Ryoncil®
(remestemcel-L-rknd) Suspension for IV infusion

*FDA-approved for children 2 months and older with acute graft-versus-host disease (acute GvHD) who did not get better with steroids*

# Understanding what's *possible* with Ryoncil®

## A guide for patients and caregivers



Actor portrayal.

**Indication and Important Safety Information for RYONCIL® (remestemcel-L-rknd)**

**What is Ryoncil?**
RYONCIL is a prescription medicine used to treat a condition called steroid-refractory acute graft-versus-host disease (SR-aGvHD) in children 2 months and older.

**Who should not receive Ryoncil?**
Do not receive Ryoncil if you are allergic to DMSO or porcine and bovine proteins (e.g., pigs or cows).

Ryoncil is not recommended if you are pregnant. Talk to your doctor about the risks and benefits of breastfeeding during Ryoncil treatment.

**Please see the RYONCIL full Prescribing Information for additional Important Safety Information.**

MOVING BEYOND

# "What if?" to "What's next?"

## A stem cell transplant can be a fresh start for many families

For some, the days and weeks after transplant can bring questions, especially if health problems come up.

Some children can get a condition called **acute graft-versus-host disease, or acute GvHD.** Doctors usually treat it with steroids. For many children, steroids help. But for about half, they don't work well enough.

When this happens, it's called **steroid-refractory acute graft-versus-host disease (acute GvHD).**

If you or your loved one has acute GvHD, you may be wondering, ***"What if steroids don't work well enough? What happens next?"*** The good news is that you have other options.

Actor portrayal.

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This guide offers helpful facts about steroid-refractory acute GvHD and its treatment. You'll learn how a first-of-its-kind treatment called RYONCIL may be the help you've been hoping for.

RYONCIL (Rye-ON-sill) is the first and only FDA-approved steroid-refractory acute GvHD therapy for children 2 months of age and older. It's the only approved option for children under 12 years of age.

### Share your RYONCIL success story

*If you've already seen what's possible with RYONCIL, you can help others see it, too.* Sharing your experience could help other families still searching for answers. Scan the code or **click here** to learn how to share your story.

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**Important Safety Information** (continued)

**What are the possible serious side effects?**

- **Allergic reactions.** Serious allergic reactions, including anaphylaxis, can happen during or after infusion. Tell your doctor or nurse right away if you experience signs of an allergic reaction, including fever, rash, hives, low blood sugar, or breathing problems.
- **Infections.** Ryoncil is made from human cells using materials from humans and porcine and bovine sources (e.g., pigs, cows). Although all donors and materials are carefully screened and tested, these measures cannot completely eliminate potential risk of transmission of infectious disease.



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**Important Safety Information** (continued)

**What are the possible serious side effects?** (continued)

- **Unusual tissue growth.** There is a theoretical risk that Ryoncil could cause growth of tissue in other places, such as bone, cartilage, or fat.

**What are the most common side effects?**

The most common side effects include infections, fever, bleeding, swelling, stomach pain, high blood pressure, vomiting, irregular heartbeat, diarrhea, rash, joint pain, low blood pressure, cough, and trouble breathing.

**What should I tell my doctor before receiving Ryoncil?**

Tell your doctor about all your medical conditions, allergies, and if you are pregnant or breastfeeding.

# Why acute GvHD sometimes happens

After a bone marrow transplant, some children get sick with a condition called acute graft-versus-host disease, or acute GvHD. This happens when donor immune cells get confused and attack parts of the child's body. Acute GvHD most often develops within the first 100 days after a bone marrow or stem cell transplant. However, sometimes it can appear later.

**Not every child who has a transplant will get acute GvHD. However, it can affect 3 to 7 out of every 10 transplant patients.**

## Treating acute GvHD in children

Treatment often starts with steroids. For about half, steroids don't work well enough. When this happens, it's called steroid-refractory acute GvHD.

## Symptoms to watch for

Steroid-refractory acute GvHD most often affects specific parts of the body. This includes the stomach and intestines **(the gastrointestinal, or GI, tract)**, the liver and/or skin. Watching for new or worsening symptoms can help you stay one step ahead of acute GvHD. If you notice changes, always tell your child's care team right away.

**Symptoms of steroid-refractory acute GvHD may include:**

| | | |
|---|---|---|
| **GI Tract:** Loose stools, nausea, belly pain, poor appetite, throwing up, blood in the stool. | **Liver:** Commonly has no symptoms you can see. May include yellow skin or eyes. | **Skin:** Redness or skin rash (anywhere on the body, including hands and feet); itchy rash that may look like a sunburn; severe rash with blisters or peeling skin. |

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In children with acute GvHD who did not get better with steroids

**When steroids fail,**

*hope doesn't have to*



Actor portrayal.

**If steroids did not work well enough for your child,** there are other options. Ask your care team what's possible with RYONCIL.

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Actor portrayal.

# Hope is now

In the past, children with steroid-refractory acute GvHD had very few treatment choices. RYONCIL is changing that, giving hope to families living with steroid-refractory acute GvHD.

**RYONCIL is the first and only FDA-approved steroid-refractory acute GvHD treatment for children 2 months of age and older. It is the only approved option for patients under 12 years of age.**

## RYONCIL is different

RYONCIL is different from medicines used to treat adults with steroid-refractory acute GvHD. It's a first-of-its-kind treatment approved just for children.

RYONCIL is made from living cells. This is called cell therapy. These cells are called **mesenchymal stromal cells, or MSCs.** They come from the bone marrow of healthy adult donors in the United States. They have been carefully tested for safety.

Unlike some treatments, **RYONCIL does not require donor matching.** It's ready to use when your child needs it.

***RYONCIL is the first and only FDA-approved MSC treatment available in the United States.***

**Important Safety Information** (continued)

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## RYONCIL works differently than a steroid

RYONCIL works in a different way than a steroid. It's believed to help calm the immune system instead of making it weaker. This gives your child's body a chance to recover from steroid-refractory acute GvHD.

**After transplant:** Donor cells may send attack signals that cause the immune system to go into overdrive, resulting in acute GvHD.

**Inflammation goes up:** Attack signals may cause inflammation affecting the gastrointestinal, or GI, tract, liver, and/or skin.

**Treatment begins:** After acute GvHD is diagnosed, doctors may treat with steroids and other medicines. In about half of children, steroids don't work well enough.

**RYONCIL treatment:** When steroids fail to control acute GvHD, RYONCIL can be used to send special cells into the bloodstream to help calm the immune system.

**Inflammation goes down:** Inflammation may go down, reducing the number of overactive immune cells.

**Calm immune response:** By calming the inflammation signals, RYONCIL may help bring the immune system back into balance.

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## With RYONCIL,

# *recovery is possible*



Actor portrayal.

Recovering from steroid-refractory acute GvHD can look different for every child and every family. Some signs of progress may be easy to see. Others can be quieter, happening day by day. **But every moment—and every sign of recovery—matters.**

Although steroids are among the first treatments used for acute GvHD, they may not always work well enough. RYONCIL was developed for moments like this, when more help is needed.

Results from a study show that recovery is possible with RYONCIL. In fact, **most children treated with RYONCIL improved within 4 weeks.***

***Many children with the worst forms of steroid-refractory acute GvHD showed signs of recovery with RYONCIL.****

**Important Safety Information** (continued)

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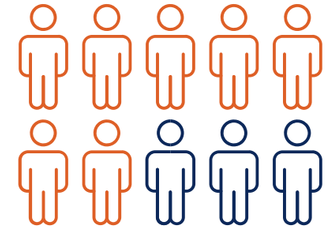
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## Results from the RYONCIL clinical study

In a study, **70% of children with steroid-refractory acute GvHD treated with RYONCIL improved within 4 weeks.*** Even very sick children had good results.

In the same study, **about 3 out of 10 children** saw *all* signs of steroid-refractory acute GvHD fully go away. **About 4 out of 10 children** showed improvement with signs of recovery.



**70% improved within 4 weeks**

**RYONCIL has helped children of many ages and stages of steroid-refractory acute GvHD**

Even some of the sickest children improved. This includes children with symptoms of the stomach, intestines, liver, and/or skin.




**These results offer hope that progress is possible for children and families facing steroid-refractory acute GvHD.**

*Results may vary.

*"We treated children who really had no other options, and the majority responded and improved on RYONCIL."*

— Dr Joanne Kurtzberg, Pediatric acute GvHD expert



**Important Safety Information** (continued)

**What are the possible serious side effects?** (continued)

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**What are the most common side effects?**

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**What should I tell my doctor before receiving Ryoncil?**

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# Specifically studied for use in children

## RYONCIL is safe and effective for children 2 months of age and older

RYONCIL was studied with safety in mind. Today, it's the **first and only FDA-approved steroid-refractory acute GvHD treatment for children 2 months of age and older. It's the only approved option for children under 12 years of age.**



Actor portrayal.

## Most common side effects

As with many IV treatments, side effects happen. The most common side effects of RYONCIL were mild to moderate in nature, including viral or bacterial infectious disorders, infections, fever, bleeding, swelling, stomach pain, and high blood pressure.

Your child's care team will watch for allergic reactions, including fever, trouble breathing, and blood pressure changes. Certain medicines are given before each infusion to help prevent allergic reactions.

RYONCIL is administered by healthcare professionals in a medical setting. Your child's care team can help monitor and manage side effects.




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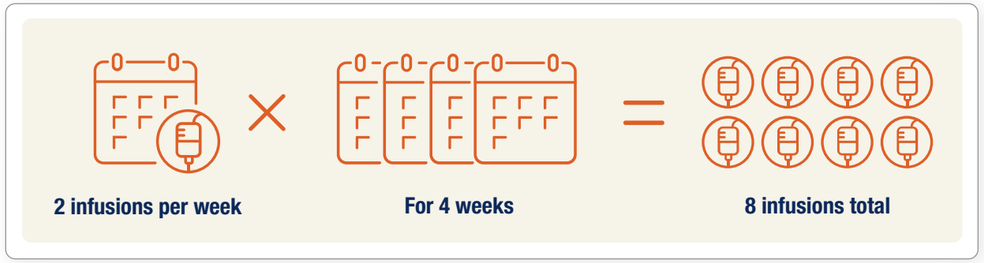
# Predictable, patient-friendly dosing

## RYONCIL is the first and only twice-weekly cell therapy for children with steroid-refractory acute GvHD

For families facing steroid-refractory acute GvHD, knowing what comes next can help. RYONCIL is a proven cell therapy with a clear treatment schedule. RYONCIL treatment is given through an IV. This usually happens twice a week for 4 weeks. That's 8 infusions, total. It's not a pill. No donor matching is required.

The care team will prescribe the dose of RYONCIL that's right for your child. This will be guided by his or her weight. Each infusion will be spaced at least 3 days apart.

Each infusion takes about an hour. Your care team can help create a treatment plan for a weekly routine that works with your family's schedule.






## Inpatient or outpatient treatment is available

Where your child gets RYONCIL depends on their needs. It may take place at your child's transplant center, a hospital, or an outpatient clinic. Your care team will work with you to choose what's right for your family.

**Important Safety Information** (continued)

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**What should I tell my doctor before receiving Ryoncil?**
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## Keeping comfort and safety in mind

Your child will be watched during treatment. About 30 minutes to an hour before each infusion, your child will get medicines to help lower the chance of an allergic reaction.

After each infusion, the care team will watch for fever, chills, or other signs of a reaction. Then your child should be free to return to his or her regular routine.

## Deciding what comes next

After about 28 days, your child's care team will decide whether more doses are needed.

**If all signs and symptoms have gone away:** no more infusions are needed.

**If steroid-refractory acute GvHD comes back after fully going away:** the full RYONCIL routine may be repeated. That would be 2 infusions per week for 4 more weeks.

**If some signs got better, while others stayed the same:** 1 more infusion per week may be given for another 4 weeks. This would be 4 more infusions.

**If there is no response, talk with your child's care team about other options.**



**Know what to expect before, during, and after treatment**
Talk with your child's care team about what to expect during treatment with RYONCIL. **Scan the QR code or click here to download the discussion guide.**

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# Empower the journey ahead



Actor portrayal.



Actor portrayal.

## Helping you move forward after steroid-refractory acute GvHD

Caring for a child with steroid-refractory acute GvHD can sometimes feel like a lot. You are not on this journey alone. This section points you toward resources that can help you stay informed, organized, and supported along the way.

## Getting the care they need should never feel out of reach

RYONCIL is covered nationwide by most private and government insurance plans. This includes Medicaid in all 50 states, plus Puerto Rico and Washington, DC.

**Talk to your child's care team to learn more.**

**Important Safety Information** (continued)

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mymesoblast™

## Get support at every step

**MyMesoblast™** is a savings and support hub. MyMesoblast team members will work with your child's care team to handle insurance and benefits questions. This way, treatment can start as soon as possible.

If you have questions about cost, MyMesoblast can help. If your child has no insurance or not enough coverage, they will work with your care team to find options. This may include a Patient Assistance Program.* There are also groups that may be able to help with copays.

**Scan the QR code or click here to learn more about your support options.**

*Eligibility rules apply.

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## Find more tools and resources

Scan here to visit ryoncil.com and get helpful tools to support your child's journey with steroid-refractory acute GvHD.

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**What are the possible serious side effects?** (continued)

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# Discover a possible path forward



Actor portrayal.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

**For additional information, see full Prescribing Information.**

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