

YOUR TREATMENT GUIDE

BALVERSA™ is a prescription medicine used to treat adults with bladder cancer (urothelial cancer) that has spread or cannot be removed by surgery:

- which has a certain type of abnormal fibroblast growth factor receptor (FGFR) gene, **and**
- who have tried at least one other chemotherapy medicine that contains platinum, and it did not work or is no longer working

Your healthcare provider will test your cancer for certain types of abnormal FGFR genes and make sure that BALVERSA™ is right for you.

It is not known if BALVERSA™ is safe and effective in children.

BALVERSA™ is approved based on tumor response. Data are not yet available to show if BALVERSA™ improves survival or symptoms.



IMPORTANT SAFETY INFORMATION

BALVERSA™ may cause serious side effects, including eye problems and high phosphate levels in the blood (hyperphosphatemia). BALVERSA™ can harm your unborn baby. You should not become pregnant during treatment with BALVERSA™.

Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.

What is bladder cancer (urothelial cancer)?

In bladder cancer (urothelial cancer), cells grow abnormally in the urinary bladder to form a tumor. Most bladder cancers start in the inner lining of the bladder, which is called the urothelium. If the tumor spreads outside the bladder, it's considered advanced bladder cancer.

“I want to learn more about bladder cancer and the role of FGFR”

What does it mean to have an abnormal FGFR gene?

FGFR stands for fibroblast growth factor receptor. FGFR helps cells grow, survive, and multiply. In certain types of cancer, like in some cases of bladder cancer, the gene that controls FGFR can change or mutate (known as an FGFR alteration). The FGFR alteration may cause cancer cells to develop, leading to rapid growth and spread.

NOTE: A glossary defining many medical terms used in this booklet appears on pages 18-19.

How many people with advanced bladder cancer have tumors with an abnormal FGFR gene?



APPROXIMATELY
20%*

of all people with advanced bladder cancer can have tumors with an abnormal FGFR gene

"How do I find out if my tumor has an abnormal FGFR gene?"

A doctor will send a tissue sample of the tumor to a lab for analysis.

*Based on data derived from tumors of patients with muscle-invasive bladder cancer (MIBC).

Learn about BALVERSA™ (erdafitinib)

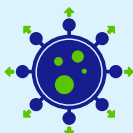
BALVERSA™ is an oral prescription medicine used to treat adults who:



Have bladder cancer (urothelial cancer) that has spread or cannot be removed by surgery



Have a tumor that carries a certain type of abnormal FGFR gene



Have tried at least one other chemotherapy medicine that contains platinum, and it did not work or is no longer working

Your doctor will perform a test to check for certain types of abnormal FGFR genes, and make sure that BALVERSA™ is right for you.

IMPORTANT SAFETY INFORMATION

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IMPORTANT SAFETY INFORMATION

Before taking BALVERSA™ (erdafitinib), tell your healthcare provider about all of your medical conditions, including if you:

- have vision or eye problems.
- are pregnant or plan to become pregnant. BALVERSA™ can harm your unborn baby. You should not become pregnant during treatment with BALVERSA™.

Females who can become pregnant:

- Your healthcare provider may do a pregnancy test before you start treatment with BALVERSA™.
- You should use effective birth control during treatment and for 1 month after the last dose of BALVERSA™. Talk to your healthcare provider about birth control methods that may be right for you.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant.

Males with female partners who can become pregnant:

- You should use effective birth control when sexually active during treatment with BALVERSA™ and for 1 month after the last dose.
- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 1 month after the last dose of BALVERSA™.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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What is BALVERSA™ (erdafitinib)?

How does BALVERSA™ work?

BALVERSA™ is a drug that is called a kinase inhibitor. A kinase inhibitor is a substance that blocks a type of enzyme (a protein) called a kinase. Human cells have many different kinases, and they help control important functions.

BALVERSA™ works by inhibiting the activity of FGFR, which is present in the bladder cancer tumor cell as well as healthy cells throughout the body. Because BALVERSA™ targets the FGFR protein and can affect all cells with this receptor, it may cause serious side effects.

BALVERSA™ is the first medicine of its kind approved by the FDA to treat people with advanced bladder cancer where the tumor carries a certain abnormal FGFR gene.

FDA = U.S. Food and Drug Administration.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of BALVERSA™?

BALVERSA™ may cause serious side effects, including:

- **Eye problems.** Eye problems are common with BALVERSA™ but can also be serious. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye), and disorders of the retina, an internal part of the eye. Tell your healthcare provider right away if you develop blurred vision, loss of vision, or other visual changes.

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Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



Is BALVERSA™ (erdafitinib) right for you?

FGFR testing

Talk to your doctor about whether BALVERSA™ may be right for you.

In order for you to receive BALVERSA™, your doctor must first test your cancer for certain types of abnormal FGFR genes.

To do this, your doctor will send a tissue sample from your tumor to a lab for analysis. This can be done with tissue from a new biopsy or with tissue that was already removed, so you may not need an additional procedure.

IMPORTANT SAFETY INFORMATION

Eye problems (cont'd). You should use artificial tear substitutes, hydrating or lubricating eye gels, or ointments at least every 2 hours during waking hours to help prevent dry eyes. During treatment with BALVERSA™, your healthcare provider will send you to see an eye specialist.

Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



“How was BALVERSA™ (erdafitinib) studied?”

Clinical study details

BALVERSA™ was studied in 87 people with advanced bladder cancer who had tried at least 1 chemotherapy.

In the clinical study for BALVERSA™, all patients had a tumor that tested positive for a certain type of abnormal FGFR gene. Everyone started on an 8-mg once-daily dose of BALVERSA™.

After about 2 weeks, all patients had a blood test to measure their phosphate levels. People with higher phosphate levels stayed at the 8-mg dose, while those with lower levels increased their dose to 9 mg once a day.

People stayed on BALVERSA™ until their tumors progressed or until they had side effects that were too severe.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of BALVERSA™?

BALVERSA™ may cause serious side effects, including:

- **High phosphate levels in the blood (hyperphosphatemia).**
Hyperphosphatemia is common with BALVERSA™ but can also be serious. Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA™, and then monthly, and may change your dose if needed.

Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



Results of the BALVERSA™ (erdafitinib) study

In the study, BALVERSA™ helped reduce the growth of tumors in patients who had an objective response

Remember, each person is different, so the results you see with BALVERSA™ may not be the same as in the study.



32.2% of patients (28 out of 87) experienced a certain amount of tumor shrinkage (called an “objective response rate,” or ORR)

- 87 people were included in the assessment of ORR
- 2.3% (2 out of 87) had a complete response and 29.9% (26 out of 87) had a partial response



Patients who had an objective response had their tumor shrinkage last for a median of **5.4 months**. This means that for 50% of the patients, the response lasted for 5.4 months or longer, and for the other 50% of the patients, it was shorter than 5.4 months.

See glossary for definitions of “objective response,” “complete response,” “partial response,” and “median.”

IMPORTANT SAFETY INFORMATION

What are the possible side effects of BALVERSA™?

The most common side effects of BALVERSA™ include:

- mouth sores
- feeling tired
- change in kidney function
- diarrhea
- dry mouth
- nails separate from the bed or poor formation of the nail
- change in liver function
- low salt (sodium) levels

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Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



“How will my doctor know if BALVERSA™ (erdafitinib) is working?”

Measuring tumor size is one way to see if there's a response

Your doctor may use several approaches to see how well BALVERSA™ is working for you.

One way is to look at whether the tumor shrinks or disappears, and if it does, how long the response lasts.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of BALVERSA™?

The most common side effects of BALVERSA™ include (continued from page 9):

- decreased appetite
- change in sense of taste
- low red blood cells (anemia)
- dry skin
- dry eyes
- hair loss
- redness, swelling, peeling or tenderness, mainly on the hands or feet (“hand-foot syndrome”)
- constipation
- stomach (abdominal) pain
- nausea
- muscle pain

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Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



“How do I take BALVERSA™ (erdafitinib)?”

BALVERSA™ is taken by mouth, once a day

You take BALVERSA™ in tablet form. That means you don't have to travel to an infusion center for treatment with BALVERSA™. You can take it anywhere you happen to be when it's time to take your medicine.

- Take BALVERSA™ exactly as your healthcare provider tells you
- Swallow BALVERSA™ tablets whole with or without food
- If you miss a dose of BALVERSA™, take the missed dose as soon as possible on the same day. Take your regular dose of BALVERSA™ the next day. Do not take more BALVERSA™ than prescribed to make up for the missed dose
- If you vomit after taking BALVERSA™, do not take another BALVERSA™ tablet. Take your regular dose of BALVERSA™ the next day.

Your dose of BALVERSA™ may change

Each person responds to medication differently. Finding the right dose of BALVERSA™ is an important first step your doctor will take.

BALVERSA™ has been associated with increased levels of phosphate (a common mineral found in your body and blood), known as hyperphosphatemia. Your doctor may adjust your dose based on blood phosphate levels or other side effects you may experience.

Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA™ and then monthly, and may change your dose if needed.

IMPORTANT SAFETY INFORMATION

What are the possible side effects of BALVERSA™?

Tell your healthcare provider right away if you develop any nail or skin problems including nails separating from the nail bed, nail pain, nail bleeding, breaking of the nails, color or texture changes in your nails, infected skin around the nail, an itchy skin rash, dry skin, or cracks in the skin.

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Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



Finding the right dose for you

Your doctor will start you on an 8-mg (two 4-mg tablets) dose of BALVERSA™ once a day.



- After 14-21 days, your doctor will test your blood to check your phosphate levels



- Then, based on your phosphate levels and any side effects you may have, your doctor may change your dose. This is to help you get the best results from BALVERSA™

Don't be discouraged if your doctor changes your dose. Dosing of BALVERSA™ is tailored to the individual.

Over the course of your therapy, your doctor will perform other tests and evaluations and adjust your dose if needed.

Your doctor may change your dose, temporarily stop, or completely stop treatment if you get certain side effects.



IMPORTANT SAFETY INFORMATION

What are the possible side effects of BALVERSA™?

BALVERSA™ may affect fertility in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all possible side effects of BALVERSA™. For more information, ask your healthcare provider or pharmacist.

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

Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



Taking BALVERSA™ (erdafitinib)

Tips for taking BALVERSA™

Take BALVERSA™ exactly as your doctor prescribes.

- Don't change your dose or stop taking BALVERSA™ without consulting your doctor



Take BALVERSA™ once a day, every day



Swallow the tablets whole



You can take BALVERSA™ with or without food

“What if I forget to take my pills?”

If you forget a dose of BALVERSA™, take it as soon as possible on the same day. Then take your regular dose of BALVERSA™ at your usual time the next day. Extra tablets should not be taken to make up for the missed dose.

If you vomit, don't take another dose until the next day. If you take too much BALVERSA™, call your doctor immediately.

IMPORTANT SAFETY INFORMATION

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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IMPORTANT SAFETY INFORMATION

Before taking BALVERSA™ (erdafitinib), tell your healthcare provider about all of your medical conditions, including if you:

- have vision or eye problems.
- are pregnant or plan to become pregnant. BALVERSA™ can harm your unborn baby. You should not become pregnant during treatment with BALVERSA™.

Females who can become pregnant:

- Your healthcare provider may do a pregnancy test before you start treatment with BALVERSA™.
- You should use effective birth control during treatment and for 1 month after the last dose of BALVERSA™. Talk to your healthcare provider about birth control methods that may be right for you.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant.

Males with female partners who can become pregnant:

- You should use effective birth control when sexually active during treatment with BALVERSA™ and for 1 month after the last dose.
- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment and for 1 month after the last dose of BALVERSA™.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of BALVERSA™?

BALVERSA™ may cause serious side effects, including:

- **Eye problems.** Eye problems are common with BALVERSA™ but can also be serious. Eye problems include dry or inflamed eyes, inflamed cornea (front part of the eye), and disorders of the retina, an internal part of the eye. Tell your healthcare provider right away if you develop blurred vision, loss of vision, or other visual changes. You should use artificial tear substitutes, hydrating or lubricating eye gels, or ointments at least every 2 hours during waking hours to help prevent dry eyes. During treatment with BALVERSA™, your healthcare provider will send you to see an eye specialist.
- **High phosphate levels in the blood (hyperphosphatemia).** Hyperphosphatemia is common with BALVERSA™ but can also be serious. Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA™, and then monthly, and may change your dose if needed.

Please see additional Important Safety Information on page 15 and [click here](#) to see full BALVERSA™ Prescribing Information.



IMPORTANT SAFETY INFORMATION (cont'd)

The most common side effects of BALVERSA™ (erdafitinib) include:

- mouth sores
- feeling tired
- change in kidney function
- diarrhea
- dry mouth
- nails separate from the bed or poor formation of the nail
- change in liver function
- low salt (sodium) levels
- decreased appetite
- change in sense of taste
- low red blood cells (anemia)
- dry skin
- dry eyes
- hair loss
- redness, swelling, peeling or tenderness, mainly on the hands or feet (“hand-foot syndrome”)
- constipation
- stomach (abdominal) pain
- nausea
- muscle pain

Tell your healthcare provider right away if you develop any nail or skin problems including nails separating from the nail bed, nail pain, nail bleeding, breaking of the nails, color or texture changes in your nails, infected skin around the nail, an itchy skin rash, dry skin, or cracks in the skin.

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Keep BALVERSA™ out of the reach of children.

General information about the safe and effective use of BALVERSA™.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use BALVERSA™ for a condition for which it was not prescribed. Do not give BALVERSA™ to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about BALVERSA™ that is written for healthcare professionals.

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Please see Important Safety Information on page 14 and [click here](#) to see full BALVERSA™ Prescribing Information.



“How can I get the most out of my treatment with BALVERSA™ (erdafitinib)?”

Record your experiences on BALVERSA™ for your doctor



Keep notes about treatment effects and a list of questions for your doctor, and bring them to your next appointment.

Tell your doctor how you are feeling and what you are experiencing. This can help your treatment team meet your needs. Even if you think it's not serious, it's best to let your doctor know right away.

IMPORTANT SAFETY INFORMATION

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Glossary

Abnormal: Not normal; different from what is considered normal

Biopsy: A tissue sample taken to diagnose disease

Bladder: The organ that stores urine

Bladder cancer: Cancer that forms in tissues of the bladder. Most bladder cancers are transitional cell carcinomas (cancer that begins in cells that make up the inner lining of the bladder)

Cell: In biology, the smallest unit that can live on its own. It makes up all living organisms and tissues in the body

Chemotherapy: Treatment that uses drugs to stop the growth of cancer cells, either by killing them or by stopping them from dividing

Complete response: The disappearance of all signs of cancer in response to treatment. This does not always mean the cancer has been cured. Also called complete remission

FGFR (fibroblast growth factor receptor): FGFR helps cells to grow, survive, and multiply; genetic alterations in FGFR are thought to be important in the development of some bladder cancers

Gene: Functional and physical unit of heredity passed from parents to offspring. Genes are large pieces or sequences of DNA

Hyperphosphatemia: Having a high level of phosphate in your blood

Infusion: A method of putting fluids, including drugs, into the bloodstream. Also called intravenous infusion

Please see Important Safety Information on pages 14-15 and [click here](#) to see full BALVERSA™ Prescribing Information.



Glossary (cont'd)

Kinase inhibitor: A substance that blocks a type of enzyme called a kinase. Human cells have many different kinases, and they help control important functions, such as cell signaling, metabolism, division, and survival. Certain kinases are more active in some types of cancer cells, and blocking them may help keep the cancer cells from growing

Median: A statistics term; the middle value in a set of measurements

Objective response rate (ORR): The percentage of patients whose measurable tumors disappear (complete response) or decrease in size (partial response) after treatment

Partial response: A decrease in the size of a tumor, or in the extent of cancer in the body, in response to treatment. Also called partial remission

Phosphate: A naturally occurring mineral in the body, found in the bones and teeth

Response: In medicine, an improvement related to treatment

Tissue sample: A sample of tumor tissue


Urothelial cancer: Cancer that begins in cells called urothelial cells that line the urethra, bladder, ureters, and renal pelvis. Urothelial cells are also called transitional cells


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TALK TO YOUR DOCTOR ABOUT **BALVERSA™** (erdafitinib)

Patient Support for BALVERSA™

 BALVERSA™ is dispensed by US Bioservices specialty pharmacy. Once you and your doctor have decided that BALVERSA™ is right for you, please call 877-757-0667 to learn more about accessing BALVERSA™.

 For information on affordability programs that may be available for you, visit JanssenPrescriptionAssistance.com.

US Bioservices is an AmerisourceBergen specialty pharmacy.

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For more information, please visit www.balversa.com

