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

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.

How should I take BALVERSA®?

Your doctor will start you on an 8 mg (two 4 mg tablets) dose of BALVERSA® once a day. After 14-21 days of taking BALVERSA®, 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.

Take BALVERSA® exactly as your doctor tells you	Take BALVERSA® tablets with or without food
Take your prescribed dose of BALVERSA® once a day	Swallow the tablets whole

- 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
- If you take too much BALVERSA®, call your doctor immediately

If you have questions or concerns about your condition or treatment, do not hesitate to:

Talk to your doctor and healthcare team to be sure you receive clear instructions and information going forward.

Call for patient support. BALVERSA® is dispensed by a specialty pharmacy (**CVS Specialty®**). Once you and your doctor have decided that BALVERSA® is right for you, please call 1.855.539.4712 or visit CVSSpecialty.com to learn more about accessing BALVERSA®.

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

Visit us at www.balversa.com for more 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®.

Please see additional Important Safety Information on page 2, and click here to see full BALVERSA® Prescribing Information.

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. 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.
  - 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

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.

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.

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 see additional Important Safety Information on page 1 and click here to see full BALVERSA® Prescribing Information.

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