Package leaflet: Information for the patient

Balversa 3 mg film-coated tablets
Balversa 4 mg film-coated tablets
Balversa 5 mg film-coated tablets
erdafitinib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Balversa is and what it is used for

Balversa is a cancer medicine that contains the active substance erdafitinib. It belongs to a group of medicines called 'tyrosine kinase inhibitors'.

Balversa is used in adults to treat urothelial carcinoma (bladder and urinary tract cancer) that is locally advanced (spread nearby) and is unresectable (meaning it cannot be removed by surgery) or metastatic (meaning it has spread to other parts of the body).

It is used when the cancer has:
- alterations in the fibroblast growth factor receptor 3 *(FGFR3)* gene, and
- worsened after treatment known as immunotherapy.

Balversa should only be used if the cancer cells have changes in the *FGFR3* gene. Before starting treatment, your doctor will test if you have such changes in the *FGFR3* gene to make sure this medicine is right for you.

The active substance in Balversa, erdafitinib, works by blocking proteins in the body called FGFR tyrosine kinases. This helps to slow down or stop the growth of cancer cells that have abnormal FGFR3 receptors resulting from changes in the *FGFR3* gene.

2. What you need to know before you take Balversa

Do not take Balversa if
- you are allergic to erdafitinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before using Balversa if you:

- have increased blood levels of phosphate
- have vision or eye problems
- are pregnant
- are a woman who can become pregnant

Eye (sight) problems
Balversa increases your risk of central serous retinopathy (CSR; a condition where fluid builds up and separates the macula, the central part of the retina at the back of the eye, causing blurred and distorted vision). The risk of CSR is higher in people aged 65 years and older.

- Before starting treatment with Balversa, you will have an extensive eye exam, including tests to check your vision, retina and eye structure.
- Your doctor will monitor your eyes closely by performing monthly eye exams for the first 4 months of treatment, and every 3 months after that.
- If you experience any symptoms of abnormal vision, your doctor will perform an urgent eye examination.
- Tell your doctor immediately if you have any symptoms of CSR, including blurred vision or reduced peripheral (side vision), a dark spot in your central vision, distorted central vision, where lines appear crooked or bent, object appearing smaller or further away than they really are, colours appearing washed out, floaters or specks passing through your field of vision, flashes of light or feeling of looking through a curtain. Also see section 4 under 'Most important side effects'.
- If you experience CSR during treatment with Balversa, your doctor may need to stop your treatment temporarily. They will permanently stop your treatment if symptoms do not resolve within 4 weeks or are very severe.

During treatment with Balversa, you should use eye drops or gels regularly to prevent and treat dry eyes.

High phosphate levels in the blood (hyperphosphataemia)
Balversa can cause an increase in phosphate levels (hyperphosphataemia) in your blood. This is a known side effect with Balversa that ususally occurs within the first few weeks of starting treatment. This can lead to a buildup of minerals such as calcium in your soft tissues, cutaneous calcinosis (a buildup of calcium in the skin, causing hard lumps or nodules) and non-uraemic calcinosis (a rare skin condition that causes painful skin ulcers due to a buildup of calcium in the blood vessels).

- Your doctor will monitor your blood phosphate levels during treatment. They may advise you to limit your intake of foods high in phosphate and avoid taking other medicines that could raise your phosphate levels.
- Vitamin D supplements are not recommended while taking Balversa, as this may also contribute to high phosphate and calcium levels.
- If your blood phosphate levels get too high, your doctor may suggest taking medicine to help control it.
- If you develop high blood levels of phosphate, your doctor may need to adjust your Balversa dose or stop your treatment altogether.
- Tell your healthcare provider right away if you develop the following symptoms, which may be signs of hyperphosphataemia:
    - painful skin lesions
    - muscle cramps
    - numbness, or

- tingling around your mouth.

Skin disorders
When taking Balversa, you may experience itching, dry skin or redness, swelling, peeling or tenderness, mainly on the hands or feet ('hand-foot syndrome'). You should monitor your skin and avoid unnecessary exposure to sunlight, excessive use of soap and bathing. You should use moisturisers regularly and avoid perfumed products.

Photosensitivity
When taking Balversa, you may become more sensitive to sunlight. This can cause skin damage. You should be careful and take precautions when spending time outside in the sun. Precautions can include wearing clothing that covers your skin and using sunscreen to protect yourself from harmful sun rays.

Nail disorders
When taking Balversa, you may experience nails separating from the bed, infected skin around the nail, or discoloured nails. You should monitor your nails for any signs of infection and practice preventative nail treatments such as good hygiene and using over-the-counter nail strengthener.

Mucosal disorders
When taking Balversa you may experience dry mouth and or mouth sores. You should practice good oral hygiene and avoid spicy or acidic foods while taking Balversa.

Children and adolescents
This medicine is not for use in children and adolescents. This is because there is no experience with using Balversa in this age group.

Other medicines and Balversa
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. Taking Balversa with certain other medicines may affect how Balversa works and can cause side effects.

The following medicines may decrease the effectiveness of Balversa by decreasing the amount of Balversa in the blood:
- carbamazepine (used to treat epilepsy)
- rifampicin (used to treat tuberculosis)
- phenytoin (used to treat epilepsy)
- St. John's wort (used to treat depression)

The following medicines may increase the risk of side effects of Balversa by increasing the amount of Balversa in the blood:
- fluconazole (used to treat fungal infections)
- itraconazole (used to treat fungal infections)
- ketoconazole (used to treat fungal infections)
- posaconazole (used to treat fungal infections)
- voriconazole (used to treat fungal infections)
- miconazole (used to treat fungal infections)
- ceritinib (used to treat lung cancer)
- clarithromycin (used to treat infections)
- telithromycin (used to treat infections)
- elvitegravir (used to treat HIV)
- ritonavir (used to treat HIV)
- paritaprevir (used to treat hepatitis)
- saquinavir (used to treat HIV)
- nefazodone (used to treat depression)
- nelfinavir (used to treat HIV)
- tipranavir (used to treat HIV)
- lopinavir (used to treat HIV)

- amiodarone (used to treat arrhythmias)
- piperine (used as a supplement)

Balversa may increase the risk of side effects of some other medicines by increasing the amount of these medicines in the blood. These include:
- midazolam (used to treat seizures)
- hormonal contraceptives
- colchicine (used to treat gout)
- digoxin (used to treat certain arrhythmias or heart failure)
- dabigatran (used as a blood thinner)
- apixaban (used as a blood thinner)

Balversa with food and drink
Do not take Balversa with grapefruit or Seville oranges (bitter oranges) – this includes eating them, drinking the juice or taking a supplement that might contain them. This is because it can increase the amount of Balversa in your blood.

Pregnancy, contraception and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice **before** taking this medicine.

Information for women
- Pregnancy
  - Balversa can harm your unborn baby.
  - You should not use Balversa during pregnancy unless you are told otherwise by your doctor.
  - You should not become pregnant during treatment with Balversa and for 1 month after the last dose of Balversa.
  - Tell your doctor immediately if you become pregnant.

- Pregnancy test
  - Your doctor will ask you to do a pregnancy test before you start treatment with Balversa.

- Contraception
  - Balversa may reduce the effectiveness of some birth control methods. Talk to your doctor about appropriate birth control while taking Balversa. Women who can become pregnant should use highly effective contraception during treatment and for at least 1 month after treatment with Balversa.

- Breast-feeding
  - Do not breast-feed during treatment with Balversa and for 1 month following the last dose of this medicine.

Information for men
Men must use effective contraception (condom) while being treated with Balversa and for 1 month after the last dose. Also, you must not donate or store semen during treatment and for 1 month after the last dose.

Driving and using machines
Eye problems have been reported in patients taking Balversa. If you have problems affecting your sight, do not drive or use any tools or machines until your sight returns to normal.

Balversa contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Balversa

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
Your doctor will work out your dose and how often you should take this medicine.
- The recommended starting dose of Balversa is 8 mg once a day by mouth.
    - You may need to take one 5 mg tablet and one 3 mg tablet or two 4 mg tablets to get this dose.

After about 2 weeks of taking Balversa, your doctor will do a blood test. This is to check the phosphate level in your blood.
- Based on the results of this blood test and on whether or not you are experiencing side effects, your doctor may increase your dose to 9 mg a day.

The doctor may also decide to decrease the dose if you have certain side effects such as sores in the mouth, redness, swelling, peeling or tenderness, mainly on the hands or feet, nail separating from the nail bed, high level of phosphate in your blood.

Taking Balversa
- Swallow Balversa tablets whole.
- You can take this medicine with or without food.
- Try to take this medicine at the same time each day. This will help you remember to take it.
- If you vomit, do not take another tablet. Take your next dose at the regular time the next day.

If you take more Balversa than you should
If you take too much Balversa, call your doctor or go to the nearest hospital emergency room right away.

If you forget to take Balversa
- If you miss a dose, take it as soon as possible on the same day. Take your regular dose of Balversa the next day.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Balversa
Do not stop taking this medicine unless your doctor tells you.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most important side effects
Tell your doctor immediately if you notice any of the serious side effects below:

Central serous retinopathy (**very common**: may affect more than 1 in 10 people)
The following symptoms may be signs of CSR:
- blurred vision or reduced peripheral (side) vision
- a dark spot in your central vision
- distorted central vision, where lines appear crooked or bent
- objects appearing smaller or further away than they really are
- colours appearing washed out
- floaters or specks passing through your field of vision, flashes of light or feeling of looking through a curtain.

Hyperphosphataemia (**very common**: may affect more than 1 in 10 people)
The following symptom may be a sign of hyperphosphataemia:
- high level of phosphate in the blood

Nail disorders (**very common**: may affect more than 1 in 10 people)
The following symptoms may be signs of nail disorders:
- nails separating from the bed (onycholysis)
- infected skin around the nail (paronychia)
- poor nail formation (nail disorder)
- discoloured nails (nail discolouration)

Skin disorders (**very common**: may affect more than 1 in 10 people)
The following symptoms may be signs of skin disorders:
- redness, swelling, peeling or tenderness, mainly on the hands or feet ('hand-foot syndrome')
- hair loss (alopecia)
- dry skin

Mucosal disorders (**very common**: may affect more than 1 in 10 people)
The following symptoms may be signs of mucosal disorders:
- sores in the mouth (stomatitis)
- dry mouth

Tell your doctor immediately if you notice any of the above signs of 'central serous retinopathy', 'hyperphosphataemia', 'nail disorders', 'skin disorders' or 'mucosal disorders'.
Your doctor may ask you to stop taking Balversa or send you to a specialist if you have eye or sight problems.

Other side effects may occur with the following frequencies:
Very common (may affect more than 1 in 10 people):
- diarrhoea
- decreased appetite
- change in sense of taste with food tasting metallic, sour, or bitter (dysgeusia)
- weight loss
- constipation
- feeling sick (nausea)
- vomiting
- stomach pain
- dry eyes
- feeling weak and very tired
- low level of sodium in blood (hyponatraemia)
- increased level of 'creatinine' in the blood (increased creatinine)
- increased level of the liver enzyme 'alanine aminotransferase' in the blood (ALT increased)
- increased level of the liver enzyme 'aspartate aminotransferase' in the blood (AST increased)
- low number of red blood cells (anaemia)
- nose bleeds (epistaxis)

Common (may affect up to 1 in 10 people):
- painful nails
- ridging or breaking of the nail or nails
- very dry skin
- cracked, thickened or flaky skin
- itching or itchy skin rash (eczema)
- abnormal growth or appearance on the skin
- rash
- dry or inflamed eyes (conjunctivitis)

- ulcers or inflamed front part of the eye (‘cornea’)
- red and swollen eyelids
- watery eyes
- high level of calcium in the blood
- low level of phosphate in the blood
- nasal dryness
- indigestion (dyspepsia)
- sudden decrease in kidney function
- high level of the hormone ‘parathyroid’ (PTH) (hyperparathyroidism)
- kidney failure (renal failure)
- problems with kidneys (renal impairment)
- liver damage (hepatic cytolysis)
- abnormal liver function
- high level of ‘bilirubin’ in the blood

Uncommon (may affect up to 1 in 100 people):
- bleeding under the nail
- nail discomfort or pain
- skin reaction
- thinning of the skin
- redness of the palms
- membrane dryness (including nose, mouth, eyes, vagina)

Talk to your doctor if you get any of the above side effects.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Balversa

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, carton and bottle after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if the packaging is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Balversa contains

- The active substance is erdafitinib.
- Each film-coated tablet contains either 3 mg, or 4 mg or 5 mg of erdafitinib.
- The other ingredients are:
  - Tablet core: Croscarmellose sodium, Magnesium stearate (E572), Mannitol (E421), Meglumine, and Microcrystalline cellulose (E460).
  - Film coating (Opadry amb II): Glycerol monocaprylocaprate Type I, Polyvinyl alcohol-partially hydrolysed, Sodium lauryl sulfate, Talc, Titanium dioxide (E171), Iron oxide yellow (E172), Iron oxide red (E172) (for the 4 mg and 5 mg tablets only), iron oxide black (E172) (for the 5 mg tablets only).

What Balversa looks like and contents of the pack

Balversa 3 mg film-coated tablets are yellow, round biconvex shaped tablet, debossed with "3" on one side; and "EF" on the other side.

Balversa 4 mg film-coated tablets are orange, round biconvex shaped tablet, debossed with "4" on one side; and "EF" on the other side.

Balversa 5 mg film-coated tablets are brown, round biconvex shaped tablet, debossed with "5" on one side; and "EF" on the other side.

The tablets are supplied in a plastic bottle with a child-resistant closure. Each bottle contains either 28, 56, or 84 film-coated tablets. Each carton contains one bottle.
Not all pack sizes may be marketed.

3 mg tablet:

- Each carton of 56 film-coated tablets contains one bottle of 56 tablets.
- Each carton of 84 film-coated tablets contains one bottle of 84 tablets.

4 mg tablet:

- Each carton of 28 film-coated tablets contains one bottle of 28 tablets.
- Each carton of 56 film-coated tablets contains one bottle of 56 tablets.

5 mg tablet:

- Each carton of 28 film-coated tablets contains one bottle of 28 tablets.

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