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Unser Zeichen: PHV-8313157-A-151103-EUIM
Ihr Zeichen:

PHV-issue: HMG-CoA Reduktasehemmer (Statine)

Sehr geehrte Damen und Herren,

Infolge der PhVWP recommendation, vom Juli 2011, zur Änderung der Produktinformation von Fusidinsäure, kam das CMDh in der Sitzung vom Oktober 2015 zu dem Schluss, europaweit die Fach- und Gebrauchsinformation aller HMG-CoA Reduktasehemmer (Statine) zu ändern. (siehe: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2015/10_2015.pdf)



Agreed harmonised text:

SmPC

Section 4.4

<Drug name> must not be co-administered with systemic formulations of fusidic acid or within 7 days of stopping fusidic acid treatment. In patients where the use of systemic fusidic acid is considered essential, statin treatment should be discontinued throughout the duration of fusidic acid treatment. There have been reports of rhabdomyolysis (including some fatalities) in patients receiving fusidic acid and statins in combination (see section 4.5). The patient should be advised to seek medical advice immediately if they experience any symptoms of muscle weakness, pain or tenderness.

Statin therapy may be re-introduced seven days after the last dose of fusidic acid.

In exceptional circumstances, where prolonged systemic fusidic acid is needed, e.g., for the treatment of severe infections, the need for co-administration of <product name> and fusidic acid should only be considered on a case by case basis and under close medical supervision.

Section 4.5

The risk of myopathy including rhabdomyolysis may be increased by the concomitant administration of systemic fusidic acid with statins. The mechanism of this interaction (whether it is pharmacodynamic or pharmacokinetic, or both) is yet unknown. There have been reports of rhabdomyolysis (including some fatalities) in patients receiving this combination.

If treatment with systemic fusidic acid is necessary, <name of statin> treatment should be discontinued throughout the duration of the fusidic acid treatment. **Also see section 4.4**

PACKAGE LEAFLET

Section 2. What you need to know before you <take> <use>

Warnings and precautions

Talk to your doctor <or> <,> <pharmacist> <or nurse> before <taking> <using> X

- If you are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and <Product name> can lead to serious muscle problems (rhabdomyolysis).

Other medicines and X

Tell your <doctor> <or> <pharmacist> if you are <taking> <using>, have recently <taken> <used> or might <take> <use> any other medicines.

- **If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart <Product name>. Taking <Product name> with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.**