Bundesamt für Sicherheit
im Gesundheitswesen

BASG / AGES
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Unser Zeichen: PHV-9280228-A-160811
Ihr Zeichen:

PHV-issue: Fenofibrat

Sehr geehrte Damen und Herren,

das CMDh kam zu dem Schluss europaweit auch die Fach- und Gebrauchsinformation aller Fenofibrat-hältigen Produkte zu ändern.
(siehe: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/cmdh_pressreleases/2016/07_2016_CMDh_Press_Release.pdf)

SmPC:

4.2 Posology and method of administration
(…)
Elderly patients (≥ 65 years old)
No dose adjustment is necessary. The usual dose is recommended, except for decreased renal function with estimated glomerular filtration rate < 60 mL/min/1.73 (see *Patients with renal impairment*).
Patients with renal impairment
Fenofibrate should not be used if severe renal impairment, defined as eGFR <30 mL/min per 1.73 m2, is present.
If eGFR is between 30 and 59 mL/min per 1.73 m2, the dose of fenofibrate should not exceed 100 mg standard or 67 mg micronized once daily.
If, during follow-up, the eGFR decreases persistently to <30 mL/min per 1.73 m2, fenofibrate should be discontinued.

4.3 Contraindications
(…)
Severe renal insufficiency (estimated glomerular filtration rate < 30 mL/min/1.73 m2)

4.4 Special warnings and precautions for use
(…)
Renal function
[Product Name] is contraindicated in severe renal impairment (see section 4.3).
[Product Name] should be used with caution in patients with mild to moderate renal insufficiency. Dose should be adjusted in patients whose estimated glomerular filtration rate is 30 to 59 mL/min/1.73 m2 (see section 4.2).
Reversible elevations in serum creatinine have been reported in patients receiving fenofibrate monotherapy or co-administered with statins. Elevations in serum creatinine were generally stable over time with no evidence for continued increases in serum creatinine with long term therapy and tended to return to baseline following discontinuation of treatment.

During clinical trials, 10% of patients had a creatinine increase from baseline greater than 30 µmol/L with co-administered fenofibrate and simvastatin versus 4.4% with statin monotherapy. 0.3% of patients receiving co-administration had clinically relevant increases in creatinine to values > 200 µmol/L.
Treatment should be interrupted when creatinine level is 50% above the upper limit of normal. It is recommended that creatinine is measured during the first 3 months after initiation of treatment and periodically thereafter.

Package leaflet:

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

Do not take <fenofibrate>:
(…)
- If you have severe kidney problems

(…)

Warnings and precautions:
Talk to your doctor or pharmacist before taking <fenofibrate> if:
(…)
- you have kidney disease

(…)

3. How to take <fenofibrate>
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will determine the appropriate strength for you, depending on your condition, your current treatment and your personal risk status.
(…)