad reaction to ganciclovir,

acyclovir or valacyclovir.

- you are allergic to other medicines, food and dyes.
- you are taking ANY other medicines (prescription or nonprescription) including herbal or natural products.
- you have any other illnesses/diseases, including a history of liver or kidney disease.
- you are receiving hemodialysis as dosage adjustment is required.
- you have blood problems or have abnormal results on your blood tests.
- you are breast-feeding or planning to breast feed. You should not take Valcyte while breastfeeding. Women who are HIV positive should not breast feed because HIV infection can be passed to the baby via the breast milk.

Pregnancy:
Tell your doctor if you are pregnant or planning to become pregnant.

Valcyte may cause birth defects in humans and should not be used during pregnancy.

If you are a woman of child-bearing potential then you should:
• avoid pregnancy
• use effective contraception during treatment and for 30 days after stopping treatment
• effective contraception includes:
    • a barrier method (e.g. condom) and
    • an additional method (e.g. birth control pills, intrauterine device)

If you are a male taking Valcyte, whose partner is female, then you should:
    • use a barrier method (e.g. condom) during treatment and for 90 days after stopping treatment , unless it is certain that the female partner is not at risk of becoming pregnant..

This information will help your doctor and you decide whether you should use VALCYTE and what extra care may need to be taken while you are on the medication. You should always consult your doctor or pharmacist before using other medications while on VALCYTE.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all medications that you are taking, including those you buy over the counter and herbal or natural products. VALCYTE may change the effect of other medications.

Tell your doctor if you are taking any of the following drugs:

- that reduce your immunity such as cyclosporine, tacrolimus, mycophenolate mofetil
- that act against tumours such as vincristine, vinblastine, doxorubicin, hydroxyurea
- that fight infections such as trimethoprim/sulphonamides, dapsone, amphotericin B, flucytosine, pentamidine
- pegylated interferons with ribavirin

The following drugs may need to have their dose changed when taken with VALCYTE:

- Videx® (didanosine, ddI)
- Retrovir® (zidovudine, ZDV, AZT)
- Benuryl™ (probenecid)

Imipenem-cilastin - talk to your doctor if you are taking imipenem-cilastin. Seizures have occurred in patients taking imipenem-cilastin and ganciclovir. You may discuss different options with your doctor.

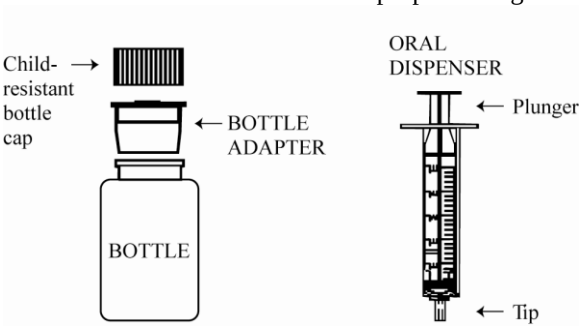
PROPER USE OF THIS MEDICATION

Dosing Considerations:

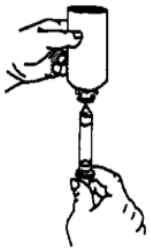
- Your doctor has prescribed VALCYTE after carefully studying your case. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours. Do not give your VALCYTE to anyone else.
- To make sure that your therapy is as effective as possible, take your VALCYTE exactly as your doctor prescribes it. Do not skip any doses, or take more than the recommended dose.
- Take VALCYTE with food.
- You have to be careful when handling the VALCYTE solution. You should avoid getting the solution on your skin, mucous membranes (lips, in the nose) or in your eyes. If you accidentally get the solution on your skin or mucous membranes, then wash the area thoroughly with soap and water. If you accidentally get any solution in your eyes, rinse your eyes thoroughly with sterile water or plain tap water if sterile water is not available. Wearing disposable gloves is recommended during reconstitution and when wiping the outer surface

of the bottle/cap and the table after reconstitution.

- If your doctor has prescribed VALCYTE oral solution, follow the directions below to ensure proper dosing:



1. Shake closed bottle well for about 5 seconds before each use.
2. Remove child-resistant cap.
3. Before inserting the tip of the dispenser into bottle adapter, push the plunger completely down toward the tip of the dispenser. Insert tip firmly into opening of the bottle adapter.
4. Turn the entire unit (bottle and dispenser) upside down.
5. Pull the plunger out slowly until the desired amount of medication is withdrawn into the dispenser (see figure).



6. Turn the entire unit right side up and remove the oral dispenser slowly from the bottle.
7. Dispense directly into mouth.
8. Close bottle with child-resistant cap after each use. Return to a refrigerator (see section "How to store it").
9. Disassemble oral dispenser, rinse under running tap water and air dry prior to next use.

- It is important that you use the syringe provided in the pack to measure your dose of VALCYTE solution. Two syringes are provided in case one of them gets lost or damaged. Each syringe is designed to measure up to a 450 mg amount of VALCYTE. Remember to take the dose exactly as prescribed by your doctor.
  - Always wash the syringe thoroughly and allow it to dry after you have taken your dose.
  - Contact your doctor or pharmacist if both syringes become lost or damaged, and they will advise you about how to continue to take your medication.

Usual Dose:

Treatment of CMV Retinitis in Patients with HIV

- The usual dosage for adults to get active CMV retinitis under control (induction therapy) is 900 mg of VALCYTE solution taken twice a day for 21 days. Use the syringe provided and take two 450 mg amounts of the solution in the morning and two 450 mg amounts in the evening.
- The usual dosage for adults to help keep CMV retinitis under control (maintenance therapy) is 900 mg VALCYTE solution taken once a day. Use the syringe provided and take two 450 mg amounts of solution.You should try to take the solution at the same time each day.

Prevention of CMV Disease Solid Organ Transplantation

- The usual dosage to prevent CMV in adults who received a solid organ transplant is 900 mg VALCYTE solution taken once a day starting within 10 days of transplant and continuing until 100 days after the transplant. Use the syringe provided and take two 450 mg 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:

In case of drug overdose or suspected drug overdose, particularly accidental oral ingestion, contact a healthcare practitioner (e.g. doctor), hospital emergency department, or regional poison control centre, 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. Two doses of VALCYTE should not be taken 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Unwanted effects are possible with all medicines. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VALCYTE.

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). VALCYTE may also cause blood creatinine elevation, increased potassium in the blood, 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.

Common side effects. VALCYTE can cause other side effects. In studies, the most common side effects with the use of VALCYTE (although not necessarily related to VALCYTE) were diarrhea, nausea, vomiting, fever, headache, trembling, graft rejection, swelling of the legs, constipation, back pain, insomnia (sleeplessness), high blood pressure.

Other side effects. Seizures, dizziness, ataxia (unsteadiness) and/or confusion have also been reported with the use of VALCYTE. If they occur, these side effects may affect a person's ability to drive a car or operate machinery.

Although there is no supporting information from clinical trials in humans, animal studies indicate that VALCYTE may cause cancer and infertility in humans.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Call your doctor or pharmacist
		Only if severe	In all cases	
Common	**Blood Problems** **-Reduced number of white blood cells** Symptoms of infection of the gums, throat, upper airways and skin include: chills, fever (over 100°F or 38°C), sore mouth, cough, redness, pain or swelling of any area of your body, or pain or burning when you pass your urine. **-Reduced number of red blood cells** Symptoms: tiredness and weakness. **-Reduced number of platelets** Symptoms: increased bruising and bleeding.	✓		
Uncommon	**Kidney Problems** **-Increase in serum creatinine** Symptoms: decreased urine output, lower back pain or side pain, or swelling of feet or lower legs.	✓		

This is not a complete list of side effects. For any unexpected effects while taking VALCYTE, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep out of the 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.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at www.healthcanada.gc.ca/medeffect**
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
  - **Fax toll-free to 1-866-678-6789, or**
  - **Mail to: Canada Vigilance Program**
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

REMINDER: This medicine has been prescribed only for you. Do not give it to anybody else. If you have any further questions, please ask your doctor or pharmacist.

This document plus the full product monograph, prepared for health professionals can be found at: www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited, at: 1-888-762-4388.

This leaflet was prepared by Hoffmann-La Roche Limited.

Last revised: December 05, 2017

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Roche

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Mississauga, Ontario L5N 5M8