

Patient Information
Marqibo® (mar-KEY-bo)
(vinCRISTine sulfate LIPOSOME injection)

Read this Patient Information before you begin receiving Marqibo® and before each Marqibo infusion. There may be new information. This information does not take the place of you talking with your doctor about your medical condition or treatment.

What is Marqibo

Marqibo is a prescription medicine used to treat adults with Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL) when:

- their leukemia has come back (relapsed) after 2 or more anti-leukemia therapies, **or**
- their leukemia became worse (progressed) after two or more anti-leukemia therapies.

It is not known if Marqibo is safe and effective in children or in elderly adults.

Do not receive Marqibo:

- if you have certain conditions of the brain or spinal cord, including Charcot-Marie-Tooth syndrome. Talk to your doctor before receiving Marqibo if you have a condition that affects your brain or spinal cord.
- if you are allergic to vincristine sulfate or any of the ingredients in Marqibo. See end of this leaflet for a list of the ingredients in Marqibo.
- as an injection into your spine (intrathecal). Marqibo causes death if given by any route other than by intravenous (IV) infusion.

What should I tell my doctor before receiving Marqibo?

Before receiving Marqibo, tell your doctor if you:

- have had treatment containing vincristine sulfate in the past
- currently have numbness or tingling in your feet or hands or decreased sensitivity to heat, cold, or pain
- have difficulty walking or picking up and holding items with your hands
- have a change in bowel regularity or constipation, and difficulty passing urine
- have head or jaw pain
- have liver problems
- are pregnant or plan to become pregnant. Marqibo can harm your unborn baby. You should not become pregnant while taking Marqibo. Use an effective method of birth control during treatment with Marqibo. Tell your doctor right away if you become pregnant while taking Marqibo.

- are breastfeeding or plan to breastfeed. It is not known if Marqibo passes into your milk. You and your doctor should decide whether you will take Marqibo or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Marqibo may affect the way other medicines work, and other medicines may affect how Marqibo works.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How will I receive Marqibo?

- You will receive Marqibo as an intravenous (IV) infusion in your vein over 1 hour. Marqibo is usually given every 7 days.
- Your doctor may change your dose, give you Marqibo less often, or stop your treatment with Marqibo if you have certain side effects.
- Your doctor should do blood tests regularly to check for side effects of Marqibo.

What should I avoid while receiving Marqibo?

- Marqibo can cause tiredness (fatigue) and nerve problems (neuropathy). You should not drive or operate machinery if you develop any of these symptoms. See "What are the possible side effects of Marqibo?"

What are the possible side effects of Marqibo?

Marqibo can cause serious side effects, including:

- **Tissue injury.** If Marqibo leaks from your vein into the tissues around your intravenous (IV) line, it can cause damage to those tissues. **Tell your doctor or nurse right away if you develop burning, redness or swelling at your IV site during or after your infusion.**
- **Nerve problems (neuropathy).** Nerve problems are common with Marqibo and may get worse over time. Your doctor may need to change your dose, or delay or stop your treatment with Marqibo if you develop nerve problems. Symptoms may include:
 - numbness and tingling, or burning in your feet or hands
 - increased or decreased feeling of sensation to pain, touch, heat, or cold in your feet or hands
 - joint and muscle pain
 - pain in your jaw or head
 - muscle spasms
 - weakness in the hands or feet

- dizziness or feel faint when you go from lying down to sitting, or from sitting to standing.
 - trouble picking up or holding items with your hands
 - slapping or dropping of the front part of your foot when walking forward (footdrop)
 - unsteadiness when standing or walking
 - difficulty speaking
 - constipation or a change from the normal regularity of your bowel movements
 - difficulty passing urine
 - difficulty with erection or ejaculation in men
- **Low blood cell counts.** Marqibo may cause you to have low red blood cells (anemia), low white blood cells (neutropenia), and low platelets (thrombocytopenia). Your doctor should do blood tests to check your blood cell counts before each dose of Marqibo. Your doctor may need to change your dose of Marqibo and treat your low blood cell counts if needed. Tell your doctor if you develop fever or cough up phlegm (productive cough).
 - **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
 - an abnormal heart beat

Your doctor will check you for TLS during treatment with Marqibo, and treat you for this problem if it happens.

- **Constipation and intestinal (bowel) blockage.** Your doctor will prescribe a bowel regimen for you to help prevent constipation or intestinal blockage. Symptoms may include:
 - stomach area (abdomen) pain, bloating or diarrhea
 - nausea or vomiting
- **Tiredness (fatigue).** Marqibo can cause severe tiredness or weariness. Your doctor may need to change your dose, or delay or stop your treatment if this happens.
- **Liver problems that can cause death.** Marqibo can cause changes in liver function tests or more serious liver problems that can cause death. Your doctor:
 - will monitor your liver function test during treatment with Marqibo.
 - may change your dose or stop your treatment with Marqibo if you develop liver problems.

Common side effects of Marqibo include:

- nausea
- fever
- diarrhea
- decreased appetite
- sleep problems

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effect of Marqibo. For more information, ask your doctor or pharmacist.

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

General information about Marqibo

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. This leaflet summarizes the most important information you need to know about Marqibo.

If you would like more information about Marqibo, talk with your doctor. You can ask your pharmacist or doctor for information about Marqibo that is written for health professionals. For more information, go to www.MarqiboRX.com or call 1-888-292-9617.

What are the ingredients in Marqibo?

Active ingredient: vincristine sulfate

Inactive ingredients: mannitol, sphingomyelin, cholesterol, sodium citrate, citric acid, sodium phosphate and sodium chloride.

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

Distributed by:

Talon Therapeutics, Inc.
South San Francisco, CA 94080

Issued August 2012