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- **Table Note:** This table provides a summary of the data. The values are used for various calculations and analyses.
12.3 Pharmacokinetics

Absorption:

- Increases the rate of absorption of Tri glide approximately 55%.

Distribution:

- Fenofibric acid exposure is not influenced by age. Since elderly patients have a higher incidence of renal impairment, caution is advised and dose adjustment is recommended.

Metabolism:

- Fenofibric acid is extensively metabolized in the body. It is conjugated with glucuronic acid and eliminated in the urine. Approximately 60% of the dose appears in the urine, with 25% as fenofibric acid and 25% as its glucuronate conjugate.

Excretion:

- The renal route is the primary pathway of elimination of fenofibric acid. In patients with moderate or severe renal impairment, dose adjustment is recommended.

- The pharmacokinetics of fenofibric acid are not significantly affected by moderate inhibitors of CYP2C9, CYP2C19, and CYP3A4. They are weak inhibitors of CYP2C8 and CYP2C19, and mild-to-moderate inhibitors of CYP2C9 at therapeutic concentrations.

- Accumulation of fenofibric acid during chronic dosing is minimal compared to that of healthy subjects.

- The clearance of fenofibric acid shows a slight decrease with increasing age. Since elderly patients have a higher incidence of renal impairment, caution is advised and dose adjustment is recommended.

- The elimination half-life of fenofibric acid is approximately 10 to 15 days.

- Fenofibric acid is a pro-drug of the active chemical moiety fenofibrate, which is the active constituent measurable in the circulation.

- Fenofibrate is converted by ester hydrolysis in the body to fenofibric acid which is the active constituent measurable in the circulation.

- Fenofibrate is known to be substantially excreted by the kidney, and the risk of adverse events increases with increasing dosage in patients with renal impairment.

- Accumulation of fenofibric acid during chronic dosing compared to that of healthy subjects is minimal.

- The reproductive performance of rats was not impaired at any dose level tested.

- No significantly different inflammatory and immune cell parameters were observed in patients treated with fenofibrate.

- Table 2 describes the effects of co-administered drugs on fenofibric acid systemic exposure.

- The tablets are supplied as follows:
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