July 2017

Aflibercept (Zaltrap▼) concentrate for solution for infusion 200 mg/8 mL: some batches contain previous Patient Information Leaflet; inform patients of warnings for heart failure

Dear Healthcare Professional,

Summary

- You may receive a batch (BN6F014A) of Aflibercept (Zaltrap▼) 200 mg/8 mL with a previous Patient Information Leaflet (PIL)
- Inform patients about the warnings for heart failure and decreased ejection fraction, including symptoms of these conditions and the need to inform a healthcare professionals before or during treatment if they occur

Background
Following the recent implementation of an updated Patient Information Leaflet (PIL) for Zaltrap concentrate for solution for infusion 200 mg/8 mL, you may receive the following batch of product where the PIL has not been updated:

BN6F014A - expiry date 05/2019

You may have already received batches containing the latest version of the PIL and therefore we wish to notify you of the changes between the two different versions.

A safety variation was approved by the European Medicines Agency (EMA) on 24 October 2016 to update sections 4.2 (Posology and method of administration), 4.4 (Special warnings and precautions for use) and 4.8 (Undesirable effects) of the Summary of Product Characteristics (SmPC) to include the adverse reactions 'cardiac failure' and 'ejection fraction decreased' and to recommend the discontinuation of Zaltrap in case these adverse reactions occur. The following additions were made to the PIL:

Section 2 – Warnings and precautions
- *Talk to your doctor, pharmacist or nurse before you are given Zaltrap and during your treatment if you experience shortness of breath (dyspnea) when you exert yourself or when you lie down, excessive tiredness or leg swelling which may be signs of heart failure.*

Section 4 – Adverse events
- ***Heart failure** (also called cardiac failure); **Uncommon** (may affect up to 1 in 100 people) – Signs may include shortness of breath when you lie down or when you exert yourself, excessive tiredness or leg swelling.*

The latest version of the Summary of Product Characteristics and the Patient Information Leaflet containing the above additional safety information can be found on the EMC website.

The MHRA have reviewed the changes to the PIL, and agreed that a withdrawal of the batches which have been manufactured and packaged with the older PIL was not necessary; therefore, this is a courtesy letter to make you aware of the updated PIL.

▼ZALTRAP is subject to additional monitoring. This will allow quick identification of new safety information. Adverse Events should be reported. Reporting forms and information can be found at:
www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Sanofi Tel: 0800 0902314

If you would like any further information regarding the above please contact:
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Yours faithfully,

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