For patients with metastatic soft tissue or lone sarcoma and their caregivers... Extend the benefit of chemotherapy with maintenance therapy



TALTORVIC is indicated to treat metastatic soft tissue sarcoma or bone sarcoma as a maintenance therapy for patients who have completed at least 4 cycles of chemotherapy without evidence of disease progression.

Please read the enclosed Patient Information and discuss it with your doctor.

# How to use this brochure

This brochure has been written to help patients and caregivers understand more about metastatic soft tissue and bone sarcoma. This includes how it may be treated with maintenance therapy. The brochure will also tell you about a treatment for metastatic soft tissue and bone sarcoma called TALTORVIC. The generic name for TALTORVIC is ridaforolimus tablets. TALTORVIC is indicated to treat metastatic soft tissue sarcoma or bone sarcoma as a maintenance therapy for patients who have completed at least 4 cycles of chemotherapy without evidence of disease progression.

Space has been left on each page for you to add questions to discuss with your doctor. Also, words in purple are defined in a glossary at the end of the brochure.

A word about symbols...

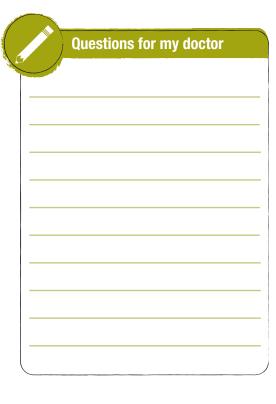


Where you see the pencil symbol, you will find space to write questions for your doctor



Where you see the "i" symbol, you will see sidebars, which provide additional information on a particular topic

Please read the enclosed Patient Information and discuss it with your doctor.



# Sarcoma is a rare type of cancer

Cancer occurs when abnormal cells in your body begin to grow out of control. Cancer cells may invade other tissues. Sarcoma is a rare type of cancer that grows in body tissue and bones that connect and support other parts of your body.

#### Where do sarcomas originate?

Soft tissue sarcomas can develop from fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. They are most commonly found in the arms or legs. They can also be found in and around your organs and other areas of your body. Signs and symptoms can include a lump, abdominal pain, blood in your stool or vomit, and black, tarry stools.

Bone sarcomas develop in the tissues of your bone marrow. Signs and symptoms can include localized pain and swelling.

#### What is metastatic sarcoma?

Often, sarcoma symptoms do not appear until the sarcoma has spread to other places in your body. At this point it is known as metastatic sarcoma.

#### Sarcoma by the numbers

Sarcoma accounts for only 1% of cancers in adults. Sarcoma occurs more commonly in teens and young adults than most other types of cancer.

Approximately 10,980 Americans were diagnosed with soft tissue sarcomas in 2011.

Approximately 2,810 Americans were diagnosed with bone sarcomas in 2011.

Soft tissue sarcomas account for approximately 80% of cases.

Bone and joint sarcomas account for approximately 20% of cases.



# **Treating metastatic sarcoma**

If your sarcoma is metastatic, you may be treated with surgery, radiation and/ or chemotherapy:

- The goal of surgery is to remove as much as the primary tumor as possible as well as pain management.
- The goal of radiation is to use strong beams of energy to kill cancer cells and keep them from growing back.
- The goal of chemotherapy is to kill rapidly dividing cancer cells. Chemotherapy is given through a needle or as a pill. Your doctor may treat you until you achieve what is known as a clinical benefit response, which can be a complete response, partial response, or stable disease.

#### Chemotherapy: Describing your response

Complete response means your cancer has completely disappeared. This is also known as a "complete remission."

Partial response means the size of your cancer has shrunk. This is also known as a "partial remission."

Stable disease means your cancer has not changed much. (Either it has stopped growing, or it has only become a little bit smaller or larger in size.)

#### What happens after a clinical benefit response?

If you have responded well to chemotherapy, your doctor may do one of the following:

- Stop giving you chemotherapy and prescribe maintenance therapy to try to keep the sarcoma from growing or spreading.
- Stop giving you chemotherapy (or any other active treatment), and watch closely for symptoms or growth of the sarcoma. This is sometimes called "active observation."
- Continue to give you chemotherapy. This may continue to slow the growth of the sarcoma.

#### What is maintenance therapy?

Maintenance therapy is a type of treatment given to some patients whose cancer has responded well to chemotherapy. Maintenance therapy with a prescription medicine may make it possible to delay the return of your cancer.





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# Maintenance therapy with TALTORVIC (ridaforolimus) tablets

TALTORVIC is indicated to treat metastatic soft tissue sarcoma or bone sarcoma as a maintenance therapy for patients who have completed at least 4 cycles of chemotherapy without evidence of disease progression.

TALTORVIC is different from other medicines you may have been given in the past to treat your sarcoma. It is an oral mTOR inhibitor. TALTORVIC is for patients with metastatic soft tissue or bone sarcoma who have responded well to chemotherapy. It is a maintenance therapy that may help slow the growth of metastatic soft tissue and bone sarcoma for a longer period of time. Maintenance therapy with TALTORVIC may help some people with metastatic soft tissue or bone sarcoma who want to do more by trying to control their cancer and prevent it from growing and spreading.

#### What happened when TALTORVIC was studied in a clinical trial?

In a large clinical trial of 711 patients, TALTORVIC significantly extended progression-free survival (PFS) in people with metastatic sarcoma compared with placebo (a sugar pill). PFS refers to the length of time during and after medication or treatment during which your cancer does not get worse. Compared with people who took placebo, more people who took TALTORVIC did not have their metastatic sarcoma grow after 3 months and 6 months.

#### What were the side effects?

TALTORVIC is one of a group of medicines that have been used before in people with other kinds of cancer. Many doctors have experience with this type of medicine. They know what kinds of side effects to expect and how to treat them. For example, TALTORVIC can cause mouth ulcers and sores. If you feel any pain or sores in your mouth when taking TALTORVIC, do not skip your dose. Call your doctor right away.

Your doctor may tell you to use a special mouthwash or mouth gel that does not contain alcohol or peroxide.

Some other side effects of TALTORVIC include:

- Cough and shortness of breath.
- Increased risk of infections.
- Nausea, vomiting, decreased appetite, and diarrhea.
- Feeling tired.
- Increase in blood sugar (if you have diabetes, tell your doctor right away if your blood sugar is higher than normal).
- Bleeding or bruising more easily than normal.
- Increase in blood lipids such as cholesterol and triglycerides (your doctor may prescribe standard lipid medications if necessary).
- Rash, dry skin, and itching.
- Laboratory abnormalities, including low red blood cells and low platelets.

Tell your doctor if you have any side effect that bothers you or that does not go away while taking TALTORVIC. These are not all the possible side effects of TALTORVIC. For more information, ask your doctor or pharmacist.

TALTORVIC has not been studied in children under the age of 13 years. There is very limited information in patients 13 through 17 years of age who have taken TALTORVIC. **Please read the enclosed Patient Information and discuss it with your doctor.** 

# Questions for my doctor ridaforolimus tablets



# How do I take TALTORVIC (ridaforolimus) tablets?

TALTORVIC pills can be taken at home. Your doctor will tell you how many TALTORVIC pills to take and when to take them. Take the pills every day, for 5 days in a row, every week. Then skip two days. You should take the pills at or around the same time every day. You should swallow TALTORVIC pills whole with water. You can take TALTORVIC with or without food. The pills should not be chewed, crushed, or broken. You should never touch broken pill pieces with your bare hands.

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
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Questions for my doctor

#### Where do I get TALTORVIC?

TALTORVIC is only available through select specialty pharmacies. Specialty pharmacies offer certain services to people with cancer. Your doctor will contact the specialty pharmacy to order your prescription for TALTORVIC. The specialty pharmacy will deliver TALTORVIC to your home, doctor's office, or any place that you choose. The specialty pharmacy will call you when it is time to refill your prescription. The specialty pharmacy can also answer any questions you may have about TALTORVIC.

# Specialty pharmacies explained

- Specialty pharmacies provide specialty medications retail pharmacies do not carry to meet specific patient needs.
- They work with doctors and caregivers to make sure you understand how to take your medication.
- Specialty pharmacists monitor your health and specialty drug needs.

TALTORVIC has not been studied in children under the age of 13 years. There is very limited information in patients 13 through 17 years of age who have taken TALTORVIC.

Please read the enclosed Patient Information and discuss it with your doctor.



# Glossary

Active observation: Describes the time during which treatment for your cancer may be stopped and you are closely watched for any signs or symptoms that your cancer has returned.

Blood lipids: Fats in the blood. Cholesterol and triglycerides are two blood lipids.

Bone sarcoma: Sarcomas that develop in the bone itself (primary bone tumors). Two common types of bone sarcomas are osteosarcoma and chondrosarcoma.

*Chemotherapy:* Agents that act by killing cells that divide rapidly. This is one of the main properties of most cancer cells.

*Cholesterol:* A blood lipid (fat). Cholesterol is important and necessary for human health. But, high levels of cholesterol in the blood have been linked to damage to arteries and cardiovascular disease.

*Clinical benefit response*: A response to chemotherapy in which a patient is completely responsive (complete remission of disease). partially responsive (partial remission of disease), or exhibits stable disease.

Complete remission: See "complete response."

*Complete response:* A response to chemotherapy in which your disease has completely disappeared.

*Maintenance therapy*: The use of medical treatment to help lower the risk of your cancer coming back after it was first treated. This type of therapy is given after a disease has responded to previous treatment.

*Metastatic sarcoma:* Sarcoma that has spread from its original site to other areas of the body.

*Mouth ulcers:* An open sore in your mouth. This is a common side effect of mTOR inhibitor therapy.

*mTOR inhibitor*: A drug that inhibits the functions of mTOR, a protein responsible for cancer cell growth. Partial remission: See "partial response."

*Partial response:* A response to chemotherapy in which a patient's disease has partially disappeared.

*Placebo:* A substance that has no medical benefit, used as a control in testing new drugs. Also known as a "sugar pill."

*Platelets:* A type of blood cell that help wounds heal and prevents bleeding by forming blood clots.

Progression-free survival: Also known as PFS. This is the length of time during and after medication or treatment during which your cancer does not get worse.

*Radiation:* Radiation therapy treats cancer by using high energy to kill tumor cells. The goal is to kill or damage cancer cells without hurting healthy cells.

Red blood cells: The body's most common type of blood cell. Red blood cells carry oxygen to all parts of your body.

*Retail pharmacies:* An independent or chain pharmacy at which prescriptions are provided to patients and caregivers.

*Sarcoma:* A rare type of cancer that grows in bone, cartilage, fat, muscle, blood vessels, and other supportive/connective tissues.

Soft tissue sarcoma: Sarcomas that develop from soft tissues like fat, muscle, nerves, fibrous tissues, blood vessels, or deep skin tissues. There are about 50 different types of soft tissue sarcomas.

Specialty pharmacies: Pharmacies that provide specialty medications by mail order (to meet specific patient needs) that retail pharmacies do not carry.

Stable disease: A response to chemotherapy in which a patient's disease has stopped growing, or has only become a little bit smaller or larger in size.

*Surgery:* The surgical removal of the primary tumor and some of the healthy surrounding tissue.

*Triglycerides:* A blood lipid (fat) in which unused calories are stored.

*Tumor:* An abnormal growth of tissue that occurs when cells divide and grow uncontrollably. Tumors may be benign (not cancerous) or malignant (cancerous).



#### Important Safety Information

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# For patients with metastatic soft tissue or lone sarcoma and their caregivers... Extend the benefit of chemotherapy with maintenance therapy

- TALTORVIC (ridaforolimus) tablets is a prescription medicine for people with metastatic soft tissue or bone sarcoma who have responded well to chemotherapy.
- Maintenance therapy with TALTORVIC may help slow the growth of metastatic soft tissue and bone sarcoma.
- In a large clinical trial, TALTORVIC significantly extended progression-free survival (PFS) and also demonstrated superior control of tumor growth.
- TALTORVIC is only available through specialty pharmacies.
- Merck offers programs for patients who have been prescribed certain Merck medicines and may not be able to afford them. To learn more, please call 888-9TALTOR (888-982-5867).
- For more information about TALTORVIC, please visit www.taltorvic.com.

Ask your doctor about maintenance therapy with TALTORVIC

Merck medicines distributed through the Patient Assistance Program are free-of-charge to all eligible patients. Merck and Merck PAP\* are not associated with any individuals or organizations that may charge patients a fee for helping them complete forms for the program. These individuals or organizations are acting independently of Merck and Merck PAP, have no affiliation with Merck or Merck PAP, and do not have the consent of Merk or Merck PAP. Although Merck PAP makes every effort to grant assistance, Merck PAP cannot guarantee patient assistance. Merck PAP reserves the right to change or discontinue the program at any time.

\*Merck Patient Assistance Program, Inc.



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