# MAVIK® Patient Information Sheet

You have been prescribed **MAVIK®** (trandolapril) which is an ACE inhibitor. This medication is an anti-hypertensive (blood pressure lowering) agent, but it also has important vascular protective properties independent of its blood pressure lowering effects.

The landmark **TRACE**[1] trial studied 1749 patients after a heart attack. These patients had evidence of left ventricular dysfunction (weakness of the heart muscle) corresponding to an ejection fraction of less than or equal to 35% (normal > 55%). Eligible subjects were randomized to receive either 1mg of MAVIK® (trandolapril) between day 3 and day 7 or placebo, followed by 2 mg after 2 days, and after 4 weeks the dose was increased to 4mg, one a day. Patients were followed for an average of 24-50 months. Mean age of patients was 67.7 years. Benefits were seen from the first month.

**Results Included:**

- ↓ All Cause Mortality by 22% RRR[§] ARR* 7% (369 vs. 304, p = 0.001) NNT[†] 14
- ↓ Cardiovascular Death by 25% RRR ARR 7% (288 vs. 226, p = 0.001) NNT 14
- ↓ Sudden Death by 24% RRR ARR 3% (133 vs. 105, p = 0.03) NNT 33
- ↓ Progression to severe Heart Failure by 29% RRR ARR 6% (171 vs. 125, p = 0.003) NNT 17

[§]RRR= relative risk reduction *ARR= absolute risk reduction [†]NNT= numbers needed to treat

The **TRACE DIABETES STUDY**[2] studied 237 patients in the same patient population as above, but with Diabetes as well. Results included:

- ↓ All Cause Mortality by 36% RRR, NNT = 6.3 (p = 0.01)
- ↓ Cardiovascular Death by 44% RRR (p = 0.001)
- ↓ Sudden Death by 54% RRR (p= 0.01)
- ↓ Progression to severe Heart Failure by 62% RRR (p = 0.001)

The landmark **BENEDICT**[3] trial studied 1204 hypertensive patients with type 2 diabetes and normal urinary albumin excretion. Patients were randomized to either MAVIK® 2mg (trandolapril) or Isoptin SR® (verapamil) 180mg plus MAVIK® (trandolapril) or Isoptin SR® (Verapamil) vs. Placebo. Average age was 62 years and duration of type 2 diabetes was 7.7 years. Mean BMI was 29.1. Mean baseline Blood Pressure was 150.8 over 87.4mm Hg and urinary albumin excretion was < 20 microg/min (< 30 microg/day). Patients were followed for 3 years.

**Results Included:**

- ↓ MAVIK® (trandolapril) reduced the risk of developing microalbuminuria by 53% RRR (p = 0.01) vs. Placebo. Results were independent of blood pressure control. NNT 39 patients for three years.

The mechanism of benefit relates to the vascular protective effects of ACE inhibitors which improve blood vessel dilatation, reverse hardening of the arteries, stabilize arterial plaques, improve endothelial function by reducing blood clotting and blood vessel inflammation and promote natural antioxidant properties. In a combined analysis of three major ACE inhibitor studies[4] [**HOPE, EUROPA and PEACE** – the latter conducted with MAVIK® (trandolapril)] ACE inhibitors significantly reduced all-cause mortality (7·8 vs. 8·9%, p=0·0004), cardiovascular mortality (4·3 vs. 5·2%, p=0·0002), non-fatal myocardial infarction (5·3 vs. 6·4%, p=0·0001), all stroke (2·2 vs 2·8%, p=0·0004), heart failure (2·1 vs. 2·7%,p=0·0007), coronary-artery bypass surgery (6·0 vs.6·9%, p=0·0036) and the composite outcomes of cardiovascular mortality, non-fatal myocardial infarction, or stroke (10·7% vs.12·8%,odds ratio, 0·82; 95% CIs 0·76–0·88; p<0·0001).

**MAVIK®** (trandolapril) is the only ACE inhibitor shown to have renal protective properties at an early stage of nephropathy. The **TRACE** and **BENEDICT** trials extend the benefit of ACE inhibitors to type 2 diabetics and should be considered in **ALL PATIENTS WITH DIABETES**.

What you need to know about MAVIK® (trandolapril):

**MAVIK®** (trandolapril) has been prescribed in your case:
- ❍ To treat mild to moderate essential hypertension.
- ❍ Following and acute heart attack.
- ❍ To treat left ventricular dysfunction (weakened heart muscle) after a heart attack with or without heart failure.
- ❍ To improve survival and reduce hospitalizations due to heart failure.

**MAVIK®** (trandolapril) has been prescribed at a dose of:
- ❍ 0.5mg capsule daily (dosage for renal impairment below 30ml/min/1.73m2 and liver impairment.)
- ❍ 1mg capsule daily (usual starting dose)
- ❍ 2mg capsule daily
- ❍ 4mg capsule daily (maintenance dose post MI.)

The therapeutic goal is to increase **MAVIK®** (trandolapril) to the highest tolerated dose to provide maximum vascular protection.

MAVIK® (trandolapril) side effects include:
- Dry non-productive cough
- Dizziness, especially with first dose or if you are dehydrated
- **Angioedema** (swelling or the face and throat). This is a rare occurrence but if it happens stop the medication and contact your physician immediately.
- Elevated potassium – potassium level should be monitored with a blood test within 2 weeks of starting ACE inhibitors medication
- Serum creatinine (a measure of kidney function) – should be monitored with a blood test within 2 weeks of starting medication

In general **MAVIK®** is well tolerated. The risk of a serious side effect is < 1 %.

**Patient Instructions:**
- Take exactly as directed.
- Do not discontinue without consulting prescribing physician.
- Hold **MAVIK®** (trandolapril) and consult prescribing physician if excess dizziness or angioedema occurs.
- **MAVIK®** (trandolapril) does not eliminate need for diet, exercise or other lifestyle modifications.
- Do not use NSAID's (anti-inflammatory agents), potassium supplements or salt substitutes without consulting prescribing physician.
- **MAVIK®** (trandolapril) should not be used in women of childbearing years unless appropriate contraceptive precautions are taken.

**IF you have any questions concerning MAVIK® (trandolapril) consult your doctor.**


1. Kober L, Torp-Pederson C, et al. A Clinical Trial of the Angiotensin-Converting Enzyme Inhibitor Trandolapril in Patients with Left-Ventricular Dysfunction after Myocardial Infarction. NEJM 1995; 333:1670-6.
2. Gustafsson I, Torp-Pederson C, Kober L, Gustafsson F, Hildebrandt P on behalf of the TRACE Group. Effect of Angiotensin-Converting Enzyme Inhibitor Trandolapril on Mortality and Morbidity in Diabetic Patients with Left Ventricular Dysfunction After Acute Myocardial Infarction. JACC 1999; 34: 83-89.
3. Rugenenti P, Fassi A, et al. For the Bergamo Nephrologic Diabetes Complications Trial (BENEDICT) Investigators. Preventing Microalbuminuria in Type 2 Diabetes. NEJM 2004;351 (19): 1941-51.
4. Dagenais G, Pogue J et al. Angiotensin-Converting Enzyme Inhibitors in Stable Vascular Disease without Left Ventricular Systolic Dysfunction or Heart Failure: A Combined Analysis of Three Trials. Lancet 2006; 368: 581–88.