

The **PATIENT'S GUIDE**

to help with managing common side effects when taking BALVERSA®

Talk to your healthcare provider right away if you are experiencing any side effects that may be associated with BALVERSA®.

WHAT IS BALVERSA® (erdafitinib)?

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 *FGFR* gene, **and**
- who have tried at least one other medicine by mouth or injection (systemic therapy) that 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.

BALVERSA® is not recommended for the treatment of people who are eligible for and have not received prior PD-1 or PD-L1 inhibitor therapy.

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

IMPORTANT SAFETY INFORMATION

Before taking BALVERSA®, 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®.

Please see additional Important Safety Information throughout this piece and [click here](#) to see full BALVERSA® Prescribing Information.



Balversa®
(erdafitinib)
3, 4, 5 mg tablets

Detecting and managing eye problems

Eye problems with BALVERSA® are common but can also be serious. During treatment with BALVERSA®, your healthcare provider will send you to an eye specialist to help detect certain eye problems.

What are the possible eye problems related to BALVERSA®?

BALVERSA® may cause:

- Dry or inflamed eyes
- Inflamed cornea (the front part of the eye)
- 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 any one of the following at least every 2 hours during waking hours to help prevent or treat dry eyes:



Artificial tear substitutes, or



Hydrating or lubricating eye gels, or



Ointments

Your doctor may change or discontinue your dose of BALVERSA® if needed.

IMPORTANT SAFETY INFORMATION (CONT'D)

Before taking BALVERSA®, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

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.

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Detecting and managing eye problems (cont'd)

What are the symptoms of eye problems?

Common symptoms are blurred vision, loss of vision, or other visual changes.

If you experience any of these, tell your healthcare provider right away.

See an eye specialist

The eye specialist will perform monthly eye exams during the first 4 months of treatment with BALVERSA® and every 3 months afterwards, and urgently at any time for visual symptoms. **Your healthcare provider will send you to see an eye specialist. You can also go to the American Academy of Ophthalmology website to find an eye specialist near you.**

The eye exam should include assessment of:



Visual acuity, meaning how clear your vision is



Slit lamp examination, which allows your doctor to microscopically examine your eyes for problems



Fundoscopy, an exam that uses a magnifying lens and a light to check the back of the inside of the eye



Optical coherence tomography, an imaging test that takes pictures of your retina

IMPORTANT SAFETY INFORMATION (CONT'D)

Before taking BALVERSA®, tell your healthcare provider about all of your medical conditions, including if you: (cont'd)

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®.

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 **Balversa®**
(erdafitinib)
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Managing high phosphate levels in the blood

High phosphate levels in the blood, called hyperphosphatemia, is common with BALVERSA® but can also be serious. High levels of phosphate in your blood may lead to build-up of minerals such as calcium in different tissues in your body. Talk to your healthcare provider about the steps you can take to help manage hyperphosphatemia.

What is hyperphosphatemia?



Hyperphosphatemia is high phosphate levels in the blood.

Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA®, and then monthly. Your healthcare provider may prescribe changes in your diet or phosphate-lowering therapy, or change or stop treatment with BALVERSA® if needed. **Tell your healthcare provider right away if you develop painful skin lesions, any muscle cramps, or numbness or tingling around your mouth.**

IMPORTANT SAFETY INFORMATION (CONT'D)

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

Please see additional Important Safety Information throughout this piece and [click here](#) to see full BALVERSA® Prescribing Information.

Managing high phosphate levels in the blood (cont'd)

What can you do to help reduce the risk of hyperphosphatemia?

The foods you eat and the medications you take may impact your phosphate levels. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Ask your healthcare provider if you should reduce or avoid consuming foods high in phosphate or make any changes to medicine you take. It is recommended to restrict phosphate intake to 600-800 mg daily.

Examples of foods with high phosphate levels are:



Beverages: beer/wine, colas, bottled iced teas, chocolate drinks



Dairy products: processed cheese, milk, ice cream, pudding, yogurt



Proteins: meat, poultry, or seafood with "phos" in the ingredients; processed meats, such as bacon and hot dogs



Breads and breakfast foods: muffins, pancakes, waffles, quick breads



Chocolate candies, caramels, fast food

From Mayo Clinic, MayoClinic.org.

These are not the only foods that are high in phosphate. Talk to your healthcare provider about specific foods you should avoid or reduce in your diet.

Please see additional Important Safety Information throughout this piece and [click here](#) to see full BALVERSA® Prescribing Information.

Fertility

BALVERSA® can harm an unborn baby if taken by a pregnant patient and may affect fertility in patients who are able to become pregnant. You should not become pregnant during treatment with BALVERSA®. Talk to your healthcare provider about any concerns you have about pregnancy.

For patients who can become pregnant:



Your healthcare provider may do a pregnancy test before you start treatment with BALVERSA®.



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.

IMPORTANT SAFETY INFORMATION (CONT'D)

What are the possible side effects of BALVERSA®?

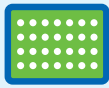
BALVERSA® may cause serious side effects, including:

- **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. High levels of phosphate in your blood may lead to build-up of minerals such as calcium in different tissues in your body. Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA®, and then monthly.

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Fertility (cont'd)

For males with female partners who can become pregnant:



Use effective birth control when sexually active during treatment with BALVERSA® and for 1 month after the last dose.

For patients who breastfeed:

You should 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.

IMPORTANT SAFETY INFORMATION (CONT'D)

High phosphate levels in the blood (hyperphosphatemia). (cont'd)

- Your healthcare provider may prescribe changes in your diet or phosphate-lowering therapy, or change or stop treatment with BALVERSA® if needed.
- Tell your healthcare provider right away if you develop painful skin lesions, any muscle cramps, or numbness or tingling around your mouth.

The most common side effects of BALVERSA® include:

- nails separate from the bed or poor formation of the nail
- mouth sores
- diarrhea
- increased level of creatinine in the blood
- increased level of the enzyme alkaline phosphatase in the blood
- change in liver function
- decreased red blood cells (anemia)
- decreased salt (sodium) levels in the blood
- tiredness
- dry mouth
- dry skin
- decreased phosphate in the blood
- decreased appetite
- change in sense of taste
- constipation
- increased level of calcium in the blood
- dry eye
- redness, swelling, peeling or tenderness, mainly on the hands or feet (hand-foot syndrome)
- increased level of potassium in the blood
- hair loss
- fluid buildup behind the retina in your eye

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Additional common side effects

The most common side effects of BALVERSA® include:

- nails separate from the bed or poor formation of the nail
- mouth sores
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- increased level of creatinine in the blood
- increased level of the enzyme alkaline phosphatase in the blood
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- redness, swelling, peeling or tenderness, mainly on the hands or feet (hand-foot syndrome)
- increased level of potassium in the blood
- hair loss
- fluid buildup behind the retina in your eye

IMPORTANT SAFETY INFORMATION (CONT'D)

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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Additional common side effects (cont'd)

Tell your healthcare provider right away if you develop any nail or skin problems, including the following:

Nail problems



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

Skin problems



An itchy skin rash, dry skin, cracks in the skin

To help manage these problems, the Mayo Clinic suggests:

For nail problems

- Keep fingernails dry and clean
- Trim nails straight across, then round the tips in a gentle curve
- Rub moisturizer into fingernails and cuticles
- Apply a nail hardener

For skin problems

- Apply moisturizer after bathing and several times a day
- Use warm, not hot, water and limit bathing time to 5-10 minutes
- Use mild soaps and cleansers
- Use a humidifier when air is dry
- Wear natural fibers, such as cotton

IMPORTANT SAFETY INFORMATION (CONT'D)

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 FDA at 1-800-FDA-1088.

Please see additional Important Safety Information throughout this piece and [click here](#) to see full BALVERSA® Prescribing Information.

IMPORTANT SAFETY INFORMATION

Before taking BALVERSA[®], 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.
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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. High levels of phosphate in your blood may lead to build-up of minerals such as calcium in different tissues in your body. Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with BALVERSA[®], and then monthly.

IMPORTANT SAFETY INFORMATION (CONT'D)

• **High phosphate levels in the blood (hyperphosphatemia). (cont'd)**

- Your healthcare provider may prescribe changes in your diet or phosphate-lowering therapy, or change or stop treatment with BALVERSA® if needed.
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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 FDA at 1-800-FDA-1088.

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 pharmacist or healthcare provider for information about BALVERSA® that is written for healthcare professionals.

**Please [click here](#) to see full BALVERSA®
Prescribing Information.**

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Talk to your healthcare provider right away if you are experiencing any side effects that may be associated with BALVERSA®.



To learn more, visit www.balversa.com.

Please see additional Important Safety Information throughout this piece and [click here](#) to see full BALVERSA® Prescribing Information.

Johnson&Johnson

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3, 4, 5 mg tablets