
# INTENSIVE MONITORING OF AFATINIB A CASE REPORT

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## BACKGROUND

The implementation of intensive monitoring programs allows identification of early occurrence of Adverse Drug Reactions (ADR), in a comprehensive and exhaustive way. Afatinib was included in this Pharmacovigilance Program (PP), which involves patient follow-up, carried out by pharmacists, to monitor the safety use of new drugs.
The aim of this study was the analysis of the results the PP of afatinib. We analyzed a the follow-ups of a 88 year old patient treated with afatinib. Data were collected by consulting the patient's clinical file and monitoring records of the Pharmaceutical Department.

## RESULTS

### Patient characterization

Female patient, 88 years old, caucasian, diagnosed with non-small cell lung cancer, with pleural metastasis and EGFR+. Started a 1st line treatment in December 2016 with oral vinorelbine, which was suspended on April 2017 due to gastrointestinal intolerance. Started Afatinib 40mg on April 2017 and was included in the PP.

| Follow-up | Date | Adverse Effects | Adopted measures |
|---|---|---|---|
| **1** | May 2017 | Erythematous/ acneiform skin reaction dispersed in limbs and trunk, intense pruritus, nausea and ocular complaints. | Therapeutic with afatinib was maintained.<br>Increase oversight.<br>ADRs were reported to the National Pharmacovigilance Unit. |
| **2** | June 2017 | Intensification of the ocular symptoms. | Therapeutic with afatinib was maintained.<br>Patient was referred to ophthalmology consult. |
| **3** | July 2017 | The ophthalmology consult resulted in the diagnostic of keratitis with ulceration in the left eye. | The threatment was suspended in August 2017. |
| **4** | November 2017 | Improvement of the adverse effects. | Afinitab was reintroduced with dose reduction to 30 mg. |
| **5/6/7** | December 2017 to February 2018 | No adverse effects reported. | None taken. |
| **8** | March 2018 | Numbness, rash and edema of the face. | Maintain therapy and increase oversight. |
| **9** | April 2018 | Increase of the symptomatology. | The threatment was suspended.<br>ADRs were reported to the National Pharmacovigilance Unit.<br>An imaging control of the disease was programed to further the decision about the treatment. In July, there was evidence of biochemical progression, and the therapy was permanently discontinued therapy. |

## CONCLUSION

The early approval of drugs that covers therapeutic gaps reveals the necessity to implement effective and systematic methodologies that allow the surveillance of their use. Monitoring by the pharmacist promotes and contributes to safety and adherence to the use of medicines. The monitorisation of the therapeutics by the pharmacist is thus of extreme importance for these new drugs, as not only promotes and contributes to safe use of these drugs but contributes to the compliance to the drug therapy.

## REFERENCES

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