

PATIENT INFORMATION
PHYRAGO™ (FYE-rah-go)
(dasatinib)
tablets

What is PHYRAGO?

PHYRAGO is a prescription medicine used to treat:

- adults with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- adults with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib.
- adults with Ph+ acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment.

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

- have problems with your immune system
- have heart problems, including a condition called congenital long QT syndrome
- have low potassium or low magnesium levels in your blood
- liver problems
- are pregnant or plan to become pregnant. PHYRAGO can harm your unborn baby.

Females who can become pregnant:

- You should not become pregnant during treatment with PHYRAGO.
- You should use effective birth control (contraception) during treatment and for 30 days after your last dose of PHYRAGO.
- Talk to your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with PHYRAGO.

Males with female partners who can become pregnant:

- You should use effective birth control (contraception) during treatment and for 30 days after your last dose of PHYRAGO.
- Your female partner should call her healthcare provider if she becomes pregnant or thinks she is pregnant during your treatment with PHYRAGO.
- are breastfeeding or plan to breastfeed. It is not known if PHYRAGO passes into your breast milk. You should not breastfeed during treatment and for 2 weeks after your last dose of PHYRAGO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, antacids, and herbal supplements. If you take an antacid medicine, take it 2 hours before or 2 hours after your dose of PHYRAGO.

How should I take PHYRAGO?

- Take PHYRAGO exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose of PHYRAGO or temporarily stop treatment with PHYRAGO. **Do not change your dose or stop taking PHYRAGO without first talking to your healthcare provider.**
- Take PHYRAGO 1 time a day.
- Take PHYRAGO with or without food, either in the morning or in the evening.
- Swallow PHYRAGO whole. Do not crush, cut or chew the tablets.
- You should not drink grapefruit juice during treatment with PHYRAGO.
- If you miss a dose of PHYRAGO, take your next scheduled dose at your regular time. Do not take two doses at the same time.
- If you take too much PHYRAGO, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of PHYRAGO?

PHYRAGO may cause serious side effects, including:

- **Low blood cell counts.** Low blood cell counts are common with dasatinib and can be severe, including low red blood cell counts (anemia), low white blood cell counts (neutropenia), and low platelet counts (thrombocytopenia). Your healthcare provider will do blood tests to check your blood cell counts regularly during your treatment with PHYRAGO. Call your healthcare provider right away if you have a fever or any signs of an infection during treatment with PHYRAGO.

- **Bleeding problems.** Bleeding problems are common with PHYRAGO. Sometimes these bleeding problems can be serious and lead to death. Call your healthcare provider right away if you have:
 - unusual bleeding or bruising of your skin
 - bright red or dark tar-like stools
 - decreased alertness, headache, or change in speech
- **Your body may hold too much fluid (fluid retention).** Fluid retention is common with PHYRAGO and can sometimes be severe. In severe cases, fluid may build up in the lining of your lungs, the sac around your heart, or your stomach cavity. Call your healthcare provider right away if you get any of these symptoms during treatment with PHYRAGO:
 - swelling all over your body
 - weight gain
 - shortness of breath, especially if this happens with low levels of physical activity or at rest
 - dry cough
 - chest pain when taking a deep breath
- **Heart and blood vessel (cardiovascular) problems.** PHYRAGO may cause heart problems, including an abnormal heart rate, a heart attack, or small strokes that last only a few minutes or a few hours, called transient ischemic attacks (TIAs). TIAs are often a warning sign that you are at risk for a more serious stroke. Your healthcare provider will monitor the potassium and magnesium levels in your blood and your heart function. Get medical help right away if you develop any of the following symptoms during treatment with PHYRAGO:
 - chest pain
 - shortness of breath
 - feeling like your heart is beating too fast or you feel abnormal heart beats
 - vision changes that may last for a short time
 - slurred speech
- **Pulmonary Arterial Hypertension (PAH).** PHYRAGO may cause high blood pressure in the vessels of your lungs. PAH may happen at any time during your treatment with PHYRAGO. Your healthcare provider should check your heart and lungs before and during treatment with PHYRAGO. Call your healthcare provider right away if you have shortness of breath, tiredness, or swelling all over your body (fluid retention).
- **Severe skin reactions.** PHYRAGO may cause skin reactions that can sometimes be severe. Get medical help right away if you get a skin reaction with fever, sore mouth or throat, or blistering or peeling of your skin or in the mouth.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure and the need for dialysis treatment, and an abnormal heartbeat. Your healthcare provider may do blood tests to check you for TLS. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with PHYRAGO:

<ul style="list-style-type: none"> ○ nausea ○ vomiting ○ weakness ○ swelling 	<ul style="list-style-type: none"> ○ shortness of breath ○ muscle cramps ○ seizures
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- **Slowing of growth and development in children.** Effects on bone growth and development in children have happened with dasatinib and can sometimes be severe. Your healthcare provider will monitor your child's bone growth and development during treatment with dasatinib. Get medical help right away if your child develops bone pain.
- **Liver problems.** PHYRAGO can cause liver problems. People who have had liver problems in the past may be at risk for getting liver problems with PHYRAGO. Your healthcare provider will monitor your liver function as needed during treatment with PHYRAGO. Call your healthcare provider or get medical help right away if you develop any symptoms of liver problems, including:

<ul style="list-style-type: none"> ○ stomach-area (abdominal) pain ○ yellowing of your skin or white part of your eyes ○ loss of appetite 	<ul style="list-style-type: none"> ○ bleeding ○ bruising ○ dark "tea-colored" urine
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The most common side effects in adults receiving dasatinib alone include:

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| <ul style="list-style-type: none"> ● diarrhea ● headache ● skin rash | <ul style="list-style-type: none"> ● tiredness ● nausea ● muscle pain |
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- shortness of breath

PHYRAGO may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of PHYRAGO.

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 PHYRAGO?

- Store PHYRAGO at room temperature between 68°F to 77°F (20°C to 25°C).
- PHYRAGO comes in a bottle with a child-resistant closure.
- PHYRAGO bottles contain a desiccant container (drying agent) to help keep the medicine dry. Keep the desiccant container in the PHYRAGO bottle after opening. **Do not** swallow or eat the desiccant container.
- Ask your healthcare provider or pharmacist about the right way to throw away expired or unused PHYRAGO.
- Wear latex or nitrile gloves when handling PHYRAGO tablets.
- Females who are pregnant should not handle PHYRAGO.

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

General information about the safe and effective use of PHYRAGO.

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

What are the ingredients in PHYRAGO?

Active ingredient: dasatinib (anhydrous)

Inactive ingredients: croscarmellose sodium, dibasic calcium phosphate, magnesium stearate, methacrylic acid-ethyl acrylate copolymer, microcrystalline cellulose, propyl gallate, and silica dimethyl silylate.

Pediatric use information is approved for Bristol-Myers Squibb Company's SPRYCEL (dasatinib) tablets. However, due to Bristol-Myers Squibb Company's marketing exclusivity rights, this drug product is not labeled with that pediatric information.

Manufactured for: Nanocopoeia, LLC, 639 Campus Dr, New Brighton, MN 55112

For more information, go to www.PHYRAGO.com or call 1-844-784-1807

This Patient Information has been approved by the U.S. Food and Drug Administration.

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