TLPH

Information for the patient
Erdaini 3mg/4mg/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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Erdaini is and what it is used for
2. What you need to know before you take Erdaini
3. How to take Erdaini
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1. What Erdaini is and what it is used for

What Erdaini is

Erdaini belongs to a class of cancer medicines called fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor It contains the active substance Erdafitinib.

What Erdaini is used for

Erdaini 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 chemotherapy medicine that contains platinum, and it did not work or is no longer working.

How Erdaini works

Erdaini is a kinase inhibitor that binds to and inhibits enzymatic activity of FGFR1, FGFR2, FGFR3 and FGFR4 based on in vitro data. Erdaini also binds to RET, CSF1R, PDGFRA, PDGFRB, FLT4, KIT, and VEGFR2. Erdaini inhibited FGFR phosphorylation and signaling and decreased cell viability in cell lines expressing FGFR genetic alterations, including point mutations, amplifications, and fusions. Erdaini demonstrated antitumor activity in FGFR-expressing cell lines and xenograft models derived from tumor types, including bladder cancer.

2. What you need to know before you take Erdaini

Do not take Erdaini

- if you are allergic to Erdafitinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Advise patients that evidence of a susceptible FGFR3 or FGFR2 mutation or gene fusion within the tumor specimen is necessary to identify patients for whom treatment is indicated
- Advise patients that their healthcare provider will assess their serum phosphate level between 14 and 21 days of initiating treatment and will adjust the dose if needed

Before taking Erdaini 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. Erdaini can harm your unborn baby. You should not become pregnant during treatment with Erdaini.

Females who can become pregnant:
· Your healthcare provider may do a pregnancy test before you start treatment with Erdaini.
· You should use effective birth control during treatment and for 1 month after the last dose of Erdaini. 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 Erdaini 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 Erdaini.

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

Pregnancy and breast-feeding

- Based on the mechanism of action and findings in animal reproduction studies, Erdaini can cause fetal harm when administered to a pregnant woman . There are no available data on Erdaini use in pregnant women to inform a drug-associated risk. Oral administration of Erdaini to pregnant rats during organogenesis caused malformations and embryofetal death at maternal exposures that were less than the human exposures at the maximum recommended human dose based on AUC . Advise pregnant women and females of reproductive potential of the potential risk to the fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

- There are no data on the presence of Erdaini in human milk, or the effects of Erdaini on the breastfed child, or on milk production. Because of the potential for serious adverse reactions from Erdaini in a breastfed child, advise lactating women not to breastfeed during treatment with Erdaini and for one month following the last dose.

General information about the safe and effective use of Erdaini.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use Erdaini for a condition for which it was not prescribed. Do not give Erdaini 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 healthcare provider for information about Erdaini that is written for healthcare professionals.

3. How to take Erdaini

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

Erdaini is taken by mouth as tablets.

Your doctor will tell you what dose of Erdaini to take. The recommended starting dose of Erdaini is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to 9 mg (three 3 mg tablets) once daily based on serum phosphate (PO4) levels and tolerability at 14 to 21 days

The recommended dose modifications for adverse reactions are listed in Table 1.

Table 1: BALVERSA Dose Reduction Schedule

Dose	1st dose reduction	2nd dose reduction	3rd dose reduction	4th dose reduction	5th dose reduction
9 mg → (three 3 mg tablets)	8 mg (two 4 mg tablets)	6 mg (two 3 mg tablets)	5 mg (one 5 mg tablet)	4 mg (one 4 mg tablet)	Stop
8 mg → (two 4 mg tablets)	6 mg (two 3 mg tablets)	5 mg (one 5 mg tablet)	4 mg (one 4 mg tablet)	Stop	

Your doctor may decide to increase or lower your dose or temporarily interrupt treatment. Con-tinue treatment at the dose prescribed by your doctor.

- Take Erdaini 1 time each day.
- Swallow Erdaini tablets whole with or without food.
- Your healthcare provider may change your dose of Erdaini, temporarily stop or completely stop treatment if you get certain side effects.
- **If you miss a dose of Erdaini**, take the missed dose as soon as possible on the same day. Take your regular dose of Erdaini the next day. Do not take more Erdaini than prescribed to make up for the missed dose.
- **If you vomit after taking Erdaini**, do not take another Erdaini tablet. Take your regular dose of Erdaini the next day.

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.

Some possible side effects may be serious:

Erdaini may cause serious side effects, including:

- Eye problems. Eye problems are common with Erdaini 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 Erdaini, your healthcare provider will send you to see an eye specialist.
- High phosphate levels in the blood (hyperphosphatemia). Hyperphosphatemia is common with Erdaini but can also be serious. Your healthcare provider will check your blood phosphate level between 14 and 21 days after starting treatment with Erdaini, and then monthly, and may change your dose if needed.

The most common side effects of Erdaini include:

- mouth sores
- feeling tired
- change in kidney function
- diarrhea
- dry mouth
- nails separate from the bed or poor formation of the nail
- change in liver function
- low salt (sodium) levels
- decreased appetite
- change in sense of taste
- low red blood cells (anemia)
- dry skin
- dry eyes
- hair loss
- redness, swelling, peeling or tenderness, mainly on the hands or feet ('hand-foot syndrome')
- constipation
- stomach (abdominal) pain
- nausea
- muscle pain

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.
Erdaini 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 Erdaini. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects.

5. How to store Erdaini

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 carton and the bottle after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

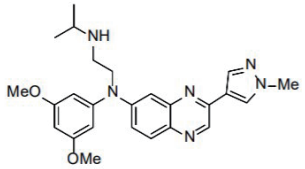
Store Erdaini tablets at room temperature between 68°F to 77°F (20°C to 25°C).

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 Erdaini contains

- The active substance is Erdafitinib is a kinase inhibitor. The chemical name is N-(3,5-di-methoxyphenyl)-N'-(1-methylethyl)-N-[3-(1-methyl-1H-pyrazol-4-yl)quinoxalin-6-yl]ethane-1,2- diamine. Erdafitinib is a yellow powder. It is practically insoluble, or insoluble to freely soluble in organic solvents, and slightly soluble to practically insoluble, or insoluble in aqueous media over a wide range of pH values. The molecular formula is $C_{25}H_{30}N_6O_2$ and molecular weight is 446.56. Chemical structure of Erdafitinib is as follows:



Each film-coated tablet contains 3mg or 4mg or 5mg erdafitinib.
- The other ingredients are: Croscarmellose sodium, Magnesium stearate (from vegetable source), Mannitol, Meglumine, and Microcrystalline Cellulose.

What Erdaini looks like and contents of the pack

Erdaini film-coated tablets are round tablets .

The tablets are provided in bottles and are available in packs containing 28 or 56 or 84 film-coated tablets .

Marketing Authorisation Holder

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd
Rd13 South,31km,Ban Naphasuk,Saithany District
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Lao PDR

Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Au-thorisation Holder:

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