

MEDICATION GUIDE
LISRAYA™ [liss-rye-uh]
(brepocitinib) tablets
for oral use

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

LISRAYA can cause serious side effects, including:

1. Serious Infections.

LISRAYA is a medicine that affects your immune system. LISRAYA can lower the ability of your immune system to fight infections. Some people have had serious infections while taking LISRAYA, including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that can spread throughout your body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting treatment with LISRAYA.
- Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with LISRAYA.
- You should not start taking LISRAYA if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster).
- Before starting LISRAYA, tell your healthcare provider if you:
 - are being treated for an infection.
 - have had an infection that does not go away or have infections that keep coming back.
 - have diabetes, chronic lung disease, HIV, or a weak immune system. People with these conditions have a higher chance of infections.
 - have TB or have been in close contact with someone with TB.
 - live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or become more severe if you take LISRAYA. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
 - have had shingles (herpes zoster)
 - have or have had hepatitis B or C.
 - think you have an infection or have symptoms of an infection such as:

• fever, sweating, or chills	• muscle aches	• cough
• shortness of breath	• feeling tired	• weight loss
• warm, red, or painful skin or sores on your body	• blood in your phlegm	• burning when you urinate or urinating more often than usual
	• diarrhea or stomach pain	

After starting LISRAYA, call your healthcare provider right away if you have any symptoms of an infection. LISRAYA can make you more likely to get infections or make any infections that you have worse. If you get a serious infection, your healthcare provider may stop your treatment with LISRAYA until your infection is controlled.

2. Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors. LISRAYA is a JAK inhibitor medicine.

3. Cancer and immune system problems.

LISRAYA may increase your risk of certain cancers by changing the way your immune system works. Lymphoma and other cancers, including skin cancers, can happen in people taking LISRAYA. People taking a medicine in the class of medicines called JAK inhibitors have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker.

Tell your healthcare provider if you have ever had any type of cancer. Follow your healthcare provider's advice about having your skin checked for skin cancer during treatment with LISRAYA. Limit the amount of time you spend in sunlight. Avoid using tanning beds or sunlamps. Wear protective clothing when you are in the sun and use a sunscreen with a high protection factor (SPF 30 and above). This is especially important if your skin is very fair or if you have a family history of skin cancer.

4. Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and taking a medicine in the class of medicines called JAK inhibitors, especially if you are a current or past smoker.

Get emergency help right away if you have any symptoms of a heart attack or stroke while taking LISRAYA, including:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech

5. Blood clots.

Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) and arteries (arterial thrombosis) can happen in some people taking LISRAYA. This may be life-threatening and cause death. Blood clots in the veins of the legs (DVT) and lungs (PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines called JAK inhibitors.

- Tell your healthcare provider if you have had blood clots in the veins of your legs or your lungs in the past
- Get medical help right away if you have signs or symptoms of blood clots during treatment with LISRAYA including:
 - Swelling, pain, warmth, or tenderness in one or both of your legs or arms
 - Shortness of breath or difficulty breathing
 - Sudden unexplained chest or upper back pain
 - Fast or irregular heartbeat
 - Coughing up blood
 - Dizziness, lightheadedness, or fainting

6. Allergic Reactions.

Symptoms such as rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat, that may mean you are having an allergic reaction have been seen in people

taking LISRAYA. Some of these reactions were serious. If any of these symptoms occur during treatment with LISRAYA, stop taking LISRAYA and get emergency medical help right away.

7. Tears (perforation) in the stomach or intestines.

Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking LISRAYA can get tears in their stomach or intestines. This happens most often in people who take nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids. Get medical help right away if you get stomach-area pain, fever, chills, nausea, or vomiting.

8. Low blood sugar (hypoglycemia) in people with diabetes.

If you have diabetes, your healthcare provider may tell you to check your blood sugar (glucose) more often during treatment with LISRAYA. Call your healthcare provider if you have any problems with low blood sugar.

9. Changes in certain laboratory test results.

Your healthcare provider should do blood tests before you start taking LISRAYA and while you take LISRAYA to check for the following:

- **low neutrophil and lymphocyte counts.** Neutrophils and lymphocytes are types of white blood cells that help the body fight off infections.
- **low red blood cell counts.** Red blood cells carry oxygen. Low red blood cells means you may have anemia, which may make you feel weak and tired.
- **increased cholesterol levels.** Your healthcare provider should do blood tests to check your cholesterol levels approximately 12 weeks after you start taking LISRAYA, and as needed.
- **elevated liver enzymes.** Liver enzymes help to tell if your liver is functioning normally. Elevated liver enzymes may indicate that your healthcare provider needs to do additional tests on your liver.

You should not take LISRAYA if your neutrophil count, lymphocyte count, or red blood cell count is too low or your liver tests are too high. Your healthcare provider may stop your LISRAYA treatment for a period of time if needed because of changes in these blood test results.

See “**What are the possible side effects of LISRAYA?**” for more information about side effects.

What is LISRAYA?

LISRAYA is a prescription medicine that works by blocking certain proteins (Janus kinase [JAK] and tyrosine kinase 2 [TYK2]) in the body. It is used to treat an inflammatory disease that affects the muscles and skin (dermatomyositis) in adults. **Do not** take LISRAYA together with other medicines called JAK inhibitors.

It is not known if LISRAYA is safe and effective in children with juvenile dermatomyositis.

Who should not take LISRAYA?

Do not take LISRAYA if you are allergic to brepocitinib or any of the ingredients in LISRAYA. See the end of this Medication Guide for a complete list of ingredients in LISRAYA.

Before taking LISRAYA, tell your healthcare provider about all of your medical conditions, including if you:

- See “**What is the most important information I should know about LISRAYA?**”
- have an infection.

- are a current or past smoker.
- have had any type of cancer.
- have had a heart attack or other heart problems, or stroke.
- have liver or kidney problems.
- have unexplained stomach (abdominal) pain, have a history of diverticulitis or ulcers in your stomach or intestines, or are taking NSAIDs.
- have diabetes.
- have low red or white blood cell counts.
- have recently received or are scheduled to receive an immunization (vaccine). People taking LISRAYA should not receive live vaccines.
- are pregnant or plan to become pregnant. LISRAYA may harm your unborn baby.
- are breastfeeding or plan to breastfeed. LISRAYA may pass into your breast milk. **Do not** breastfeed during treatment with LISRAYA and for 3 days after your last dose of LISRAYA.

Females who are able to become pregnant:

- Your healthcare provider will check whether or not you are pregnant before you start treatment with LISRAYA.
- You should use effective birth control (contraception) to avoid becoming pregnant during treatment with LISRAYA and for 3 days after your last dose of LISRAYA.
- Tell your healthcare provider if you think you are pregnant or become pregnant during treatment with LISRAYA.
 - **Pregnancy Safety Study.** There is a pregnancy safety study for women who become pregnant during treatment with LISRAYA. The purpose of this pregnancy safety study is to collect information about your health and your baby's health. You or your healthcare provider should report your pregnancy by calling 1-800-511-9141 or emailing contactcenter@priosant.com.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LISRAYA and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take medicines that affect your immune system as these medicines may increase your risk of infection. Ask your healthcare provider or pharmacist if you are not sure if you are taking any of these medicines.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take LISRAYA?

- Take LISRAYA exactly as your healthcare provider tells you to use it.
- Take LISRAYA 1 time a day with or without food.
- If you take too much LISRAYA, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of LISRAYA?

LISRAYA may cause serious side effects including:

- See **"What is the most important information I should know about LISRAYA?"**

The most common side effects of LISRAYA in people treated with dermatomyositis include:

- common cold, sinus infections, or sore throat (upper respiratory tract infections)
- headache
- tired or lack of energy (fatigue)
- urinary tract infection
- nausea
- bronchitis
- joint pain (arthralgia)
- diarrhea
- back pain
- fall
- flu (influenza)
- acne

These are not all the possible side effects of LISRAYA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LISRAYA?

Store LISRAYA tablets below 86°F (30°C).

Keep LISRAYA and all medicines out of the reach of children.

General information about the safe and effective use of LISRAYA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LISRAYA for a condition for which it was not prescribed. Do not give LISRAYA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LISRAYA that is written for health professionals.

What are the ingredients in LISRAYA 30 mg tablets?

Active ingredients: brepocitinib tosylate

Inactive ingredients: hydroxypropyl methylcellulose, iron oxide red, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide and triacetin.

Manufactured for:
Privant Therapeutics, Inc.
Durham, NC 27703
LISRAYA is a trademark of Privant Therapeutics, Inc.
For more information, call 1-800-511-9141 or go to www.LISRAYA.com