

# PRODUCT MONOGRAPH

**Pr RITUXAN<sup>®</sup> SC**  
rituximab  
120 mg/mL Solution for Subcutaneous Injection

Professed Standard

Antineoplastic

Hoffmann-La Roche Ltd.  
7070 Mississauga Road  
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L5N 5M8

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[www.rochecanada.com](http://www.rochecanada.com)

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### PART III: CONSUMER INFORMATION

**Pr** **RITUXAN**<sup>®</sup> SC  
rituximab

**1400 mg (120 mg/mL) Solution for Subcutaneous Injection**

***Pronounced: rih TUCKS en***

#### Single Use Vial for Non-Hodgkin's Lymphoma

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

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

RITUXAN SC (also known as rituximab) is a cancer medicine that is used to stop cancer cell growth and ideally cause the death of cancer cells. It must be prescribed by a doctor.

It is used to treat patients with certain types of non-Hodgkin's lymphoma (NHL).

#### **What is non-Hodgkin's lymphoma?**

Non-Hodgkin's lymphoma is a cancer of the lymph cells (lymphocytes), which are found in the blood and in the lymph nodes. Lymph nodes are located in the head and neck area, under the arms, in the groin and throughout the chest and abdomen. Lymphocytes are a type of white blood cell. There are two types: B lymphocytes and T lymphocytes. B lymphocytes produce antibodies or proteins that help our immune system to fight foreign substances which enter the body. All B-cells have a marker on their surface. This marker is called CD20.

#### **What RITUXAN SC does:**

Our bodies have a natural defence system against cancer cells. When cancer cells appear, our bodies respond by making special proteins called antibodies. Researchers studied this response and learned how to create antibodies outside the body that help with cancer treatment. These are called monoclonal antibodies.

Monoclonal antibodies are now made to target tumours in an effort to control the growth of cancer.

RITUXAN SC belongs to a family of medicine called monoclonal antibodies. It is an antibody that targets the CD-20 B-cell lymphocyte to stop its activity. RITUXAN SC attaches to the CD20 marker that is located on the B-cell. When in place, it works to stop the growth of the cancer cells and may destroy them.

RITUXAN SC is most active in patients whose lymphomas are of the B-cell type.

#### **Who should take RITUXAN SC?**

RITUXAN SC is given to patients with low-grade CD20 antigen positive B-cell non-Hodgkin's lymphoma, who have not received prior treatment or who are no longer responding to their current anti-cancer treatment or where the lymphoma has returned despite previous anti-cancer treatment.

Depending on the type of lymphoma, RITUXAN SC is given in combination with chemotherapy regimens called CHOP or CVP. CHOP stands for the following drugs: cyclophosphamide, doxorubicin, vincristine and prednisone while CVP stands for cyclophosphamide, vincristine and prednisolone.

RITUXAN SC may also be used as a continuous (maintenance) treatment for patients who have responded to initial therapy.

#### **When it should not be used:**

If you are allergic to rituximab or proteins of similar mouse or human origin or any other ingredient in RITUXAN SC or if you have ever had a rare infection of the brain called progressive multifocal leukoencephalopathy (PML) you should not take RITUXAN SC.

#### **What should you tell your doctor before you start taking RITUXAN SC?**

Before beginning treatment with the subcutaneous formulation of RITUXAN, make sure your doctor knows if:

- You ever had a bad reaction to RITUXAN or any of the non-medicinal ingredients.
- You are allergic to rituximab, other proteins which are like rituximab, or any of the other ingredients of this medicine
- You are allergic to hyaluronidase (an enzyme that is part of the formulation that helps to increase the absorption of injected active substance)
- You have a history of heart attack or stroke.
- You are taking any other medicines (including those not prescribed by the doctor).
- If you are taking medication to reduce blood pressure.
- If you are planning to be immunized with a vaccine during or after the completion of your RITUXAN SC therapy.
- If you have ever taken medicines which affect your immune system – such as chemotherapy or immune-suppressive medicines
- You have a pre-existing lung disease as you may have a greater chance of breathing difficulties during your RITUXAN SC treatment injection.
- You have a history of hepatitis B, current hepatitis B or tuberculosis infection.
- You are pregnant or could become pregnant or are breast-feeding a child.

*This information will help your doctor and you decide whether you should use RITUXAN SC and what extra care may need to be taken while you are on the medication.*

**What the medicinal ingredient is:**

RITUXAN SC contains the active ingredient rituximab.

**What the non-medicinal ingredients are (in alphabetical order):**

$\alpha,\alpha$ -trehalose dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, recombinant human hyaluronidase (rHuPH20), water for injection.

**What dosage forms it comes in:**

RITUXAN SC has been prescribed for you as a medicine for injection under your skin (called RITUXAN SC 1400 mg, solution for subcutaneous injection).

feeding, be sure to discuss with your doctor whether RITUXAN is right for you. Women should avoid pregnancy and use effective birth control methods during treatment with RITUXAN and for one year after treatment. Patients who are pregnant or become pregnant should not receive or continue to receive RITUXAN SC.

If you have ever had heart disease [for example angina (heart pain), arrhythmia (palpitations/ irregular heartbeat), or heart failure] or breathing problems, your doctor will take special care of you during therapy with RITUXAN.

In some cases, patients who have had hepatitis B might have a repeat attack of hepatitis. Tell the doctor if you think you have had hepatitis in the past.

Infection with hepatitis B virus causes inflammation of the liver which may show as mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue. If you experience any of these symptoms immediately contact your doctor. If you show evidence of hepatitis B virus infection you may be referred to a liver disease expert for ongoing monitoring and management.

RITUXAN is not to be used in patients with active hepatitis B viral disease. Tell your doctor if you think you have hepatitis B.

Live viral vaccines should not be given with RITUXAN. Your doctor will check if you should have any vaccines before or after you receive RITUXAN.

Cases of Progressive Multifocal Leukoencephalopathy (PML) have been reported during use of RITUXAN in NHL. PML is a condition that causes nerve damage within the brain. Tell your doctor immediately if you have memory loss, trouble thinking, and difficulty with walking, clumsiness, falls or weakness on one side of the body, changes in mood or loss of vision. Your doctor will check if you need to see a neurologist.

Cases of Tumour Lysis Syndrome (TLS) have been reported during the use of RITUXAN. TLS is a condition that causes sudden kidney failure and abnormal heart rhythms due to changes in blood chemistry, which may be fatal. Tell your doctor immediately if you have palpitations/irregular heartbeats; vomiting; fatigue/weakness; difficulty concentrating/trouble thinking; swelling, numbness or tingling in hands, face or feet; back pain; muscle cramps; fainting or trouble breathing. Some patients with TLS in its early stages have no symptoms, and your doctor will be performing blood tests for this and other side effects.

Bowel problems, including blockage or tears in the bowels that can sometimes lead to death can happen if you receive RITUXAN with chemotherapy medicines to treat non-Hodgkin's lymphoma. Tell your doctor immediately if you have any abdominal pain during treatment with RITUXAN.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

Some side effects associated with RITUXAN are severe and may be life-threatening. This drug should only be used by health professionals experienced in treating cancer in a facility where sudden and life-threatening reactions can be immediately treated.

Fatal allergic reactions have occurred. Tumour lysis syndrome (TLS) causing kidney damage have been observed. Fatal instances of TLS have been reported in NHL patients.

Repeat and sometimes fatal attacks of hepatitis have occurred. Recurrence of hepatitis B virus infection has occurred in patients who show evidence of the virus in a blood test. It is advised that all patients be tested for hepatitis B virus infection before starting treatment with RITUXAN.

Patients with NHL who received treatment with RITUXAN may have an increased risk of JC virus infection resulting in progressive multifocal leukoencephalopathy (PML), which is a condition that leads to nerve damage within the brain. PML can cause disability, and deaths have been reported in patients with NHL. It is hard to predict who will get PML, but it is more common in people with weakened immune systems.

Severe skin reactions such as Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported very rarely. Some cases have resulted in death.

Serious and potentially fatal cardiovascular events have been reported rarely following treatment with RITUXAN.

RITUXAN has not been studied in pregnant or breast-feeding women. If you are pregnant, could become pregnant or are breast-

## INTERACTIONS WITH THIS MEDICATION

Before starting treatment, make sure your doctor knows if you are taking or have recently taken any other medicines (including those you have bought for yourself from a pharmacy, supermarket or health store). This is extremely important, as using more than one medicine at the same time can strengthen or weaken their effect. RITUXAN should not be used with other drugs unless your doctor has told you it is safe to do so.

## PROPER USE OF THIS MEDICATION

*Your doctor has prescribed RITUXAN SC after carefully studying your case. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours.*

RITUXAN SC will be given to you by a doctor or nurse who is experienced in the use of this treatment. Before you are given RITUXAN SC, you will be given other medicines (pre-medication) to prevent or reduce possible side effects.

You will always be given RITUXAN as a drip (intra-venous infusion) at the start of your treatment. After this, you may be given RITUXAN SC as an injection under your skin) over approximately 5 minutes.

Your doctor or nurse will watch you closely while you are being given this medicine. This is in case you get any side effects.

Your doctor will decide when to start RITUXAN SC injections.

When injected under your skin, RITUXAN SC is given in the stomach area, not in other sites of the body, and not into areas of the stomach where the skin is red, bruised, tender, hard or where there are moles or scars. You will be observed for at least 15 minutes after your injection. The observation period may be longer if you are at risk of hypersensitivity reactions.

RITUXAN SC will be given to you on the same day as your chemotherapy. This is usually given every 3 weeks up to 8 times. If you respond well to treatment, you may be given RITUXAN SC as a maintenance treatment every 2 or 3 months for two years. Your doctor may change this, depending on how you respond to the medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### Missed Dose

If you miss a dose of RITUXAN SC, contact your physician immediately. Your physician will decide when you should receive your next dose.

### Overdose

It is unlikely that you will receive too much RITUXAN SC as you will be closely monitored by Healthcare Professionals during your

administration. However, if you suspect you received too much RITUXAN SC contact your physician and poison control centre immediately.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

*Unwanted effects are possible with all medicines. Tell your doctor, nurse or pharmacist immediately if you do not feel well while you are receiving treatment with RITUXAN SC.*

Many patients get some local side effects where RITUXAN is subcutaneously injected. These include: pain, swelling, bruising, bleeding, skin redness, itching and rash.

Your doctor may decide to stop your RITUXAN SC treatment if these reactions are serious.

Tell your doctor immediately if you get signs of an infection including:

- fever, cough, sore throat, burning pain when passing urine or feeling weak or generally unwell
- memory loss, trouble thinking, difficulty walking or sight loss - these may be due to a very rare, serious brain infection, which has been fatal (Progressive Multifocal Leukoencephalopathy or PML).

You might get infections more easily during your treatment with RITUXAN SC. These are often colds, but there have been cases of pneumonia or urinary infections.

There are also possible unwanted effects which could be serious but occur less commonly:

- Chest pain, fast or irregular or uneven heartbeat.
- Decreased white blood cells, red blood cells and platelets in the blood, infection and bleeding.
- Rapid destruction of cells sometimes leading to kidney, heart or breathing problems (Tumour Lysis Syndrome).
- Redness or blistering of the skin and the inside of the mouth.
- Recurrence of Hepatitis B infection. Signs and symptoms of Hepatitis B include mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue.
- Increasing weakness on one side of the body, clumsiness or falls, trouble with thinking or memory, changes in mood, change in vision.

*If you have been given RITUXAN SC in combination with chemotherapy, the following additional unwanted effects may occur:*

- Sudden loss of speech, weakness or numbness of part or all of one side of the body, loss of vision or blurred vision, unexplained dizziness and/or sudden falls.
- Herpes zoster also known as shingles. Symptoms of shingles include itching, tingling or severe burning pain with red patches that develop into blisters and are grouped in a cluster usually on the trunk of the body.

Please consult your doctor, nurse or pharmacist for possible unwanted effects that may be caused by CHOP, CVP chemotherapy.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM					
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist	
		Only if severe	In all cases		
<b>Common</b> (1% to less than 10% of patients)	New fever or if your temperature becomes higher than 38°C		✓		
	Shortness of breath, difficulty breathing, wheezing, coughing		✓		
	Symptoms of infection that include: -fever, temperature at 38°C or higher. -Sore throat -Cough -Any redness or swelling -Pain when you pass your urine			✓	
	Any bleeding or unusual bruising		✓		
	Skin rash, itching, hives or sore joints		✓		
	Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles			✓	
	Symptoms of Hepatitis B such as mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue.			✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM					
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist	
		Only if severe	In all cases		
<b>Uncommon</b> (0.1% to less than 1% of patients)	Chest pain, fast heart rate or an irregular or uneven heart rate		✓		
	Kidney problems such as lower back or side pain, swelling of feet or lower legs, numbness or tingling in feet or hands.		✓		
	Redness or blistering of the skin and the inside of the mouth		✓	✓	
	Sudden loss of speech, increasing weakness or numbness of part or all of one side of the body, loss of vision or blurred vision, unexplained dizziness and/or clumsiness or sudden falls, trouble with thinking or memory, changes in mood, change in vision, change in mental status (for example, confusion), seizures.			✓	✓
	Symptoms of shingles such as itching, tingling, or severe burning pain with red patches that develop into blisters and are grouped in a cluster usually on the trunk of the body.			✓	

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

*This document does not provide all known information about RITUXAN SC. If you have any questions or concerns about your treatment, please speak with your doctor, nurse or pharmacist.*

**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](http://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, Ontario  
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](http://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**

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Hoffmann-La Roche Limited at: [www.rochecanada.com](http://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.

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Hoffmann-La Roche Limited  
Mississauga, ON L5N 5M8

**PART III: CONSUMER INFORMATION**Pr **RITUXAN® SC**

rituximab

**1600 mg (120 mg/mL) Solution for Subcutaneous Injection*****Pronounced: rih TUCKS en*****Single Use Vial for Chronic Lymphocytic Leukemia**

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

**ABOUT THIS MEDICATION****What the medication is used for:**

RITUXAN SC (also known as rituximab) is a cancer medicine that is used to stop cancer cell growth and ideally cause the death of cancer cells. It must be prescribed by a doctor.

It is used to treat patients with certain types of chronic lymphocytic leukemia (CLL).

**What is chronic lymphocytic leukemia?**

Chronic lymphocytic leukemia is a cancer of the bone marrow (spongy tissue inside bones where blood cells are made). It affects lymph cells (lymphocytes) which are a type of white blood cell. There are two types: B lymphocytes and T lymphocytes. B lymphocytes produce antibodies or proteins that help our immune system to fight foreign substances which enter the body. All B-cells have a marker on their surface. This marker is called CD20.

**What RITUXAN SC does:**

Our bodies have a natural defence system against cancer cells. When cancer cells appear, our bodies respond by making special proteins called antibodies. Researchers studied this response and learned how to create antibodies outside the body that help with cancer treatment. These are called monoclonal antibodies.

Monoclonal antibodies are now made to target tumours in an effort to control the growth of cancer.

RITUXAN SC belongs to a family of medicine called monoclonal antibodies. It is an antibody that targets the CD-20 B-cell lymphocyte to stop its activity. RITUXAN SC attaches to the CD20 marker that is located on the B-cell. When in place, it works to stop the growth of the cancer cells and may destroy them. RITUXAN SC is most active in patients whose lymphomas are of the B-cell type.

**Who should take RITUXAN SC?**

RITUXAN SC is used to treat patients with moderate or severe [stage B or C] B-cell chronic lymphocytic leukemia. In the CLL trial RITUXAN was used with 2 other chemotherapy drugs FC

[which stands for fludarabine and cyclophosphamide].

**When it should not be used:**

If you are allergic to rituximab or proteins of similar mouse or human origin or any other ingredient in RITUXAN SC or if you have ever had a rare infection of the brain called progressive multifocal leukoencephalopathy (PML) you should not take RITUXAN SC.

**What should you tell your doctor before you start taking RITUXAN SC?**

Before beginning treatment with the subcutaneous formulation of RITUXAN, make sure your doctor knows if:

- You ever had a bad reaction to RITUXAN or any of the non-medicinal ingredients.
- You are allergic to rituximab, other proteins which are like rituximab, or any of the other ingredients of this medicine
- You are allergic to hyaluronidase (an enzyme that is part of the formulation that helps to increase the absorption of injected active substance)
- You have a history of heart attack or stroke.
- You are taking any other medicines (including those not prescribed by the doctor).
- If you are taking medication to reduce blood pressure.
- If you are planning to be immunized with a vaccine during or after the completion of your RITUXAN SC therapy.
- If you have ever taken medicines which affect your immune system – such as chemotherapy or immune-suppressive medicines
- You have a pre-existing lung disease as you may have a greater chance of breathing difficulties during your RITUXAN SC treatment injection.
- You have a history of hepatitis B, current hepatitis B or tuberculosis infection.
- You are pregnant or could become pregnant or are breast-feeding a child.

*This information will help your doctor and you decide whether you should use RITUXAN SC and what extra care may need to be taken while you are on the medication.*

**What the medicinal ingredient is:**

RITUXAN SC contains the active ingredient rituximab.

**What the non-medicinal ingredients are (in alphabetical order):**

$\alpha,\alpha$ -trehalose dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, recombinant human hyaluronidase (rHuPH20), water for injection.

**What dosage forms it comes in:**

RITUXAN SC has been prescribed for you as a medicine for injection under your skin (called RITUXAN SC 1600 mg, solution for subcutaneous injection).

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

Some side effects associated with RITUXAN are severe and may be life-threatening. This drug should only be used by health professionals experienced in treating cancer in a facility where sudden and life-threatening reactions can be immediately treated.

Fatal allergic reactions have occurred. Tumour lysis syndrome (TLS) causing kidney damage have been observed. Fatal instances of TLS have been reported in NHL patients.

Repeat and sometimes fatal attacks of hepatitis have occurred. Recurrence of hepatitis B virus infection has occurred in patients who show evidence of the virus in a blood test. It is advised that all patients be tested for hepatitis B virus infection before starting treatment with RITUXAN.

Patients with CLL who received treatment with RITUXAN may have an increased risk of JC virus infection resulting in progressive multifocal leukoencephalopathy (PML), which is a condition that leads to nerve damage within the brain. PML can cause disability and death. It is hard to predict who will get PML, but it is more common in people with weakened immune systems.

Severe skin reactions such as Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported very rarely. Some cases have resulted in death.

Serious and potentially fatal cardiovascular events have been reported rarely following treatment with RITUXAN.

RITUXAN has not been studied in pregnant or breast-feeding women. If you are pregnant, could become pregnant or are breast-feeding, be sure to discuss with your doctor whether RITUXAN is right for you. Women should avoid pregnancy and use effective birth control methods during treatment with RITUXAN and for one year after treatment. Patients who are pregnant or become pregnant should not receive or continue to receive RITUXAN SC.

If you have ever had heart disease [for example angina (heart pain), arrhythmia (palpitations/ irregular heartbeat), or heart failure] or breathing problems, your doctor will take special care of you during therapy with RITUXAN.

One patient with CLL who had a tuberculosis infection had repeat and severe attacks when treated with RITUXAN. Tell the doctor if you think you had tuberculosis; you will be carefully checked for signs of tuberculosis infection.

In some cases, patients who have had hepatitis B might have a repeat attack of hepatitis. Tell the doctor if you think you have had hepatitis in the past.

Infection with hepatitis B virus causes inflammation of the liver which may show as mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue. If you experience any of these symptoms immediately contact your doctor. If you show evidence of hepatitis B virus infection you may be referred to a liver disease expert for ongoing monitoring and management.

RITUXAN is not to be used in patients with active hepatitis B viral disease. Tell your doctor if you think you have hepatitis B.

Live viral vaccines should not be given with RITUXAN. Your doctor will check if you should have any vaccines before or after you receive RITUXAN.

Cases of Progressive Multifocal Leukoencephalopathy (PML) have been reported during use of RITUXAN in CLL. PML is a condition that causes nerve damage within the brain. Tell your doctor immediately if you have memory loss, trouble thinking, and difficulty with walking, clumsiness, falls or weakness on one side of the body, changes in mood or loss of vision. Your doctor will check if you need to see a neurologist.

Cases of Tumour Lysis Syndrome (TLS) have been reported during the use of RITUXAN. TLS is a condition that causes sudden kidney failure and abnormal heart rhythms due to changes in blood chemistry, which may be fatal. Tell your doctor immediately if you have palpitations/irregular heartbeats; vomiting; fatigue/weakness; difficulty concentrating/trouble thinking; swelling, numbness or tingling in hands, face or feet; back pain; muscle cramps; fainting or trouble breathing. Some patients with TLS in its early stages have no symptoms, and your doctor will be performing blood tests for this and other side effects.

Bowel problems, including blockage or tears in the bowels that can sometimes lead to death can happen if you receive RITUXAN with chemotherapy medicines to treat non-Hodgkin's lymphoma. Tell your doctor immediately if you have any abdominal pain during treatment with RITUXAN.

**INTERACTIONS WITH THIS MEDICATION**

Before starting treatment, make sure your doctor knows if you are taking or have recently taken any other medicines (including those you have bought for yourself from a pharmacy, supermarket or health store). This is extremely important, as using more than one medicine at the same time can strengthen or weaken their effect. RITUXAN should not be used with other drugs unless your doctor has told you it is safe to do so.

**PROPER USE OF THIS MEDICATION**

*Your doctor has prescribed RITUXAN SC after carefully studying your case. Other people may not benefit from taking this medicine, even though their problems may seem similar to yours.*

RITUXAN SC will be given to you by a doctor or nurse who is experienced in the use of this treatment. Before you are given RITUXAN SC, you will be given other medicines (pre-medication) to prevent or reduce possible side effects.

You will always be given RITUXAN as a drip (intra-venous infusion) at the start of your treatment. After this, you may be given RITUXAN SC as an injection under your skin) over approximately 7 minutes.

Your doctor or nurse will watch you closely while you are being given this medicine. This is in case you get any side effects.

Your doctor will decide when to start RITUXAN SC injections.

When injected under your skin, RITUXAN SC is given in the stomach area, not in other sites of the body, and not into areas of the stomach where the skin is red, bruised, tender, hard or where there are moles or scars. You will be observed for at least 15 minutes after your injection. The observation period may be longer if you are at risk of hypersensitivity reactions.

RITUXAN SC will be given to you on the same day as your chemotherapy. This is usually given every 4 weeks up to 5 times.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Missed Dose

If you miss a dose of RITUXAN SC, contact your physician immediately. Your physician will decide when you should receive your next dose.

Overdose

It is unlikely that you will receive too much RITUXAN SC as you will be closely monitored by Healthcare Professionals during your administration. However, if you suspect you received too much RITUXAN SC contact your physician and poison control centre immediately.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

*Unwanted effects are possible with all medicines. Tell your doctor, nurse or pharmacist immediately if you do not feel well while you are receiving treatment with RITUXAN SC.*

Many patients get some local side effects where RITUXAN is subcutaneously injected. These include: pain, swelling, bruising, bleeding, skin redness, itching and rash.

Your doctor may decide to stop your RITUXAN SC treatment if these reactions are serious.

Tell your doctor immediately if you get signs of an infection including:

- fever, cough, sore throat, burning pain when passing urine or feeling weak or generally unwell
- memory loss, trouble thinking, difficulty walking or sight loss - these may be due to a very rare, serious brain infection, which has been fatal (Progressive Multifocal Leukoencephalopathy or PML).

You might get infections more easily during your treatment with RITUXAN SC. These are often colds, but there have been cases of pneumonia or urinary infections.

There are also possible unwanted effects which could be serious but occur less commonly:

- Chest pain, fast or irregular or uneven heartbeat.
- Decreased white blood cells, red blood cells and platelets in the blood, infection and bleeding.
- Rapid destruction of cells sometimes leading to kidney, heart or breathing problems (Tumour Lysis Syndrome).
- Redness or blistering of the skin and the inside of the mouth.
- Recurrence of Hepatitis B infection. Signs and symptoms of Hepatitis B include mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue.
- Increasing weakness on one side of the body, clumsiness or falls, trouble with thinking or memory, changes in mood, change in vision.

*If you have been given RITUXAN SC in combination with chemotherapy, the following additional unwanted effects may occur:*

- Sudden loss of speech, weakness or numbness of part or all of one side of the body, loss of vision or blurred vision, unexplained dizziness and/or sudden falls.
- Herpes zoster also known as shingles. Symptoms of shingles include itching, tingling or severe burning pain with red patches that develop into blisters and are grouped in a cluster usually on the trunk of the body.

*Please consult your doctor, nurse or pharmacist for possible unwanted effects that may be caused by FC chemotherapy.*

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist	
	Only if severe	In all cases		
<b>Common</b> (1% to less than 10% of patients)	New fever or if your temperature becomes higher than 38°C		✓	
	Shortness of breath, difficulty breathing, wheezing, coughing		✓	
	Symptoms of infection that include: -fever, temperature at 38°C or higher. -Sore throat -Cough -Any redness or swelling -Pain when you pass your urine		✓	
	Any bleeding or unusual bruising		✓	
	Skin rash, itching, hives or sore joints		✓	
	Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, swelling of the hands, feet or ankles		✓	
	Symptoms of Hepatitis B such as mild fever, feeling of sickness, fatigue, loss of appetite, joint and/or abdominal pain and yellowing of whites of the eyes, skin and tongue.		✓	
<b>Uncommon</b> (0.1% to less than 1% of patients)	Chest pain, fast heart rate or an irregular or uneven heart rate		✓	
	Kidney problems such as lower back or side pain, swelling of feet or lower legs, numbness or tingling in feet or hands.		✓	
	Redness or blistering of the skin and the inside of the mouth		✓	✓

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Sudden loss of speech, increasing weakness or numbness of part or all of one side of the body, loss of vision or blurred vision, unexplained dizziness and/or clumsiness or sudden falls, trouble with thinking or memory, changes in mood, change in vision, change in mental status (for example, confusion), seizures.		✓	✓
	Symptoms of shingles such as itching, tingling, or severe burning pain with red patches that develop into blisters and are grouped in a cluster usually on the trunk of the body.		✓

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

*This document does not provide all known information about RITUXAN SC. If you have any questions or concerns about your treatment, please speak with your doctor, nurse or pharmacist.*

**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](http://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, Ontario  
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](http://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**

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

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