The combination of rosiglitazone maleate and metformin hydrochloride tablets should only be started in patients with evidence of type 2 diabetes who are unable to control their diabetes with diet and exercise or who require more intensive treatment than can be achieved with diet and exercise alone. Patients should be informed of the following:

**Diabetes**

- **New or worse heart failure**: This can happen if you are sick with a fever, vomiting or diarrhea for a long time. Your heart might not be able to pump blood as well as it usually does. This can cause your heart to fail. If you have symptoms of heart failure, call your doctor right away.
- **Symptoms of a heart attack can include the following:**
  - Chest pain or discomfort lasting more than a few minutes, or that goes away and comes back
  - Shortness of breath
  - Feeling light-headed or faint
  - Feeling short of breath or without chest discomfort
  - Breathing fast and shallow
  - Skin that is cool, pale, or blue
  - Feeling weak or dizzy
  - Feeling nauseated or vomiting
  - Feeling like you might pass out
  - Coughing up foam-like blood
  - Sweating

**Disorders**

- **Severe blood sugar lower than expected**: This can happen if you are sick with a fever, vomiting or diarrhea for a long time. Your body may need more insulin or diabetes medicine. If you have any of these symptoms, call your doctor right away.
- **Severe infection, or a stroke**: Call your doctor right away if you have any of these symptoms.

**In the Back of the Eye**

- **Blurred vision**: If you have blurry vision, call your doctor right away.
- **Severe vision changes**: If you have severe vision changes, call your doctor right away.
- **Severe eye pain**: If you have severe eye pain, call your doctor right away.

**In Men**

- **Prostate problems**: If you have prostate problems, call your doctor right away.

**In Women**

- **Problems with breathing or swallowing**: If you have problems with breathing or swallowing, call your doctor right away.
- **Problems with heartburn or acid reflux**: If you have problems with heartburn or acid reflux, call your doctor right away.

**Drug Interactions**

- **Avoid taking rosiglitazone maleate and metformin hydrochloride tablets if you are taking other diabetes medicines**. This will depend on how well your diabetes is controlled, how much medicine you are taking, and other medicines you are taking. Contact your doctor or pharmacist for more information.

**Missed Doses**

- **If you remember, take the missed dose as soon as you remember. If you do not remember, take the next dose at your regular time. Do not take double doses to make up for a missed dose.**

**Precautions**

- **Patients who are taking insulin**: Your doctor may need to change your dose of insulin. Contact your doctor or pharmacist for more information.

**Lactic Acidosis**

- **Lactic acidosis**: This can happen if you have severe kidney problems. Call your doctor right away if you have any of these symptoms.

**Pregnancy**

- **Are you pregnant or planning to become pregnant?**: If you are pregnant or planning to become pregnant while taking rosiglitazone maleate and metformin hydrochloride tablets, contact your doctor or pharmacist right away.

**Breastfeeding**

- **Are you breastfeeding?**: If you are breastfeeding while taking rosiglitazone maleate and metformin hydrochloride tablets, contact your doctor or pharmacist right away.

**Hepatic Impairment**

- **Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment**. Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment. Rosiglitazone maleate and metformin hydrochloride is contraindicated in these patients.

**Renal Impairment**

- **Rosiglitazone maleate and metformin hydrochloride tablets are not recommended for patients who are on dialysis**. If you are on dialysis, rosiglitazone maleate and metformin hydrochloride tablets should not be started until your healthcare professional decides it is safe to do so.

**HbA1c (%)**

- **Lactic acidosis**: This can happen if you are sick with a fever, vomiting or diarrhea for a long time. Your body may need more insulin or diabetes medicine. If you have any of these symptoms, call your doctor right away.

**Lung Disorders**

- **Problems with breathing or swallowing**: If you have problems with breathing or swallowing, call your doctor right away.

**Hepatic Impairment**

- **Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment**. Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment. Rosiglitazone maleate and metformin hydrochloride is contraindicated in these patients.

**Renal Impairment**

- **Rosiglitazone maleate and metformin hydrochloride tablets are not recommended for patients who are on dialysis**. If you are on dialysis, rosiglitazone maleate and metformin hydrochloride tablets should not be started until your healthcare professional decides it is safe to do so.

**HbA1c (%)**

- **Lactic acidosis**: This can happen if you are sick with a fever, vomiting or diarrhea for a long time. Your body may need more insulin or diabetes medicine. If you have any of these symptoms, call your doctor right away.

**Lung Disorders**

- **Problems with breathing or swallowing**: If you have problems with breathing or swallowing, call your doctor right away.

**Hepatic Impairment**

- **Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment**. Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment. Rosiglitazone maleate and metformin hydrochloride is contraindicated in these patients.

**Renal Impairment**

- **Rosiglitazone maleate and metformin hydrochloride tablets are not recommended for patients who are on dialysis**. If you are on dialysis, rosiglitazone maleate and metformin hydrochloride tablets should not be started until your healthcare professional decides it is safe to do so.

**HbA1c (%)**

- **Lactic acidosis**: This can happen if you are sick with a fever, vomiting or diarrhea for a long time. Your body may need more insulin or diabetes medicine. If you have any of these symptoms, call your doctor right away.

**Lung Disorders**

- **Problems with breathing or swallowing**: If you have problems with breathing or swallowing, call your doctor right away.

**Hepatic Impairment**

- **Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment**. Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment. Rosiglitazone maleate and metformin hydrochloride is contraindicated in these patients.

**Renal Impairment**

- **Rosiglitazone maleate and metformin hydrochloride tablets are not recommended for patients who are on dialysis**. If you are on dialysis, rosiglitazone maleate and metformin hydrochloride tablets should not be started until your healthcare professional decides it is safe to do so.

**HbA1c (%)**

- **Lactic acidosis**: This can happen if you are sick with a fever, vomiting or diarrhea for a long time. Your body may need more insulin or diabetes medicine. If you have any of these symptoms, call your doctor right away.

**Lung Disorders**

- **Problems with breathing or swallowing**: If you have problems with breathing or swallowing, call your doctor right away.

**Hepatic Impairment**

- **Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment**. Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment. Rosiglitazone maleate and metformin hydrochloride is contraindicated in these patients.

**Renal Impairment**

- **Rosiglitazone maleate and metformin hydrochloride tablets are not recommended for patients who are on dialysis**. If you are on dialysis, rosiglitazone maleate and metformin hydrochloride tablets should not be started until your healthcare professional decides it is safe to do so.

**HbA1c (%)**

- **Lactic acidosis**: This can happen if you are sick with a fever, vomiting or diarrhea for a long time. Your body may need more insulin or diabetes medicine. If you have any of these symptoms, call your doctor right away.

**Lung Disorders**

- **Problems with breathing or swallowing**: If you have problems with breathing or swallowing, call your doctor right away.

**Hepatic Impairment**

- **Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment**. Unbound oral clearance of rosiglitazone was significantly lower in patients with liver impairment. Rosiglitazone maleate and metformin hydrochloride is contraindicated in these patients.

**Renal Impairment**

- **Rosiglitazone maleate and metformin hydrochloride tablets are not recommended for patients who are on dialysis**. If you are on dialysis, rosiglitazone maleate and metformin hydrochloride tablets should not be started until your healthcare professional decides it is safe to do so.
Lactic acidosis 

Call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

• shortness of breath with or without chest discomfort
• chest discomfort that feels like uncomfortable pressure, squeezing, pain, or heavy feeling in the center of your chest
• nausea or vomiting
• feeling light-headed
• cold, clammy skin
• fast or irregular heartbeat
• sweating
• weakness
• shortness of breath or swelling, even if these symptoms are mild
• unusual muscle pain, weakness, or tenderness, especially in your legs or arms
• unusual tiredness or weakness
• increased need to use the bathroom
• feeling like you might faint or feel dizzy
• confusion
• feeling very weak or tired
• have unusual (not normal) breathing
• have unusual pain in your stomach
• have jaundice (yellowing of the skin or eyes)
• have pain when you swallow
• have very rapid or shallow breathing
• have yellowing of the skin or eyes

Rosiglitazone maleate and metformin hydrochloride tablets may cause serious side effects, including:

• liver problems while taking PERZOLAR® (rosiglitazone maleate and metformin hydrochloride tablets) or KOMBOUR® (rosiglitazone maleate and metformin hydrochloride tablets)
• developing a serious condition such as heart attack or stroke while taking PERZOLAR® (rosiglitazone maleate and metformin hydrochloride tablets) or KOMBOUR® (rosiglitazone maleate and metformin hydrochloride tablets)
• new or worse heart failure while taking rosiglitazone maleate and metformin hydrochloride tablets
• an allergic reaction while taking rosiglitazone maleate and metformin hydrochloride tablets
• heart failure from metformin is to tell your doctor if you have:

• a slow or irregular heartbeat
• New or worse heart failure

Rosiglitazone maleate and metformin hydrochloride tablets contain two prescription medicines for treating type 2 ("non-insulin dependent") diabetes ("high blood sugar"). This medicine in rosiglitazone maleate and metformin hydrochloride tablets may increase your chance of becoming pregnant and having a baby that is born healthy. This Medication Guide has been approved by the U.S. Food and Drug Administration. This summary describes important information about rosiglitazone maleate and metformin hydrochloride tablets. It is not meant to replace the information your doctor has given you about how to use this medicine for your condition.

Rosiglitazone maleate and metformin hydrochloride tablets should be taken by mouth and with meals. Rosiglitazone maleate and metformin hydrochloride tablets are safe and effective in children age 10 years and older. But children are a premenopausal woman (before the "change of life" or menopause occurs) and the baby is a newborn. This Medication Guide describes the important information you need to know about rosiglitazone maleate and metformin hydrochloride tablets. Weight gain while taking rosiglitazone maleate and metformin hydrochloride tablets may increase your chance of becoming pregnant and having a baby that is born healthy. This Medication Guide describes the important information you need to know about rosiglitazone maleate and metformin hydrochloride tablets.