



Patient Information Sheet

Angiotensin-Converting Enzyme Inhibitor Drugs (ACE Inhibitors)

This is a summary of the most important information about prescription ACE inhibitors. For more information, talk to your healthcare professional.

FDA ALERT [06/2006]: Blood pressure medicines called angiotensin-converting enzyme inhibitors (ACE inhibitors) may be associated with increased risk of birth defects if taken during early pregnancy (first three months, or first trimester).

On June 8, 2006, the *New England Journal of Medicine* published an article reporting a study that showed babies whose mothers had taken an ACE inhibitor during the first three months of pregnancy had an increased risk of birth defects. The number of birth defects was small, and the study has not been repeated.

Before this study, it was known that ACE inhibitors can harm an unborn baby when taken during the last six months of pregnancy (second and third trimester).

If you are pregnant or planning to become pregnant and take a blood pressure medicine, talk with your healthcare professional. High blood pressure is a condition that needs treatment. Your healthcare professional can advise you on the blood pressure medicine that is best for you and your baby during pregnancy.

This information reflects FDA's preliminary analysis of data concerning these drugs. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Are ACE inhibitors?

- ACE inhibitors are used alone or with other medicines to treat high blood pressure in adults.

ACE inhibitors include: Benazepril (Lotensin), Captopril (Capoten), Enalapril/Enalaprilat (Vasotec oral and injectable), Fosinopril (Monopril), Lisinopril (Zestril and Prinivil), Moexipril (Univasc), Perindopril (Aceon), Quinapril (Accupril), Ramipril (Altace), and Trandolapril (Mavik).

There is a list of prescription ACE inhibitors available at: http://www.fda.gov/cder/drug/infopage/ace_inhibitors/default.htm

Who Should Not Take ACE Inhibitors?

If you are pregnant or planning to become pregnant and take a blood pressure medicine, talk with your healthcare professional. ACE inhibitors can harm or even cause death to

an unborn baby (fetus) if taken during the last six months of pregnancy.

What Are The Risks?

The following are the major potential risks and side effects of ACE inhibitor therapy. However, this list is not complete.

- **Birth defects or death of an unborn baby.**
- **Kidney problems** that include worsening of kidney problems that you already have. Symptoms include a sudden weight gain and swelling of your arms, hands, legs, and feet.

The most common side effects with ACE inhibitors are:

- Dizziness
- Dry cough
- Sore throat

What Should I Tell My Healthcare Professional?

Before you start taking an ACE inhibitor, tell your healthcare professional if you:

- have had hives or allergic-type reactions after taking another ACE inhibitor
- have kidney problems
- are trying to become pregnant, are already pregnant, or are breast-feeding

If you are already taking an ACE inhibitor, tell your healthcare professional if you

- become pregnant.
- notice swelling of your face, mouth or throat, or have difficulty swallowing or breathing – this could be serious and you should get medical help right away.

Can Other Medicines or Food Affect ACE Inhibitors?

ACE inhibitors and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them with you to show your healthcare professional.

