

Preventive measure regarding the detection of an impurity in medicines containing the active substance valsartan

Dear Doctors and Pharmacists,

Denk Pharma puts the patients' safety above all, and complying with that belief we want to inform you that, on behalf of our patients' safety, Denk Pharma is taking action. As a preventive measure we are performing a recall of all of our products containing the active substance valsartan:

- Valsar-Denk 40mg
- Valsar-Denk 80mg
- Valsar-Denk 160mg
- Valsar-Denk 320mg
- CoValsar-Denk 80mg/12.5mg (combination of valsartan/hydrochlorothiazide)
- CoValsar-Denk 160mg/12.5mg (combination of valsartan/hydrochlorothiazide)
- CoValsar-Denk 320mg/12.5mg (combination of valsartan/hydrochlorothiazide)
- Amva Denk 5mg/80mg (combination of amlodipine/valsartan)
- Amva Denk 5mg/160mg (combination of amlodipine/valsartan)
- Amva Denk 10mg/160mg (combination of amlodipine/valsartan)
- Amva +HCT Denk 5mg/160mg/12.5mg (combination of amlodipine/valsartan/hydrochlorothiazide)
- Amva +HCT Denk 10mg/160mg/12.5mg (combination of amlodipine/valsartan/hydrochlorothiazide)
- Amva +HCT Denk 10mg/160mg/25mg (combination of amlodipine/valsartan/hydrochlorothiazide)

The European Medicines Agency (EMA) is reviewing medicines containing the active substance valsartan due to an impurity detected in the valsartan active substance. The review of this impurity and its potential impact for the patients is being carried out by the Committee for Medicinal Products for Human Use (CHMP). Until the EMA has issued a final conclusive decision of this review we have decided to recall our valsartan-containing products as a precaution.

The impurity of the active substance valsartan has affected many European pharmaceutical distributors, therefore it is possible that an "out-of-stock" situation of Valsartan Medicines can happen in your region, regardless of the manufacturer, which could have an impact on the availability of the medicine in your country.

We put the following measures at your disposal so that you are prepared

1. According to the EMA patients should not stop taking their valsartan medicine unless they are told so by their treating physician. This is because the immediate risks of abruptly stopping the medicine far outweighs the long-term risks of the impurity itself.
2. Doctors should consider, due to a potential worldwide "shortage" of valsartan, a long-term treatment alternative that replaces valsartan. For example with another ARB product, like Losar-Denk or CoLosar-Denk, depending on the patients' medical history.

Please rest assured that we will keep you posted as soon as any further official information is made available.

Yours sincerely,

Stephan Huber, CEO