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
- was previously treated with chemotherapy, which did not work or is no longer working; and
- 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 problems.
- have or have had liver problems.

Other warnings you should know about:

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

- **BALVERSA® may cause:**
  - **Eye problems**, which are common 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)**, which are common and can be serious.
    - Adhere to a low phosphate diet. Ask your healthcare professional for dietary advice. Avoid the use of medicines 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.
    - If you develop increased levels of phosphate in your blood, you may be prescribed another medicine to manage this side effect.

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

- **Female patients:**
  - **Pregnancy and birth control**
    - If you are able to become pregnant:
      - 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.
      - Use an effective method of birth control while taking BALVERSA®. Talk to your healthcare professional about birth control methods that may be right for you.
      - Keep using birth control for 3 months after stopping BALVERSA®.
    - If you become pregnant while taking BALVERSA®, tell your healthcare professional right away.
    - If you plan to get pregnant after taking your last dose of BALVERSA®, ask your healthcare professional for advice. This is because BALVERSA® may remain in your body after the last dose.
  - **Breastfeeding**
    - 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 healthcare professional about the best way to feed your baby.

- **Male patients:**
  - **Pregnancy and birth control**
    - 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 healthcare professional right away.
    - Use an effective method of birth control while taking BALVERSA®. Talk to your healthcare professional 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.
    - Keep using birth control and do **NOT** donate or store semen for 3 months after stopping BALVERSA®.

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

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

- **Check-ups and testing:**
  You will have regular visits with your healthcare professional during treatment with BALVERSA®. They will:

- Do blood tests to monitor your phosphate levels, and check your liver and kidney health. The tests will be done:
  - before you start on BALVERSA®,
  - about 2 weeks after starting treatment, and
  - once a month thereafter during treatment with BALVERSA®.

  Your healthcare professional will tell you if your blood test results are abnormal.
- Check your eyes.
  - You will be sent to see an eye specialist to examine and monitor your eyes. This will be done before you start on BALVERSA® and if you develop eyes or vision problems while taking BALVERSA®.
  - Your healthcare professional will also check your eyes once a month during treatment using an Amsler grid test. They may give you instructions on using the grid so you can monitor your vision at home between visits.

- **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 healthcare professional if you are not sure.
- Your healthcare professional 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 healthcare professional.
- Take BALVERSA® with or without food at about the same time each day.
- If you take digoxin, your healthcare professional 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 healthcare professional may adjust your dose, temporarily stop or completely stop your treatment. This may happen:
- based on your blood test and eye exam 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 think you, or a person you are caring for, have taken too much BALVERSA®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

- If you forget to take your dose of 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
- nose bleeds

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 which may include: nails separating from the bed, infected skin around the nail, poor nail formation, discolored nails, nail pain, breaking of the nails, ridging of nails, nail bleeding		✓	
Skin problems which may include: itching, itching skin rash (eczema), crack in the skin		✓	
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), blurred vision, vision loss		✓	
Urinary tract infection (infection in urinary system including kidneys, ureters, bladder and urethra): burning feeling when you urinate		✓	

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**	
Hematuria: blood in urine		✓	
Anemia (low red blood cells): feeling tired, looking pale and you may feel your heart pumping		✓	
COMMON			
Acute kidney injury (sudden decrease in kidney function): less urination, confusion, puffiness in your face and hands, swelling in your feet or ankles		✓	

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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.
- **Keep out of reach and sight of children.**
- 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.

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); 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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