Therapy management*
for patients receiving erdafitinib ▼

Erdafitinib as monotherapy is indicated for the treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC), harbouring susceptible FGFR3 genetic alterations who have previously received at least one line of therapy containing a PD-1 or PD-L1 inhibitor in the unresectable or metastatic treatment setting. [1]

CP-532273 - Julio 2025 - Janssen-Cilag, S.A.

▼ Este medicamento está sujeto a seguimiento adicional, es prioritaria la notificación de sospechas de reacciones adversas asociadas a este medicamento.

Ficha Técnica disponible en: https://static.janssen-emea.com/sites/default/files/Spain/SMPC/ES-PL-0241.pdf

***Para mayor información acerca del manejo de erdafitinib consulte la Ficha Técnica.**

FGFR, fibroblast growth factor receptor; mUC, metastatic urothelial carcinoma; PD-1, programmed cell death protein 1; PD-(L)1, programmed cell death-(ligand) 1.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

1. Erdafitinib **management**

Overall timeline of assessments **before and during treatment**[1,2]

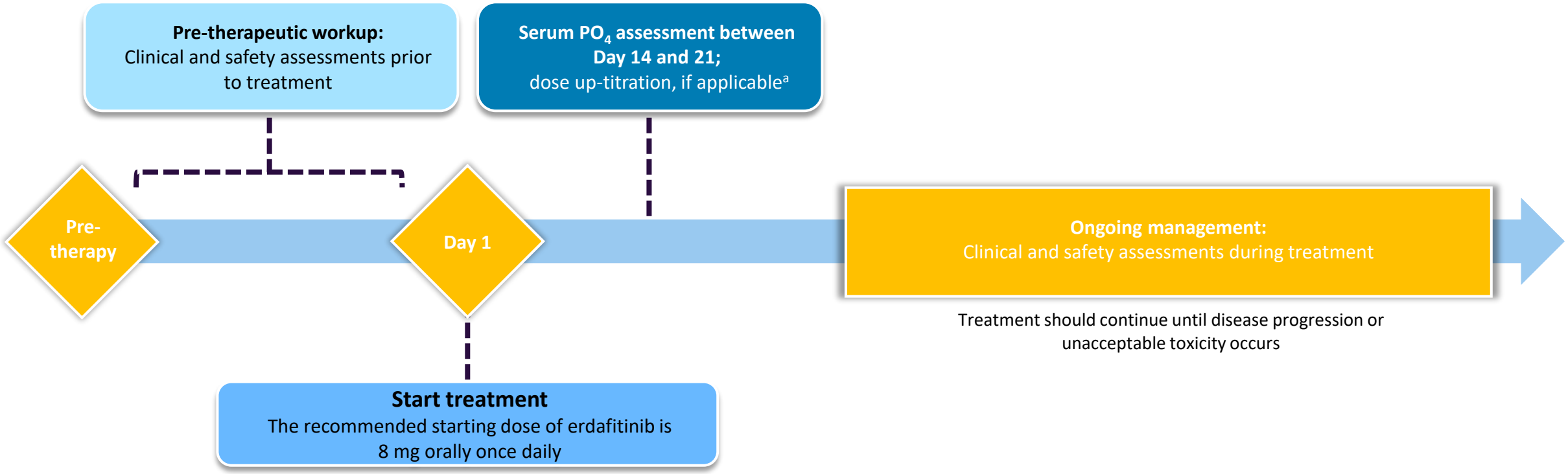


Figure based on Loriot Y, et al. 2023. Study in protocol supplement and Erdafitinib Summary of Product Characteristics [1,2]

[a]Up-titre the dose to 9 mg once daily if the serum PO_4 level is <9.0 mg/dl (<2.91 mmol/l) and there is no drug-related toxicity. If the PO_4 level is 9.0 mg/dl or higher, follow relevant dose modifications as described in the erdafitinib SmPC (section 4.2). After Day 21, serum PO_4 level should not be used to guide up-titration decision.[2]

PO_4, phosphate; SmPC: Summary of Product Characteristics

1. Loriot Y, et al. *N Engl J Med*. 2023;389(21):1961–1971. Study protocol in supplement. 2. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Clinical and safety assessments **prior to treatment**[1,2]

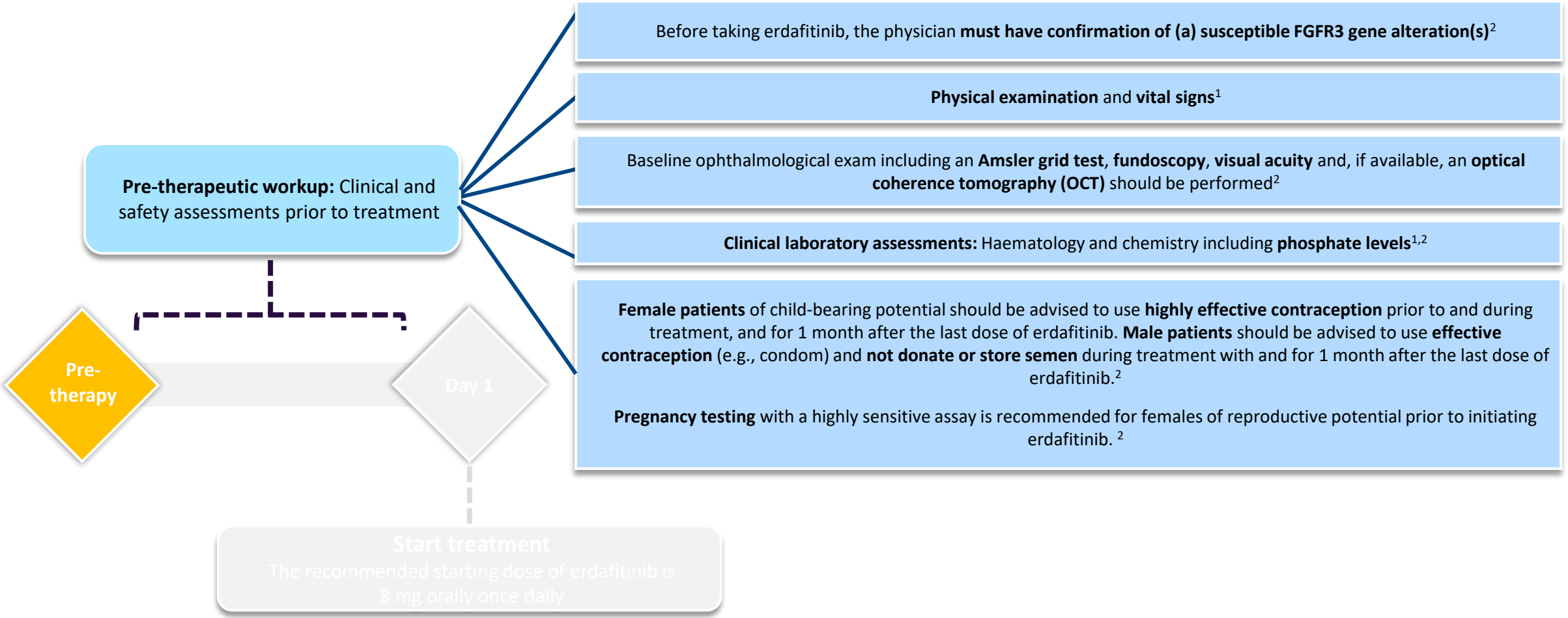


Figure based on Loriot Y, et al. 2023. Study in protocol supplement and Erdafitinib Summary of Product Characteristics [1,2]

PO_4, phosphate.

1. Loriot Y, et al. *N Engl J Med*. 2023;389(21):1961–1971. Study protocol in supplement. 2. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Erdafitinib **dosage and administration**[1,2]

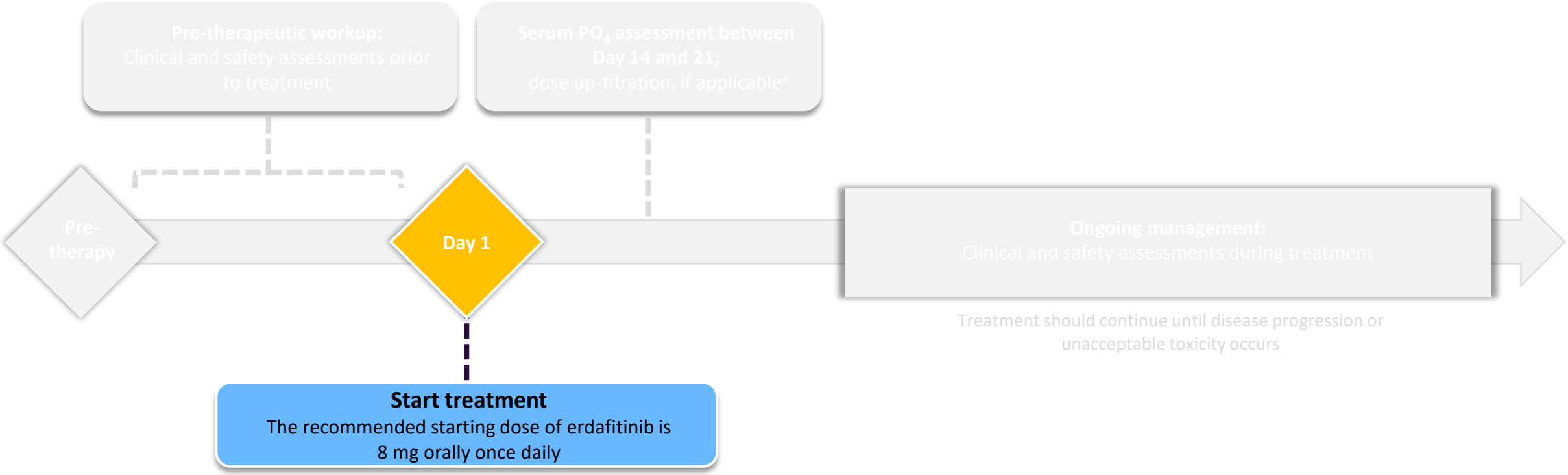


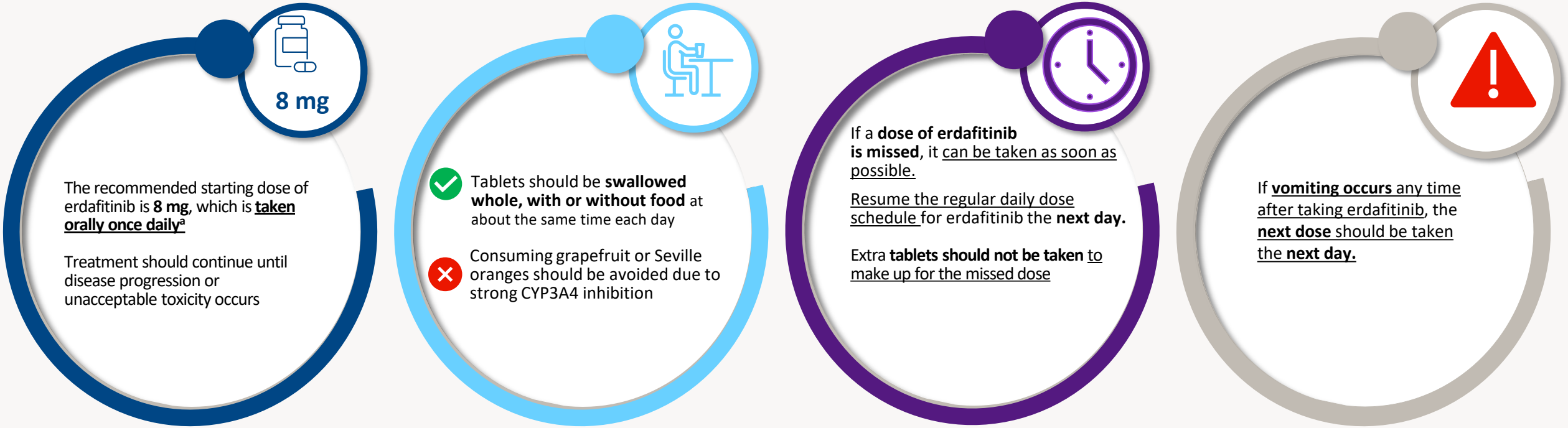
Figure based on Loriot Y, et al. 2023. Study in protocol supplement and Erdafitinib Summary of Product Characteristics [1,2]

[a]Up-titre the dose to 9 mg once daily if the serum PO_4 level is <9.0 mg/dl (<2.91 mmol/l) and there is no drug-related toxicity. If the PO_4 level is 9.0 mg/dl or higher, follow relevant dose modifications as described in the erdafitinib SmPC (section 4.2). After Day 21, serum PO_4 level should not be used to guide up-titration decision.[2]

PO_4, phosphate; SmPC: Summary of Product Characteristics

1. Loriot Y, et al. *N Engl J Med*. 2023;389(21):1961–1971. Study protocol in supplement. 2. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Erdafitinib **dosage and administration**[1*]

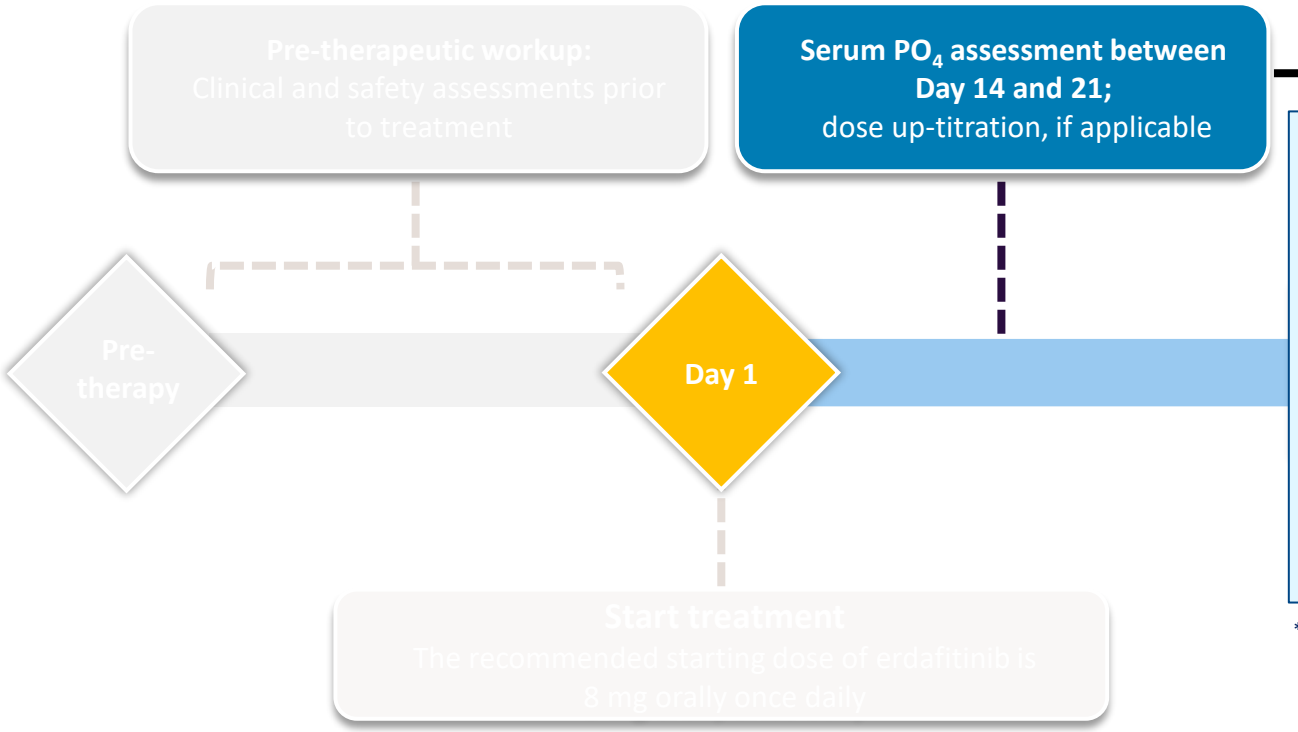


Care should be taken to **avoid interaction with other medicinal products and other forms of interaction**.**

*Para ver la información completa relativa a posología y forma de administración consulte la sección 4.2 de la Ficha Técnica de erdafitinib.
** Para ver la información completa relativa a Interacción con otros medicamentos y otras formas de interacción consulte la sección 4.5 de la Ficha Técnica de erdafitinib.

[a]Up-titre the dose to 9 mg once daily if the serum PO_4 level is <9.0 mg/dl (<2.91 mmol/l) and there is no drug-related toxicity. If the PO_4 level is 9.0 mg/dl or higher, follow relevant dose modifications as described in the erdafitinib SmPC (section 4.2). After Day 21, serum PO_4 level should not be used to guide up-titration decision.[1]
PO_4, phosphate. CYP3A4: Citocromo P450 familia 3 subfamilia A miembro 4.
1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

PO_4 assessment and erdafitinib dose up-titration[1,2]



- **Up-titre** the dose to **9 mg** once daily if the serum **PO_4 level is <9.0 mg/dl** (<2.91 mmol/l) and there is no drug-related toxicity. [2]
- If the **PO_4 level is 9.0 mg/dl or higher**, follow relevant **dose modifications** as described in the erdafitinib SmPC (section 4.2). [2*]
- **After Day 21,** serum **PO_4 level** should not be used to guide up-titration decision.[2]

*Para más información consulte la sección 4.2 de la Ficha Técnica.

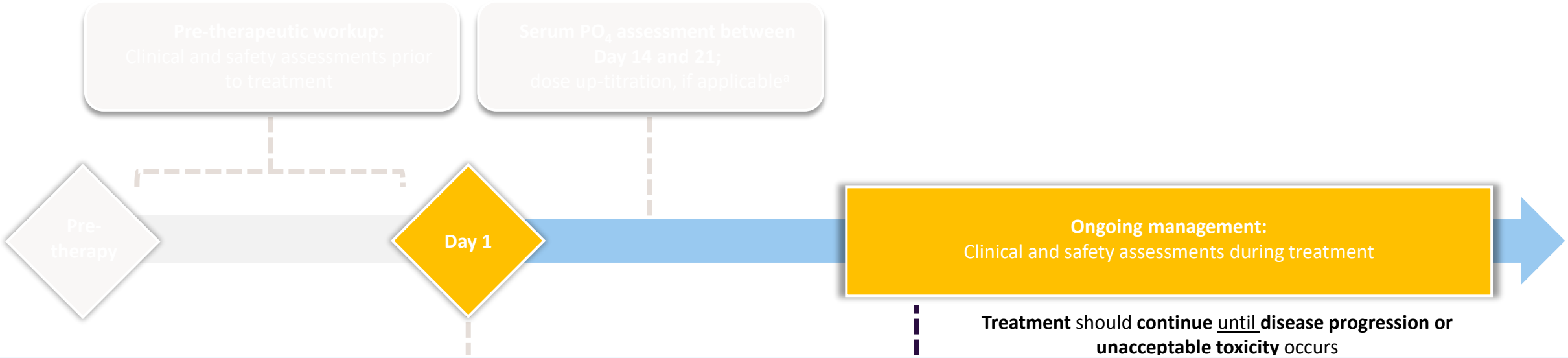
Figure based on Loriot Y, et al. 2023. Study in protocol supplement and Erdafitinib Summary of Product Characteristics [1,2]

Para ver la información completa relativa a posología y forma de administración consulte la sección 4.2 de la Ficha Técnica de erdafitinib.

PO_4, phosphate; SmPC: Summary of Product Characteristics

1. Loriot Y, et al. *N Engl J Med*. 2023;389(21):1961–1971. Study protocol in supplement. 2. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Clinical and safety assessments during treatment[1,2]



- **Ophthalmological examinations** [2] **:**
  - Perform **monthly** ophthalmological examinations including an Amsler grid test during the **first 4 months** of treatment**, every 3 months afterwards**, and urgently at any time for visual symptoms. [2]
    - **Ophthalmological examination should include** assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography. [2]
- **Physical examination, vital signs, haematology, chemistry** assessments[1]
  - Creatinine elevations, hyponatraemia, transaminase elevations, and anaemia have been reported in patients receiving erdafitinib. **Complete blood counts** and **serum chemistries** should be **performed regularly** during treatment with erdafitinib to monitor for these changes. [2]
    - **Serum PO_4 should be monitor monthly** [2]
- Continuous monitoring for **AEs**[1, 2]

Figure based on Loriot Y, et al. 2023. Study in protocol supplement and Erdafitinib Summary of Product Characteristics [1,2]

PO_4, phosphate.

1. Loriot Y, et al. *N Engl J Med*. 2023;389(21):1961–1971. Study protocol in supplement. 2. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

2. **Management of AEs** in patients treated with erdafitinib

General erdafitinib dose reduction levels and dose modification guidelines based on erdafitinib-related toxicity[1]*

Erdafitinib dose reduction schedule

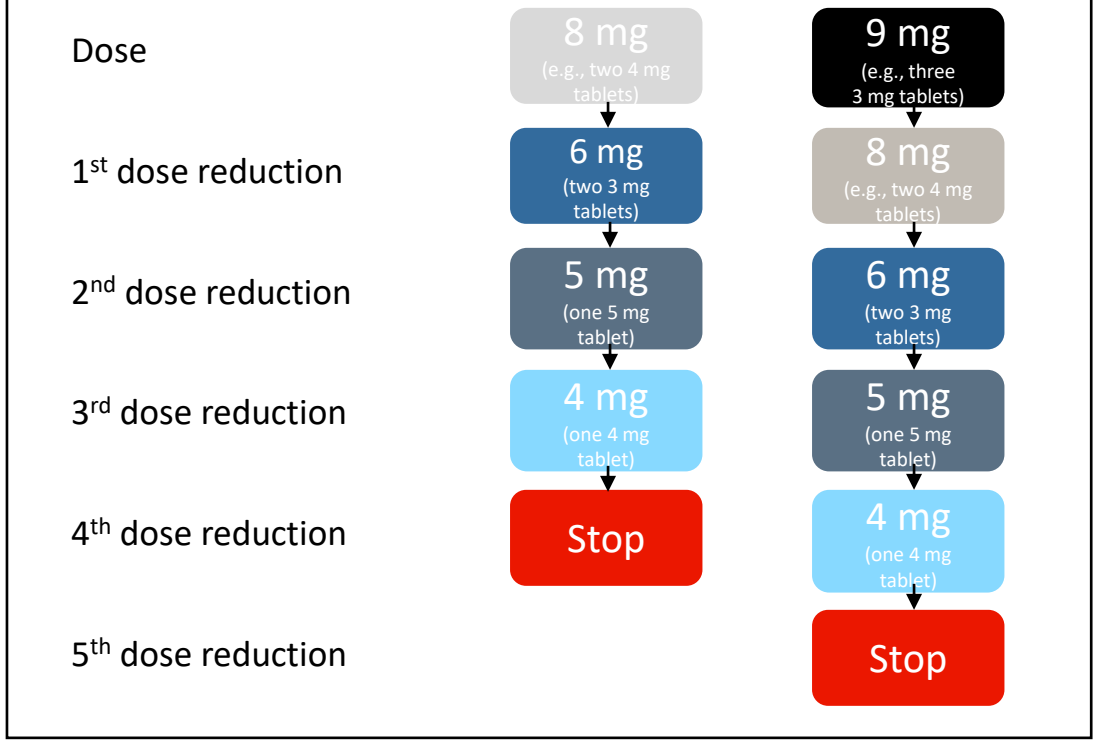


Figure based on Table 1 -Section 4.2.-Erdafitinib Summary of Product Characteristics.

Ver la pauta recomendada de reducción de dosis en las tablas 1 a 5, sección 4.2, de la Ficha Técnica.

Erdafitinib dose modification

Dose modifications for **specific AEs** are outlined in the SmPC (section 4.2)** and summarised in the following slides *(hyperphosphataemia; eye disorders; nail, skin and mucosal changes)*

**Para más información consulte la sección 4.2 de la Ficha Técnica.

Recommended dose modifications for **other** adverse reactions with use of erdafitinib

Other adverse reactions [a]	
Grade 3	**Withhold erdafitinib** until toxicity **resolves to Grade 1 or baseline**, then may resume erdafitinib at the **next lower dose.**
Grade 4	**Permanently discontinue**.

Figure based on Table 5 -Section 4.2.-Erdafitinib Summary of Product Characteristics.

[a] Dose adjustment graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAEv5.0).

*Para ver la información completa relativa a posología y forma de administración consulte la sección 4.2 de la Ficha Técnica de erdafitinib.

AE, adverse event; PO_4, phosphate; SmPC: Summary of Product Characteristics

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Management of some AEs in patients treated with erdafitinib[1*]

- **Hyperphosphataemia management**
- **Eye disorder management**
- **Skin disorders**
- **Nail disorders**
- **Mucosal disorders**

Click to navigate to each section

*Para ver la información completa relativa al manejo de efectos adversos en pacientes tratados con erdafitinib, por favor consulte la Ficha Técnica.

AE, adverse event

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Hyperphosphataemia management

Hyperphosphataemia[1]

- Hyperphosphataemia is an **expected**, **transient pharmacodynamic effect of FGFR inhibitors.**
- **Monitor for hyperphosphataemia throughout treatment.** Phosphate concentrations should be **assessed prior to the first dose** and then **monitored monthly.**
- Hyperphosphataemia was reported as an adverse event in **78.5% of patients** treated with erdafitinib.

- Hyperphosphataemia was **reported early during erdafitinib** treatment, with **most events occurring** within the **first 3-4 months** and **Grade 3 events** occurring within the **first month**.
- The median onset time for any grade event of hyperphosphataemia was 16 days.

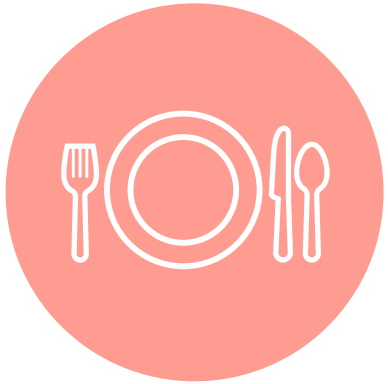
Prolonged hyperphosphataemia can lead to:

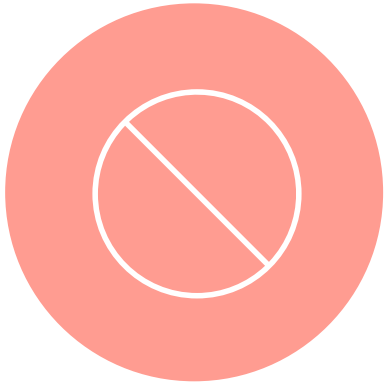
- Soft tissue mineralisation
- Cutaneous calcinosis
- Non-uraemic calciphylaxis
- Hypocalcaemia
- Anaemia
- Secondary hyperparathyroidism
- Muscle cramps
- Seizure activity
- QT interval prolongation
- Arrhythmias

El perfil de seguridad se basa en los datos acumulados de 479 pacientes con carcinoma urotelial localmente avanzado irresecable o metastásico que fueron tratados con erdafitinib en estudios clínicos.
Para más información consulte la sección 4.8 de la Ficha Técnica de erdafitinib.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Hyperphosphataemia:
Considerations for patients on erdafitinib[1]





Dietary phosphate intake (600-800 mg daily) should be restricted and **concomitant use of agents that may increase serum phosphate levels** should be avoided for **serum phosphate levels ≥5.5 mg/dL.**

Supplementation with **vitamin D** in patients receiving erdafitinib is not recommended due to potential contribution to increased serum phosphate and calcium levels

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Recommended **dose modifications** based on serum phosphate concentrations with the use of erdafitinib after up-titration. [1*]

- For **elevated phosphate concentrations** in patients treated with erdafitinib **dose modification guidelines in Table 2-Erdafitinib SmPC** should be followed.
- For **persistently elevated phosphate concentrations**, adding a **non-calcium containing phosphate binder** (e.g., sevelamer carbonate) should be considered as needed (see Table 2-Erdafitinib SmPC).

Serum phosphate concentration	Erdafitinib management
For phosphate concentrations ≥5.5 mg/dL (1.75 mmol/L), restrict phosphate intake to 600- 800 mg/day.	
<6.99 mg/dL (<2.24 mmol/L)	• Continue erdafitinib at current dose.
7.00-8.99 mg/dL (2.25-2.90 mmol/L)	• Continue erdafitinib treatment. • Start phosphate binder with food until phosphate level is <7.00 mg/dL. • A dose reduction should be implemented for a sustained serum phosphate level of ≥7.00 mg/dL for a period of 2 months or in the presence of additional adverse events or additional electrolyte disturbances linked to prolonged hyperphosphataemia.
9.00-10.00 mg/dL (2.91-3.20 mmol/L)	• Withhold erdafitinib treatment until serum phosphate level returns to <7.00 mg/dL (weekly testing recommended). • Start phosphate binder with food until serum phosphate level returns to <7.00 mg/dL. • Re-start treatment at the same dose level (see erdafitinib SmPC-Table 1). • A dose reduction should be implemented for sustained serum phosphate level of ≥9.00 mg/dL for a period of 1 month or in the presence of additional adverse events or additional electrolyte disturbances linked to prolonged hyperphosphataemia.
>10.00 mg/dL (>3.20 mmol/L)	• Withhold erdafitinib treatment until serum phosphate level returns to <7.00 mg/dL (weekly testing recommended). • Re-start treatment at the first reduced dose level (see erdafitinib SmPC-Table 1). • If serum phosphate level of ≥10.00 mg/dL is sustained for >2 weeks, erdafitinib should be discontinued permanently. • Medical management of symptoms as clinically appropriate (see erdafitinib SmPC-Section 4.4).
Significant alteration from baseline renal function or Grade 3 hypocalcaemia due to hyperphosphataemia.	• Erdafitinib should be discontinued permanently. • Medical management as clinically appropriate.

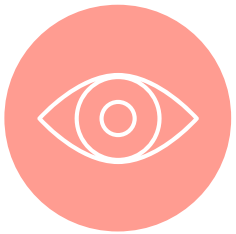
Elaborado a partir de la Tabla 2 de la sección 4.2 de la Ficha Técnica.
*Para más información consultar la sección 4.2 de la Ficha Técnica.

SmPC: Summary of Product Characteristics

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Eye disorder management

Eye disorders [1]



Erdafitinib can cause ocular disorders, including central serous retinopathy (CSR) (a grouped term including retinal pigment epithelial detachment (RPED)) **resulting in visual field defect.**

Prior to initiating erdafitinib, a **baseline ophthalmological exam** including an Amsler grid test, fundoscopy, visual acuity and, if available, an OCT should be performed.

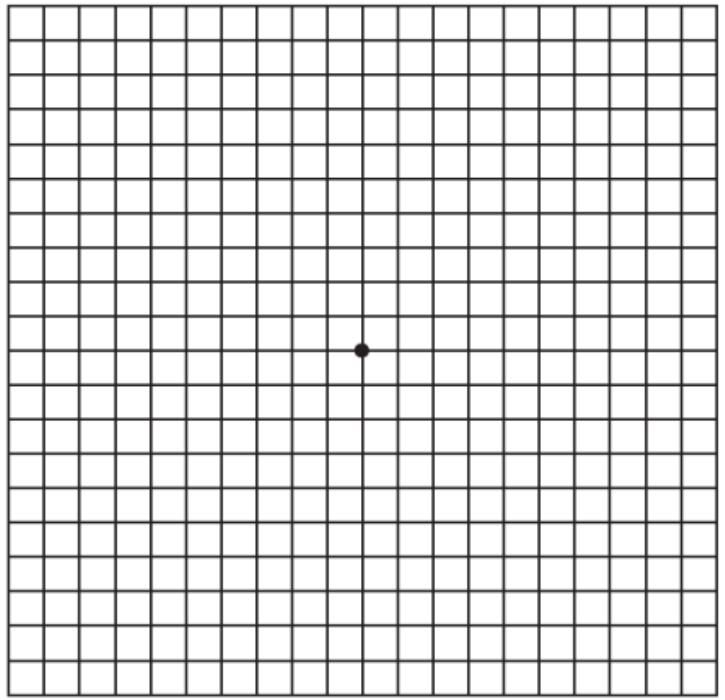
Close clinical monitoring is recommended in patients aged ≥65 years as well as with patients that have clinically significant medical eye disorders (such as retinal disorders, including but not limited to, central serous retinopathy, macular/retinal degeneration, diabetic retinopathy, and previous retinal detachment).

CRS, central serous retinopathy; OCT, optical coherence tomography.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Ophthalmological examinations for patients treated with erdafitinib [1,2]

- Perform monthly **ophthalmological examinations** including an Amsler grid test during the first 4 months of treatment and every 3 months afterwards, and urgently at any time for visual symptoms[1].
- If any **abnormality is observed**, follow the management guidelines in Table 3-Erdafitinib SmPC[1].
- **Ophthalmological examination should include** assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography[1].
- **Close monitoring** including clinical ophthalmological examinations should be performed in patients who have restarted erdafitinib after an ocular adverse event[1].



Amsler Grid. Loriot Y, et al. *N Engl J Med*. 2023;389(21):1961–1971. Study protocol in supplement. Attachment 4- Amendment 6.

Observation of wavy, broken or distorted lines, or a blurred/missing area of vision is equivalent to a positive Amsler grid test. [2]

SmPC: Summary of Product Characteristics

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025. 2. Loriot Y, et al. *N Engl J Med.* 2023;389(21):1961–1971. Study protocol in supplement. Amendment 6.

Central serous retinopathy [1]

- Adverse reactions of **CSR were reported in 31.5% of patients** with a median time to first onset, for an event of any grade, of **51 days**[1].
- The most commonly reported events were *vision blurred, chorioretinopathy, detachment of RPE, visual acuity reduced, visual impairment, retinal detachment, retinopathy,* and *subretinal fluid*[1].
- **Grade 3 or 4** CSR was reported in **2.7% of patients**[1].
- The majority of central serous retinopathy events occurred within the first 90 days of treatment[1].
- At the time of data cutoff, CSR had resolved for 43.0% of patients[1].
- When **CSR occurs erdafitinib should be withheld** and **permanently discontinued** if it does not resolve within 4 weeks or if Grade 4 in severity[1]

Other eye disorders [1]

- **Eye disorders** (other than central serous retinopathy) were reported in **36.3%** of patients.[1]
- The median time to first **onset** for eye disorders was **53 days.**[1]
- The **most commonly reported** events were dry eye (16.7%), conjunctivitis (9.8%) and lacrimation increased (9.2%).[1]
- **Dry eye symptoms** were Grade 3 or 4 in **0.3%** of patients[1].
  - **Prophylactic management:**
    All patients should receive dry eye prophylaxis or treatment with ocular demulcents (*e.g., artificial tear substitutes, hydrating or lubricating eye gels or ointment*) **at least every 2 hours during waking hours.**[1]
  - Severe treatment-related dry eye should be evaluated by an ophthalmologist.[1]

El perfil de seguridad se basa en los datos acumulados de 479 pacientes con carcinoma urotelial localmente avanzado irresecable o metastásico que fueron tratados con erdafitinib en estudios clínicos.
Para más información consulte la sección 4.8 de la Ficha Técnica de erdafitinib.

CSR, central serous retinopathy; SmPC: Summary of Product Characteristics

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Guideline for management of eye disorders with use of erdafitinib [1*]

- Treatment with erdafitinib should be discontinued or modified based on erdafitinib-related toxicity as described in Table 3-Erdafitinib SmPC.

Severity grading	Erdafitinib dose management
Grade 1 Asymptomatic or mild symptoms; clinical or diagnostic observations only, or abnormal Amsler grid test.	• Refer for an ophthalmologic examination (OE). If an OE cannot be performed within 7 days, withhold erdafitinib until an OE can be performed. • If no evidence of eye toxicity on OE, continue erdafitinib at same dose level. • If diagnosis from OE is keratitis or retinal abnormality (e.g., CSR[a]), withhold erdafitinib until resolution. If reversible in 4 weeks on OE, resume at next lower dose. • Upon restarting erdafitinib, monitor for recurrence every 1-2 weeks for a month and as clinically appropriate thereafter. Consider dose reescalation if no recurrence.
Grade 2 Moderate; limiting age appropriate instrumental activities of daily living (ADL).	• Immediately withhold erdafitinib and refer for an OE. • If there is no evidence of eye toxicity, resume erdafitinib therapy at the next lower dose level upon resolution. • If resolved (complete resolution or stabilisation and asymptomatic) within 4 weeks on OE, resume erdafitinib at the next lower dose level. • Upon restarting erdafitinib, monitor for recurrence every 1 to 2 weeks for a month and as clinically appropriate thereafter.
Grade 3 Severe or medically significant but not immediate sight-threatening; limiting self-care ADL.	• Immediately withhold erdafitinib and refer for an OE • If resolved (complete resolution or stabilisation and asymptomatic) within 4 weeks, then erdafitinib may be resumed at 2 dose levels lower. • Upon restarting erdafitinib, monitor for recurrence every 1 to 2 weeks for a month and as clinically appropriate thereafter. • Consider permanent discontinuation of erdafitinib for recurrence
Grade 4 Sight-threatening consequences; blindness (20/200 or worse).	• Permanently discontinue erdafitinib. • Monitor until complete resolution or stabilisation.

[a]CSR, central serous retinopathy, see section 4.4- Erdafitinib SmPC;

Elaborado a partir de la Tabla 3 de la sección 4.2 de la Ficha Técnica.

*Para más información consultar la sección 4.2 de la Ficha Técnica.

When **CSR** occurs, **erdafitinib should be withheld** and **permanently discontinued** if it does not resolve within 4 weeks, or if Grade 4 in severity.

OE, ophthalmological examination. SmPC: Summary of Product Characteristics

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Skin disorders management

Skin disorders during treatment with erdafitinib [1]

- **Skin disorders** including dry skin, palmar-plantar erythrodysaesthesia (PPES) syndrome, alopecia and pruritus can occur very commonly with erdafitinib treatment[1].
- Skin disorders were reported in **54.5%** of patients[1].
- The **most commonly** reported events were **dry skin** (28%), and **palmar-plantar erythrodysaesthesia syndrome** (25.5%)[1].
- The median time to onset for any grade skin disorder was 47 days[1].
- Patients should be monitored and **provided supportive care such as:**
  - Avoiding unnecessary exposure to sunlight
  - Avoiding excessive use of soap and bathing
  - Patients should use moisturisers regularly
  - Avoid perfumed products.

El perfil de seguridad se basa en los datos acumulados de 479 pacientes con carcinoma urotelial localmente avanzado irresecable o metastásico que fueron tratados con erdafitinib en estudios clínicos.
Para más información consulte la sección 4.8 de la Ficha Técnica de erdafitinib.

PPES, palmar-plantar erythrodysaesthesia; SmPC: Summary of Product Characteristics.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Recommended dose modifications for skin adverse reactions with use of erdafitinib [1*]

Severity of adverse reaction	Erdafitinib dose management
Dry skin and skin toxicity	
Grade 1	• Continue erdafitinib at current dose.
Grade 2	• Continue erdafitinib at current doce.
Grade 3	• Withhold erdafitinib (for up to 28 days), with weekly reassessments of clinical condition. • When resolves to ≤Grade 1 or baseline, restart at next lower dose.
Grade 4	• Discontinue erdafitinib.

Elaborado a partir de la Tabla 4 de la sección 4.2 de la Ficha Técnica. Ver tabla completa en la Tabla 4 de la sección 4.2 de la Ficha Técnica anexa al material.
*Para más información consultar la sección 4.2 de la Ficha Técnica.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Nail disorders management

Nail disorders [1]

- **Nail disorders** including **onycholysis**, **nail discolouration** and **paronychia** can occur very commonly with erdafitinib treatment[1].
- Nail disorders were reported in **62.6%** of patients[1].
- The **most commonly reported** events included[1]: onycholysis (21.7%), nail discoloration (15.9%), paronychia (12.5%), nail dystrophy (11.9%) and onychomadesis (11.5%).
- The incidence of nail disorders increased after the first month of exposure. The median time to **onset** for any grade nail disorder was **63 days**[1].

- Patients should be **monitored for signs and symptoms of nail toxicities.** [1]
- Patients should be advised on **preventative treatment such as**[1]**:**

  - Good hygiene practices
  - Over-the-counter nail strengthener as needed
  - Monitor for signs of infection.

El perfil de seguridad se basa en los datos acumulados de 479 pacientes con carcinoma urotelial localmente avanzado irresecable o metastásico que fueron tratados con erdafitinib en estudios clínicos.
Para más información consulte la sección 4.8 de la Ficha Técnica de erdafitinib.

SmPC: Summary of Product Characteristics

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Recommended dose modifications for **nail adverse reactions** with use of erdafitinib [1] *

Severity of adverse reaction	Erdafitinib dose management
Nail disorder	
Grade 1	• Continue erdafitinib at current dose.
Grade 2	• Withhold erdafitinib with reassessment in 1-2 weeks. • If first occurrence and it resolves to ≤Grade 1 or baseline within 2 weeks, restart at same dose. • If recurrent event or takes >2 weeks to resolve to ≤Grade 1 or baseline, then restart at next lower dose.
Grade 3	• Withhold erdafitinib, with reassessment in 1-2 weeks. • When resolves to ≤Grade 1 or baseline, restart at next lower dose.
Grade 4	• Discontinue erdafitinib.

Elaborado a partir de la Tabla 4 de la sección 4.2 de la Ficha Técnica. Ver tabla completa en la Tabla 4 de la sección 4.2 de la Ficha Técnica anexa al material.
*Para más información consultar la sección 4.2 de la Ficha Técnica.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Mucosal disorders management

Mucosal disorders [1]

- **Stomatitis** and **dry mouth** can occur very commonly with erdafitinib treatment[1].
- Stomatitis was reported in **52,8%** of patients, and dry mouth in the **39,9%**[1].

- Patients should be counselled to **seek medical attention should symptoms worsen.**
- Patients should be **monitored and provided supportive care as such as:**
  - Good oral hygiene
  - Baking soda mouthwashes 3 or 4 times per day as needed
  - Avoidance of spicy and/or acidic foods

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Recommended dose modifications for **dry mouth** with use of erdafitinib [1] *

Severity of adverse reaction	Erdafitinib dose management
Dry mouth	
Grade 1	• Continue erdafitinib at current dose.
Grade 2	• Continue erdafitinib at current dose
Grade 3	• Withhold erdafitinib (for up to 28 days), with weekly reassessments of clinical condition. • When resolved to ≤Grade 1 or baseline, restart at next lower dose.

Elaborado a partir de la Tabla 4 de la sección 4.2 de la Ficha Técnica. Ver tabla completa en la Tabla 4 de la sección 4.2 de la Ficha Técnica anexa al material.
*Para más información consultar la sección 4.2 de la Ficha Técnica.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Recommended dose modifications for **oral mucositis** with use of erdafitinib [1] *

Severity of adverse reaction	Erdafitinib dose management
Oral mucositis	
Grade 1	• Continue erdafitinib at current doce.
Grade 2	• Withhold erdafitinib if the subject has other concomitant erdafitinib related Grade 2 adverse reactions. • Withhold erdafitinib if the subject was already on symptom management for more than a week. • If erdaftinib is withheld, reassess in 1-2 weeks. • If this is the first occurrence of toxicity and resolves to ≤Grade 1 or baseline within 2 weeks, restart at same dose. • If recurrent event or takes >2 weeks to resolve to ≤Grade 1 or baseline, then restart at next lower dose.
Grade 3	• Withhold erdafitinib, with reassessments of clinical condition in 1-2 weeks. • When resolves to ≤Grade 1 or baseline, restart at next lower dose.
Grade 4	• Discontinue erdafitinib.

Elaborado a partir de la Tabla 4 de la sección 4.2 de la Ficha Técnica. Ver tabla completa en la Tabla 4 de la sección 4.2 de la Ficha Técnica anexa al material.
*Para más información consultar la sección 4.2 de la Ficha Técnica.

1. European Medicines Agency. Erdafitinib Summary of Product Characteristics. Updated February 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/balversa-epar-product-information_en.pdf. Accessed July 2025.

Ficha Técnica disponible en: https://static.janssen-emea.com/sites/default/files/Spain/SMPC/ES-PL-0241.pdf

Para mayor información acerca del manejo de erdafitinib consulte la Ficha Técnica.

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