

What is the most important information I should know about LYMPHIR?

LYMPHIR treatment can cause a serious condition called capillary leak syndrome (CLS), which can be life-threatening or fatal. Your doctor will monitor your weight, blood pressure, any areas of swelling (called edema), and levels of a blood protein (called albumin) before and during LYMPHIR treatment.

What is CTCL?

CTCL is a type of non-Hodgkin lymphoma.

Non-Hodgkin lymphomas are white blood cell cancers, but they can also affect other areas of the body. White blood cells are part of the body's immune system—they help fight infection and other diseases.

CTCL, specifically, is a type of blood cancer that affects the skin, causing itching and sores. CTCL is relatively rare, being only 4% of non-Hodgkin lymphoma diagnoses.

It's normal to be scared, confused, or frustrated if you have been diagnosed with CTCL.

In CTCL treatment, it is common for patients to move from treatment to treatment to find relief. Even if something else worked for a while, your symptoms may have started to come back or get worse.

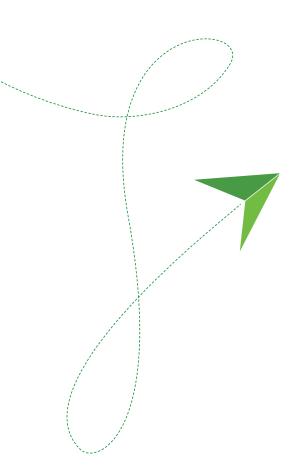
You have been given this brochure because your doctor has prescribed or may be thinking of prescribing LYMPHIR, a targeted treatment for CTCL. As you begin treatment with LYMPHIR, it is important to stay as informed as possible.

This guide was developed to provide you with more information about LYMPHIR and walk you through your next steps.

WHY LYMPHIR?
WHAT IS LYMPHIR?
HOW WELL DOES LYMPHIR WORK AT TREATING CTCL?
WHAT SHOULD I DISCUSS WITH MY DOCTOR BEFORE I START TREATMENT WITH LYMPHIR?
HOW IS LYMPHIR GIVEN?
HOW LONG DOES THE INFUSION TAKE?
HOW LONG WILL I BE ON LYMPHIR?
HOW DO I PREPARE FOR MY LYMPHIR INFUSIONS?
WHAT DO I DO AFTER MY INFUSION?
HOW DO I PREPARE FOR MY DOCTOR VISITS?
WHAT ARE SOME OF THE SIDE EFFECTS OF LYMPHIR?
WHAT CAN I DO IF I EXPERIENCE SIDE EFFECTS?1
WHAT ELSE SHOULD I KNOW ABOUT TREATMENT WITH LYMPHIR?
WHAT PATIENT ASSISTANCE OR FINANCIAL SUPPORT IS AVAILABLE?1
WHAT OTHER RESOURCES ARE AVAILABLE TO ME? 1

The information in this brochure is not meant to take the place of talking with your doctor, nurse, or other health care providers. Always talk with your doctor if you have any questions about your treatment, or if you experience any side effects.

Also, know that you are not alone in your CTCL treatment journey. See page 14 for resources to support you and connect you with people who can help you take charge of your CTCL.



Why LYMPHIR?

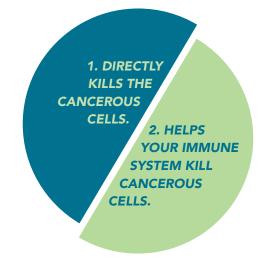
Your doctor has decided to prescribe LYMPHIR based on your past CTCL treatments and disease severity or progression.

What is LYMPHIR?

LYMPHIR is a prescription medicine used to treat CTCL in adults who have tried at least 1 prior therapy (taken by mouth, injection, or infusion) that did not work or in whom the disease has come back. The 1 prior therapy does not include topicals (medicine you rub on your skin) or phototherapy.



It is a targeted immune therapy that treats your CTCL in 2 different ways.



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- Swelling of the hands and feet
- Changes in blood pressure or dizziness when standing up from a sitting position
- Sudden weight gain
- Shortness of breath

These symptoms do not all have to happen at the same time to be considered CLS and can appear up to 2 weeks after an infusion. If you do experience CLS, your doctor may pause your LYMPHIR treatment until your symptoms resolve.

You should regularly monitor your weight and blood pressure with your doctor. Your doctor may also perform additional tests to monitor other potential signs of CLS.

Please see additional Important Safety Information on page 15 and accompanying full Prescribing Information, including Boxed Warning.

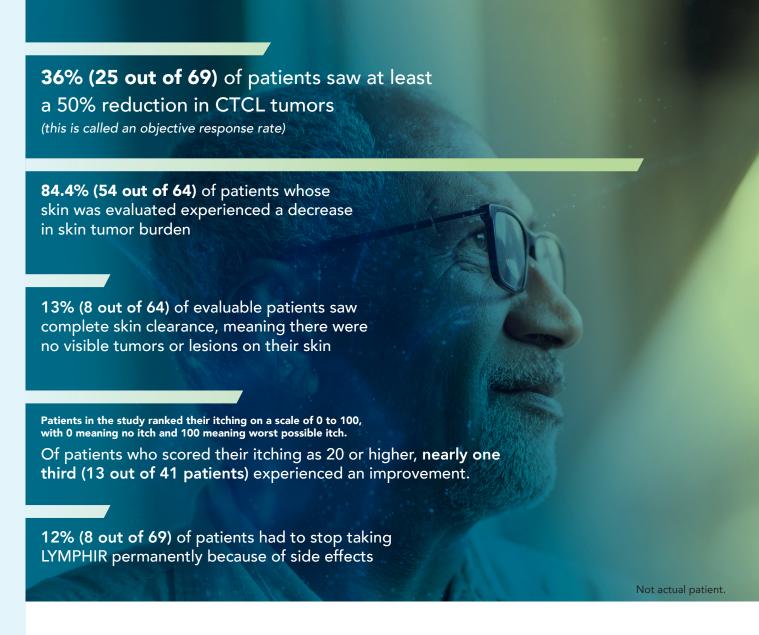
How well does LYMPHIR work at treating CTCL?

LYMPHIR, like other CTCL treatments, does not cure CTCL. However, LYMPHIR may help clear your skin and relieve itching.

LYMPHIR was studied in a clinical trial by itself (single arm) in 69 heavily pretreated adult patients whose disease returned after taking 1 or more systemic (administered by mouth, injection or infusion) treatments. This study measured how many patients had their CTCL skin lesions reduced by half (called objective response rate) or achieved remission (called

a complete response rate). It's also possible to achieve a partial reduction in disease.

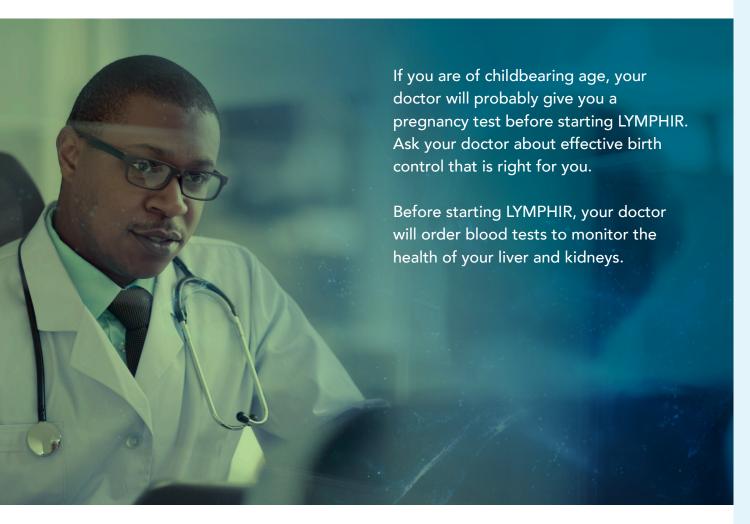
Just like your planned treatment cycle, patients received a 1-hour LYMPHIR infusion each day for 5 days. After 16 days without infusions, the 21-day cycle was repeated—5 days of infusions and 16 days off. LYMPHIR treatment continued until the CTCL got worse or if side effects could not be tolerated. Here are some of the results of the clinical study:



What should I discuss with my doctor before I start treatment with LYMPHIR?

Before starting treatment, it's important to tell your doctor about the following:

- All your medical conditions
- Current medications, including nonprescription drugs, and any herbal or vitamin supplements you may be taking
- If you are breastfeeding or pregnant



What are the other possible serious side effects of LYMPHIR?

Visual Impairment: LYMPHIR can cause serious visual impairment, including changes in vision. If you experience changes in visual clarity, changes in ability to see color accurately, or blurred vision, your doctor may refer you to an ophthalmologist. Your doctor may pause or stop your treatment with LYMPHIR if your vision changes are serious.

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How is LYMPHIR given?

LYMPHIR is given as an intravenous infusion (medicine given directly into a vein) at an infusion center.

The infusion is given every day for 5 days with the next 16 days off.

DAY 1 1-HOUR INFUSION	DAY 2 1-HOUR INFUSION	DAY 3 1-HOUR INFUSION	DAY 4 1-HOUR INFUSION	DAY 5 1-HOUR INFUSION	DAY 6	DAY 7
DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14
DAY 15	DAY 16	DAY 17	DAY 18	DAY 19	DAY 20	DAY 21

X=no treatment.



How long does the infusion take?

The infusion takes about 1 hour.

Your doctor may ask you to come in early to prepare and stay afterward for monitoring.

Your doctor may have prescribed other medications for you to take 30 minutes to an hour before your LYMPHIR infusion. These medications will be given to you by the care team at your infusion center to ensure you are taking them at the right time.



How long will I be on LYMPHIR?

Even if you experience relief from your CTCL symptoms, you will continue to take LYMPHIR until your doctor decides to stop your treatment. This may happen if your CTCL gets worse, or if your doctor determines that continuing treatment with LYMPHIR could lead to significant side effects.

6/7



How do I prepare for my LYMPHIR infusions?

Working with your health care team and learning what to expect from treatment can help you feel more comfortable. Ask your health care team where your LYMPHIR infusions will be given. Also, plan out how you will get there, and follow these tips to prepare for the infusion:

- Start by drinking a lot of water (6 to 8 cups) the day before your infusion and on the day of the infusion
- Wear comfortable, loose-fitting clothing
- Bring something with you to do while you wait for your infusion to be completed:
- A caretaker or friend to talk to
- Your mobile phone to talk to a friend, watch a movie, or listen to music
- A book, magazine, or newspaper

What do I do after my infusion?

- If you have an infusion scheduled for the next day, keep drinking water (6 to 8 cups)
- Take a picture of the affected skin areas to compare changes you might experience after a couple of treatment cycles
- Set aside a notebook to write down any side effects you experience (make sure to bring this to your doctor visits)

The following side effects may indicate a condition called infusion reaction.

Tell a health care worker right away if you experience:



-EVER



HLLS



BREATHING PROBLEMS



CHEST PAIN



HIVES



A significant change in your weight or blood pressure may be a sign of a serious side effect called capillary leak syndrome, or CLS. CLS is most likely to occur during the first 2 infusion cycles. Learn more about CLS on page 13 of this brochure.

What are the other possible serious side effects of LYMPHIR? (CONT'D)

Infusion-Related Reactions (IRRs): LYMPHIR can cause serious IRRs. The most common symptoms include nausea, fatigue or tiredness, chills, pain of the muscles or bones, vomiting, fever, and joint stiffness. To reduce the risk of IRRs, your doctor will prescribe other medications you will need to take before your first 3 LYMPHIR treatment cycles. Your health care team will monitor you during your LYMPHIR treatment. You may need to stop LYMPHIR if you have a severe IRR.

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Track your weight and blood pressure

Because of the potential risk for CLS, you should weigh yourself every day and monitor your blood pressure. This is especially important during the first 2 treatment cycles. Talk to your doctor about what your weight and blood pressure measurements may mean for you.

Weight tracker

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14
DAY 15	DAY 16	DAY 17	DAY 18	DAY 19	DAY 20	DAY 21

Blood pressure tracker

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14
DAY 15	DAY 16	DAY 17	DAY 18	DAY 19	DAY 20	DAY 21

8 / 9





Here are a few questions your doctor may ask:

- Have your CTCL skin problems gotten better, stayed the same, or gotten worse?
- What are the worst affected parts of your body?
- How severe is your itching? Has it changed since the last visit?
- Are there any areas of your skin that are painful? Very painful?
- Have you experienced any new or worsening side effects since your last visit?
- Have you gained a lot of weight recently? Is there swelling in your hands and feet?
- Has your blood pressure gone down a lot?
- How happy are you with the results of your treatment?



Questions you can ask your doctor:

- Do you think my treatment is helping my CTCL?
- Are you concerned about my weight or blood pressure change, or any of my side effects?
- What are my latest lab results and what do they mean?
- Is there assistance available to help me afford my treatment?

What are the other possible serious side effects of LYMPHIR? (CONT'D)

Liver Toxicity: LYMPHIR can cause a rise in alanine transaminase (ALT) and aspartate aminotransferase (AST), 2 liver enzymes, which might mean your liver is being harmed. Your doctor will monitor levels of these enzymes and another liver protein (bilirubin) before and during LYMPHIR treatment. Your doctor may pause, lower your dose, or discontinue your treatment with LYMPHIR if your liver is being harmed. Contact your doctor immediately if you experience signs of liver toxicity, including fatigue, anorexia, right upper stomach discomfort, dark urine, or yellowing of the skin or eyes (jaundice).

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Write down any additional questions you may want to ask your health care team here:				

10/11

What are some of the side effects of LYMPHIR?

In a safety analysis of 119 patients, the most common side effects that happened in 20% or more of patients were:



• Increased liver enzymes



- Lower albumin (a blood protein that keeps fluid inside your blood vessels to help maintain proper blood pressure)
- Swelling due to fluid buildup
- Lower hemoglobin (a protein in your blood that helps carry oxygen throughout your body)
- Capillary leak syndrome, sometimes referred to as CLS



- Fatigue or tiredness
- Pain in the muscles, bones, or tendons
- Rash
- Chills
- Fever



- Nause
- Constipation

What can I do if I experience side effects?

If you experience any side effects, be sure to tell your health care team as soon as possible.

Getting medical treatment right away may help keep these problems from becoming more serious. If side effects are severe or do not get better, your doctor may decide to pause or stop your LYMPHIR infusions.

Talk to your doctor if you are experiencing side effects. In clinical trials, most patients taking LYMPHIR did not need to stop treatment due to side effects.

It is important to always talk to your health care team about how you are feeling throughout your treatment.

What are the other possible serious side effects of LYMPHIR? (CONT'D)

Embryo-Fetal Toxicity: If you are a woman of reproductive age, you should know that LYMPHIR can pose a potential risk to an unborn baby. Inform your health care provider of a known or suspected pregnancy and use effective birth control for at least 7 days after your final dose of LYMPHIR.

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What else should I know about treatment with LYMPHIR?

Capillary leak syndrome

LYMPHIR treatment can cause a condition called CLS. This condition happens when the liquid part of your blood (plasma) leaks out of tiny blood vessels called capillaries. Contact your health care provider immediately if you experience any of the following symptoms:

- Swelling of the hands and feet
- Changes in blood pressure (take your blood pressure every day) or dizziness when standing up from a sitting position
- Sudden weight gain (weigh yourself every day)

CLS doesn't always happen right away after an infusion. Symptoms can appear up to 2 weeks after an infusion. If you do experience CLS, your doctor may pause your LYMPHIR treatment until the reaction gets better or permanently stop it. Your doctor will work with you to manage your symptoms and help prevent CLS from happening again.

Vision changes

If you notice any changes in your vision, such as blurriness or changes in your color vision, report it to your health care provider immediately.

Liver harm

LYMPHIR treatment may cause a rise in liver proteins that might mean your liver is becoming harmed from your treatment.
Tell your doctor or nurse if you notice any of the following symptoms: fatigue (tiredness), loss of appetite, discomfort in the upper right side of your stomach, dark urine, and/or jaundice (yellow color of the skin or eyes).

If your treatment cycle is interrupted by CLS, vision changes, harm to your liver, or a serious infusion reaction, the infusions will be stopped and then started again no sooner than 16 days.

Breastfeeding

Do not breastfeed during LYMPHIR treatment and for 7 days following the final dose.

Fetal harm

If you are a woman of reproductive age, you should know that LYMPHIR can pose a potential risk to an unborn baby. Inform your health care provider of a known or suspected pregnancy and use effective birth control for at least 7 days after the final dose.

Infusion reactions

An infusion reaction can occur if your immune system has a strong reaction to LYMPHIR. To help prevent this, your health care team may give you medications before your infusion:

- Acetaminophen
- Antihistamine
- Antinausea medication
- Intravenous hydration

Contact your health care provider immediately if you experience any of the following symptoms of an infusion reaction:

- Fever
- Chills
- Breathing problems
- Chest pain
- Hives (red, sometimes itchy bumps on your skin that suddenly appear after an infusion)

If you do experience an infusion reaction, your doctor may pause the infusion until the reaction gets better or permanently stop your LYMPHIR treatment. Your doctor may add a steroid pill to your premedications list to help prevent another infusion reaction.

What patient assistance or financial support is available?

The Citius Advantage Patient Support Program can get you the help you need.

- Get individualized support from:
- Clinical nurses
- Pharmacists
- Speak with a dedicated reimbursement specialist at Citius Advantage to see if you are eligible for copay assistance or patient assistance programs
- Access resources designed to help you through the prescription process. Contact a Citius Advantage representative for more information

Citius Advantage is available at 1-844-459-6744 Monday through Friday, 8 AM to 8 PM ET.



What other resources are available to me?

You are not alone. The following organizations allow you to connect with CTCL experts and others living with or supporting someone with CTCL. These organizations offer additional patient resources, in-person events, and webinars.

Cutaneous Lymphoma Foundation https://www.clfoundation.org/

Lymphoma Research Foundation https://www.lymphoma.org

14/15

What is LYMPHIR™ (denileukin diftitox-cxdl)?

LYMPHIR is a prescription medicine used to treat a cancer known as cutaneous T-cell lymphoma (CTCL) in adults who have tried at least one prior treatment (taken by mouth, injection, or infusion) that did not work or in whom the disease has come back. The one prior treatment does not include topicals (medicine you rub on your skin) or phototherapy.

What is the most important information I should know about LYMPHIR?

LYMPHIR treatment can cause a serious condition called capillary leak syndrome (CLS), which can be lifethreatening or fatal. Your doctor will monitor your weight, blood pressure, any areas of swelling (called edema), and levels of a blood protein (called albumin) before and during LYMPHIR treatment. Contact your doctor immediately if you experience any of the following symptoms:

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Liver Toxicity: LYMPHIR can cause a rise in alanine transaminase (ALT) and aspartate aminotransferase (AST), 2 liver enzymes, which might mean your liver is being harmed. Your doctor will monitor levels of these enzymes and another liver protein (bilirubin) before and during LYMPHIR treatment. Your doctor may pause, lower your dose, or discontinue your treatment with LYMPHIR if your

liver is being harmed. Contact your doctor immediately if you experience signs of liver toxicity, including fatigue, anorexia, right upper stomach discomfort, dark urine, or yellowing of the skin or eyes (jaundice).

Embryo-Fetal Toxicity: If you are a woman of reproductive age, you should know that LYMPHIR can pose a potential risk to an unborn baby. Inform your health care provider of a known or suspected pregnancy and use effective birth control for at least 7 days after your final dose of LYMPHIR.

What are the most common side effects of LYMPHIR?

Across 3 clinical trials, the most common side effects that happened in 20% or more of patients include:

- CLS
- increased liver enzymes
- decreased levels of albumin in the blood
- nausea
- swelling due to fluid buildup
- decreased levels of hemoglobin in the blood
- fatigue or tiredness
- pain in the muscles, bones, or tendons
- rash
- chills
- constipation
- fever

These are not all the possible side effects of LYMPHIR. Tell your doctor about any side effect that bothers you or does not go away. If you have certain side effects, your doctor may lower your dose or delay or stop your LYMPHIR treatment.

What should I tell my doctor before I start treatment with IYMPHIR?

- About all your medical conditions, including if you have liver problems, vision problems, body swelling, or previously experienced an IRR
- If you are pregnant or plan to become pregnant.
 LYMPHIR may harm your unborn baby. Females who
 are able to become pregnant: Your doctor should give
 you a pregnancy test before starting LYMPHIR treatment.
 You should use effective birth control during LYMPHIR
 treatment and for 7 days after your last dose of LYMPHIR.
 Tell your doctor right away if you become pregnant or
 think you are pregnant during LYMPHIR treatment
- LYMPHIR may also have an impact on male fertility.
 Talk to your doctor if you plan on having children in the future
- If you are breastfeeding or plan to breastfeed. Do not breastfeed during LYMPHIR treatment and for 7 days after your final dose

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Citius Oncology at 1-844-459-6744.



The next step in your treatment of CTCL

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