PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrBALVERSA®
erdafitinib tablets

Read this carefully before you start taking **BALVERSA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BALVERSA®**.

What is BALVERSA® used for?

For the following indication BALVERSA® has been approved *with conditions* (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

BALVERSA® is used to treat a type of bladder cancer called urothelial carcinoma (cancer in the bladder and urinary tract organs). It is used in adults:

- whose cancer has spread to other parts of the body or cannot be removed by surgery; and
- whose cancer was previously treated with chemotherapy, which did not work or is no longer working; and
- whose cancer has changes in certain genes called FGFR (known as fibroblast growth factor receptors).

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does BALVERSA® work?

Fibroblast growth factor receptors (FGFRs) are proteins found on cells that help them grow and divide. Some people with bladder cancer have FGFRs that are abnormally active. BALVERSA® works by blocking the activity of FGFRs to slow down the growth and spread of bladder cancer cells.

What are the ingredients in BALVERSA®?

Medicinal ingredients: erdafitinib

Non-medicinal ingredients: croscarmellose sodium, ferrosoferric oxide/iron oxide black (for the brown tablets only), glycerol monocaprylocaprate Type I, iron oxide red (for the orange and brown tablets only), iron oxide yellow, magnesium stearate (from vegetable source), mannitol, meglumine, microcrystalline cellulose, polyvinyl alcohol partially hydrolyzed, sodium lauryl sulfate, talc, titanium dioxide

BALVERSA® comes in the following dosage forms:

Tablets (film-coated): 3 mg (yellow), 4 mg (orange) and 5 mg (brown)

Do not use BALVERSA® if:

- you are allergic to erdafitinib or to any other ingredient in the medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BALVERSA®. Talk about any health conditions or problems you may have, including if you:

- have vision or eye problems.
- have or have had kidney or liver problems.

Other warnings you should know about:

General:
Only a doctor who has experience treating cancer should treat you with this drug.
Before prescribing you BALVERSA®, your doctor will perform a test. This test will confirm that your disease is suitable for treatment with this drug.

Eye problems:
Eye problems are common with BALVERSA® and can be serious. Eye problems include dry eyes, disorders of the cornea (front part of eye) and disorders of the retina (an internal part of the eye). Tell your healthcare professional right away if you develop any eye problem or if your vision changes while taking BALVERSA®. Use a lubricating eye ointment or a tear replacement therapy at least every 2 hours while awake to prevent and treat dry eyes.

High phosphate levels in the blood (hyperphosphatemia):
Hyperphosphatemia is common with BALVERSA® but also can be serious. Adhere to a low phosphate diet. Ask your doctor for dietary advice. Avoid the use of drugs that can increase the levels of phosphate in your blood. This includes potassium phosphate supplements, vitamin D supplements, antacids, and phosphate-containing enemas and laxatives.

Stomatitis (mouth sores, inflammation of the mouth):
Stomatitis is common with BALVERSA®.

Pregnancy, birth control and breastfeeding – information for women and men:

Pregnancy – information for women
- A pregnancy test should be done before you start to take BALVERSA®.
- Avoid becoming pregnant while taking BALVERSA®. It may harm your unborn child or make you lose the pregnancy.
- If you become pregnant while taking BALVERSA®, tell your doctor right away.

- If you plan to get pregnant after taking your last dose of BALVERSA®, ask your doctor for advice. This is because BALVERSA® may remain in your body after the last dose.

Pregnancy – information for men
- Avoid fathering a child while taking BALVERSA®. It may harm your unborn child.
- If your partner becomes pregnant while you are taking BALVERSA®, tell your partner's doctor right away.

Birth Control – information for women and men
- Use an effective method of birth control while taking BALVERSA®.
- Talk to your doctor about birth control methods that may be right for you.
- Men taking BALVERSA® must use a condom. Do **NOT** donate or store semen while taking it. This is because the drug may pass into the sperm.
- **After you finish treatment with BALVERSA®:**
    - **Women who are able to become pregnant:** Keep using birth control for 3 months after stopping BALVERSA®.
    - **Males with female partners who are pregnant or able to become pregnant:** Keep using birth control and do **NOT** donate or store semen for 3 months after stopping BALVERSA®.

Breastfeeding – information for women
- BALVERSA® may pass into breast milk. Do **NOT** breast-feed while you are taking it and for 3 months after taking your last dose of BALVERSA®. Talk to your doctor about the best way to feed your baby.

Fertility – information for women and men:
BALVERSA® may affect your fertility. Talk to your doctor if this is a concern for you.

Children and adolescents:
BALVERSA® is **NOT** recommended for use in patients under the age of 18 years.

Driving and using machines:
Eye problems are common in patients taking BALVERSA®. Give yourself time after taking BALVERSA® to see how you feel before driving a vehicle or using machinery. If you develop symptoms affecting your vision, do **NOT** drive or use machines as long as these last.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with BALVERSA®:

- clarithromycin, ciprofloxacin, rifampin - used to treat bacterial infections
- itraconazole, fluconazole, miconazole - used to treat fungal infections
- atazanavir, darunavir/ritonavir, cobicistat - used to treat viral infections, primarily HIV
- enzalutamide, apalutamide – used to treat prostate cancer
- mitotane – used to treat adrenal cancer
- carbamazepine and phenytoin - used to prevent seizures or to treat epilepsy or to treat a painful condition of the face called trigeminal neuralgia
- St. John's Wort (Hypericum perforatum) - an herbal medicine used for depression
- digoxin - used for heart problems

- metformin – used to treat diabetes
- alprazolam – used to treat anxiety
- cyclosporine – used to prevent organ transplant rejection
- dihydroergotamine – used to treat migraine and headaches

How to take BALVERSA®:

- Take BALVERSA® exactly as your healthcare professional has told you. Check with your doctor, pharmacist or nurse if you are not sure.
- Your doctor will tell you how much BALVERSA® to take. It is important that you take the recommended daily dose.
- Do **NOT** change your dose or stop taking BALVERSA® without first talking with your doctor.
- Take BALVERSA® with or without food at about the same time each day.
- If you take digoxin, your doctor may adjust the time that you take your medications.
- Swallow BALVERSA® tablets whole.
- If you vomit after taking your dose, do **NOT** take another one. Take your next dose the next day at the normal time.

Usual dose:

Usual adult starting dose:
8 mg: Take two 4 mg tablets by mouth once a day.
Your doctor may adjust your dose, temporarily stop or completely stop your treatment. This may happen:

- based on your blood test results.
- if you are taking medicines that may interact with BALVERSA®.
- if you have certain side effects while taking BALVERSA®.

Increased adult dose:
9 mg: Take three 3 mg tablets by mouth once a day.

Reduced adult dose:
6 mg: Take two 3 mg tablets by mouth once a day.
5 mg: Take one 5 mg tablet by mouth once a day.
4 mg: Take one 4 mg tablet by mouth once a day.

Overdose:

If you take too much BALVERSA®, call your healthcare professional or go to the nearest hospital emergency room right away.

Missed dose:

- If you are late in taking BALVERSA®, take it as soon as you remember if it is on the same day. Continue with taking the next scheduled dose the next day at the normal time.
- If you miss a day's dose, do NOT take a double dose to make up for the missed dose. Instead, wait until it is time and take your regular dose at the normal time.

What are possible side effects from using BALVERSA®?

These are not all the possible side effects you may feel when taking BALVERSA®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- decreased appetite
- mouth sores
- diarrhea
- constipation
- nausea
- vomiting
- stomach (abdominal) pain
- dry mouth
- dry skin
- hair loss
- nasal dryness
- vagina dryness
- feeling tired
- feeling weak
- fever
- muscle pain
- change in sense of taste
- weight loss
- sore throat

BALVERSA® can cause abnormal blood test results including liver and kidney blood tests. It may also affect the phosphate levels in your blood. Your healthcare professional will test your blood:

- before you start on BALVERSA®,
- about 2 weeks after starting treatment, and
- once a month thereafter during treatment with BALVERSA®.

Your doctor will interpret the results and tell you if your test results are abnormal. Your doctor may tell you to temporarily or completely stop taking BALVERSA®. Your doctor may also adjust your dose. If you develop increased levels of phosphate in your blood, your doctor may give you medicine to manage this side effect.

BALVERSA® can cause eye problems. Your healthcare professional will send you to see an eye specialist to examine and monitor your eyes:

- before you start on BALVERSA®, and
- if you develop eye or vision problems while taking BALVERSA®.

Your healthcare professional will check your eyes monthly for vision problems using an Amsler grid test. They may also provide you with instructions on using the grid. This is so you can monitor your vision at home between visits. Your doctor may tell you to temporarily or completely stop taking BALVERSA®. Your doctor may also adjust your dose to manage this side effect.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Nail or skin problems: nails separating from the bed, infected skin around the nail, poor nail formation, discolored nails		✓	
Palmar-Plantar erythrodysesthesia syndrome (hand-foot syndrome): swelling, peeling or tenderness, mainly on the hands or feet		✓	
Eye (vision) problems: dry eyes, inflamed eyes, watering eyes, disorders of the retina (an internal part of the eye)		✓	
Urinary tract infection: burning feeling when you urinate		✓	
Hematuria: blood in urine		✓	
Anemia (low red blood cells): feeling tired, looking pale and you may feel your heart pumping		✓	
COMMON			
Nail or skin problems: nail pain, itching, crack in the skin, ridging of nails, breaking of the nails, thickened skin, flaky skin, abnormal growth or appearance on the skin, very dry skin, bleeding under the nail, thinning of the skin, skin reaction, nail discomfort		✓	
Eczema: itchy skin rash		✓	
Eczema Nummular: itchy skin rash with round spots		✓	
Eye (vision) problems: blurred vision, inflamed cornea (front part of the eye), vision loss (detached retina), swelling of the retina, disease of the retina, ulcers on the cornea (front part of the eye),		✓	

Serious side effects and what to do about them			
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a gel-like substance separates from the retina			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store BALVERSA® at room temperature between 15ºC - 30ºC.
- Do **NOT** throw away any medicines via wastewater or household waste. Ask your healthcare provider or pharmacist about the right way to throw away outdated or unused BALVERSA®. These measures will help protect the environment.
- **Keep out of reach and sight of children.**

If you want more information about BALVERSA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (http://hc-sc.gc.ca/index-eng.php); the manufacturer's website (www.janssen.com/canada), or by calling Janssen Inc. at: 1-800-567-3331 or 1-800-387-8781.

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