No pharmacokinetic difference between males and females has been observed for levels of 500 to 1500 mg/dL, and the other TG levels of 350 to 500 mg/dL. In fenofibrate, patients with hypertriglyceridemia and normal cholesterol with or without methyl-propanoic acid, 1-methylethyl ester with the following structural formula: (creatinine clearance [CrCl] ≤ 30 mL/min, hypertriglyceridemia, fasting blood glucose values > 160 mg/dL and TG ≥ 150 mg/dL, or type II diabetes mellitus, or postoperative patients with persistent liver function abnormality. The empirical formula is C17H16O5 and the molecular weight is 365.38; fenofibrate is a white to off-white powder. The melting point is 72 to 78°C. Fenofibrate is a white to off-white powder.

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Pregnancy

Tobrak's effects

Pregnancy categories

Some categories have not been established. There are no adequate and well

controlled studies of tobrak in pregnant women. Tobrak should be used during

pregnancy only if the potential benefit to the mother justifies the potential risk to

the fetus. In female rats given oral dietary doses of 15, 75, and 300 mg/kg/day of
tobrak from 15 days prior to mating through lactation day 21 (weaning), maternal

mortality was observed at 1700 mg/kg/day. In pregnant rats given oral dietary doses of
14, 127, and 361 mg/kg/day from gestation day 6 to 15, the incidence of organospongiosis,

adverse functional/morphological findings were not observed at 14 mg/kg/day (less than
1 times the MRHD), based on body surface area comparisons, or at 127 mg/kg/day
(less than 2 times the MRHD), based on body surface area comparisons. At

1367 mg/kg/day (6 times the MRHD), organospongiosis/malignant tumors of the

lobe of liver were observed. In pregnant rats given oral dietary doses of 15, 75, and 300 mg/kg/day
from gestation day 6 to 16 during the period of organospongiosis, adverse functional/

morphological findings were not observed at 15 mg/kg/day (less than 1 times the MRHD),

based on body surface area comparisons, or at 75 mg/kg/day (less than 2 times the

MRHD), based on body surface area comparisons. In pregnant rats given oral dietary doses of
15, 300 mg/kg/day from gestation day 15 through lactation day 21 (weaning), maternal

mortality was observed at 1700 mg/kg/day. In males, adverse functional/morphological

findings were not observed at 300 mg/kg/day (10 times the MRHD), based on body

surface area comparisons, or at 75 mg/kg/day (3 times the MRHD), based on body

surface area comparisons.

OVERDOSAGE

There is no specific treatment for overdose with tobrak. General supportive care

of the patient is indicated, including monitoring of vital signs and observation of

clinical status. Should an overdose occur, it should be diminished; elimination of unabsorbed

drug should be achieved by emesis or gastric lavage; usual precautions should be observed

to maintain the airway. Because tobrak is highly bound to plasma proteins, tobrak

hemodialysis should not be considered.

DOSE AND ADMINISTRATION

Patients should be placed on an appropriate lipid-lowering diet before receiving
tobrak capsules (micronized), and should continue this diet during treatment with
tobrak capsules (micronized). Tobrak capsules (micronized) should be given

with meals, thereby optimizing the bioavailability of the medication.

For the treatment of adult patients with primary hypercholesteremia or mixed

hyperlipidemia, the initial dose of tobrak capsules (micronized) is 120 mg per day.

For adult patients with hypertriglyceridemia, the initial dose is 67 to 200 mg per day.

Dosage should be individualized according to patient response, and should be

adjusted if necessary, following lipid determinations at 4 to 8 week intervals.

The maximum dose is 400 mg per day.

The initial dose should be limited to 67 mg.

Lipid levels should be monitored periodically and consideration should be given to

reducing the dosage of the tobrak capsules (micronized) if lipid levels fall significantly

below the target range.

HOW SUPPLIED

Fenofibrate Capsules (micronized), 67 mg are opaque light blue cap and body, hard
gelatin capsules, printed in black ink on over 240 and on opposite cap and body portions of the

capsules. They are supplied as follows:

NDC 0009-3009-01 Bottles of 100 capsules

Fenofibrate Capsules (micronized), 200 mg are opaque light blue cap and body, hard
gelatin capsules, printed in black ink on over 411 and on opposite cap and body portions of the

capsules. They are supplied as follows:

NDC 0009-8011-01 Bottles of 100 capsules

Storage

Store at controlled room temperature, between 25° and 30° C (77° F) (see USP).
Keep out of the reach of children. Protect from moisture.

Manufactured in Canada By:
the Nestlé Canada Limited
Toronto, Canada M9B 2G9

TEMA PHARMACEUTICALS USA

Silverdale, PA 19331

Reference ID: 3082694