

SAFETY OF HORMONE THERAPY WITH ABEMACICLIB IN HER2 NEGATIVE ADVANCED LUMINAL BREAST CANCER

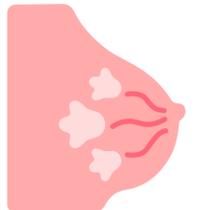
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Background and importance

- **Abemaciclib** is a CDK4/6 inhibitor (CDKi) indicated for treatment of **HER2- advanced luminal breast cancer (ALBC)**. Its **safety profile** is **decisive** in clinical practice.



Aim and objectives

- To analyse abemaciclib's safety and its impact on treatment course of patients with HER2- ALBC.

Materials and methods

- Design: multicentric, observational, descriptive and retrospective study.
- Inclusion criteria: Cáceres and Badajoz patients who started abemaciclib during 1/7/17-31/3/24.
- Exclusion criteria: early-stage patients starting adjuvant treatment.
- Follow-up period: from 1/7/17 to 31/3/25.
- Data: age at abemaciclib beginning, medical history, adverse events (AEs) classified per CTCAE, treatment suspensions, dose reductions and switches to another CDKi.
- Data collection and processing: electronic health record, Farmatools® and Excel®.

Results

- 64 patients met the inclusion criteria and finally **30 women** resulted after exclusion criteria applied.
- Median age at beginning: **59 years** (IQR:55.25–71.5).
- Comorbidities: hypertension (10), dyslipidemia (10), smoking (10), cardiovascular events (4), diabetes (4), other neoplasms (6), and one immune-mediated disease.

Table 1. Recorded AEs by grade

Adverse Event	Grade <3 (%)	Grade ≥3 (%)	Adverse Event	Grade <3 (%)	Grade ≥3 (%)
Diarrhoea	46.7	10.0	Constipation	<7	3.3
Asthenia/Fatigue	30.0	6.7	Alopecia	<7	—
Hyporexia/Anorexia	20.0	—	Headache	<7	—
Anaemia	16.7	3.3	Dysgeusia	<7	—
Skin Rash	16.7	6.7	Lymphoedema	<7	—
Infections	16.7	6.7	Renal Damage	<7	3.3
Hypertransaminasaemia	13.3	6.7	Pneumonitis	<7	—
Nausea	10.0	3.3	Epigastric Pain	<7	—
Thrombocytopenia	10.0	3.3	Hyperbilirubinaemia	—	6.7
Musculoskeletal Pain	10.0	3.3	Pulmonary	—	3.3
Onychopathy	10.0	—	Thromboembolism (PTE)	—	3.3
Neutropenia	10.0	3.3	Fever	—	3.3
Vomiting	<7	—	Dyspnoea	—	3.3
			Arterial Hypotension	—	3.3

The implications of these AEs during the course of therapy:

- Dose reductions due to toxicity: 33.3% of cases.
- Temporary suspensions due to toxicity: 43.3% of cases.
- Permanent suspensions due to toxicity: 23.3% of cases, of which 85.7% switched to another CDKi.

Conclusion and relevance

- The **most common AEs** of any grade was **diarrhoea**, followed by **asthenia/fatigue**.
- **Serious** but **uncommon** AEs included **PTE, neutropenia, pneumonitis**.
- These AEs meant that **more than 40%** of patients had to **temporarily suspend** treatment, in **more than 30%** the **dose** was **reduced**, and **more than 20%** **permanently suspended treatment to switch to another CDKi**.

