

Aliskiren

DrugPoint 综述

DOSING/ADMINISTRATION

Adult Dosing

Chronic kidney disease, Nondiabetic

- 150 mg ORALLY once daily [1]

Diabetic nephropathy - Hypertension

- 150 [2][3][4] or 300 mg orally daily (off-label dosage) [2][5][3][4]

Hypertension

- Initial, 150 mg orally once daily; may increase to 300 mg/day based on clinical response. Take consistently with regard to meals [6]

Pediatric Dosing

Hypertension

- (6 to 17 years and 20 to 50 kg) Initial, 75 mg orally once daily; MAX 150 mg/dose. Take consistently with regard to meals [6]
- (6 to 17 years and 50 kg or greater) Initial, 150 mg orally once daily; may increase to 300 mg once daily based on clinical response. Take consistently with regard to meals [6]

FDA Uses

- Hypertension

Labeled Uses

- Hypertension

Non-FDA Uses

- Chronic kidney disease, Nondiabetic
- Diabetic nephropathy - Hypertension

Dose Adjustments

- Renal impairment: No adjustment necessary; however, safety and effectiveness have not been established in patients with a CrCl less than 30 mL/min or in pediatric patients with a GFR less than 30 mL/min/1.73m² [6]
- Hepatic impairment (mild to severe): No initial adjustment necessary [6]
- Geriatric: No initial adjustment necessary [7]
- Hemodialysis with ESRD: No adjustment necessary [6]

Administration

Oral

- Take consistently with regard to meals; high-fat meals reduce absorption significantly [6].
- (Oral pellets) Do not swallow the dispensing capsule containing the oral pellets [6].
- (Oral pellets) Do not empty contents of pellet directly into mouth and do not crush or chew the pellets [6].

- (Oral pellets) Take by emptying capsule contents into a spoon and then administering by mouth, followed with milk (dairy or soy-based) or water immediately without crushing or chewing [6].
- (Oral pellets) Alternatively may take by mixing capsule contents with 1 teaspoon of one of the following dosing vehicles: Milk- or soy-based vanilla pudding, milk- or soy-based vanilla ice cream, dairy or soy-based milk, or water. Other dosing vehicles are not recommended. More or less dosing vehicle may be used, if desired [6].

Comparative Efficacy

无可用结果

Place In Therapy

无可用结果

MEDICATION SAFETY

Contraindications

- Concomitant use of angiotensin receptor blockers or ACE inhibitors in patients with diabetes [6]
- Hypersensitivity to aliskiren or any component of the product [6]
- Pediatric patients younger than 2 years of age [6]

Precautions

- Cardiovascular: Symptomatic hypotension may occur in patients with salt or volume depletion or concomitant use of agents acting on the renin-angiotensin system; correct volume or salt depletion prior to use [6]
- Concomitant use: Avoid concomitant use with ACE inhibitors or angiotensin receptor blockers, especially in patient with CrCl less than 60 mL/min [6]
- Concomitant use: Avoid concomitant cyclosporine or itraconazole [6]
- Endocrine and metabolic: Hyperkalemia may occur; monitoring recommended [6]
- Immunologic: Anaphylactic reactions and angioedema of the face, extremities, lips, tongue, glottis, or larynx (requiring hospitalization and intubation) have been reported; discontinue and do not restart [6]
- Renal: Changes in renal function (including acute renal failure), may occur, with an increased risk when renal function depends on the activity of the renin-angiotensin system (eg, renal artery stenosis, severe heart failure, post myocardial infarction, volume depletion) or with concomitant angiotensin receptor blockers, ACE inhibitors, NSAIDs, or COX-2 inhibitors; monitoring recommended and interruption or discontinuation may be warranted [6]

Adverse Effects

Common

- **Gastrointestinal:** Diarrhea (2.3%)
- **Musculoskeletal:** Musculoskeletal symptom
- **Neurologic:** Dizziness, Headache (2.4% to 6.2%)
- **Renal:** Serum blood urea nitrogen raised, Serum creatinine raised

Serious

- **Cardiovascular:** Hypotension
- **Endocrine metabolic:** Hyperkalemia (0.9%)
- **Immunologic:** Anaphylaxis, Hypersensitivity reaction
- **Musculoskeletal:** Increased creatine kinase level (1%)
- **Neurologic:** Seizure
- **Renal:** Renal impairment
- **Other:** Angioedema (0.06%)

Black Box Warning

Oral (Pellet; Tablet)

- When pregnancy is detected, discontinue aliskiren as soon as possible, since drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus [6].

REMS

无可用结果

Drug Interactions (single)**Drug-Drug 相互作用 (28)**

| 药物: | 严重性: | 文档: | 综述: |
|---|--|-------------|---|
| CAPTOPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and CAPTOPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| LOSARTAN [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and LOSARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| LISINOPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and LISINOPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| ALISKIREN -- AZILSARTAN |  Contraindicated | Good | Concurrent use of ALISKIREN and AZILSARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| interact(s) with: 相互作用物质 | | | |
| CANDESARTAN [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and CANDESARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| FOSINOPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and FOSINOPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| PERINDOPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and PERINDOPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| MOEXIPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and MOEXIPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| RAMIPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and RAMIPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| ENALAPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and ENALAPRIL may result in |

| | | | |
|---|--|-------------|--|
| ENALAPRILAT [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | an increased risk of hyperkalemia, renal impairment, and hypotension. |
| QUINAPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and ENALAPRILAT may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| TRANDOLAPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and QUINAPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| EPROSARTAN [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and TRANDOLAPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| TELMISARTAN [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and EPROSARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| VALSARTAN [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and TELMISARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| IRBESARTAN [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and VALSARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| BENAZEPRIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and IRBESARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| OLMESARTAN MEDOXOMIL [Systemic] -- ALISKIREN [Systemic] |  Contraindicated | Good | Concurrent use of ALISKIREN and BENAZEPRIL may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| ITRACONAZOLE [Systemic] -- ALISKIREN [Systemic] |  Major | Good | Concurrent use of ALISKIREN and OLMESARTAN may result in an increased risk of hyperkalemia, renal impairment, and hypotension. |
| CYCLOSPORINE [Systemic] -- ALISKIREN [Systemic] |  Major | Good | Concurrent use of ALISKIREN and ITRACONAZOLE may result in increased aliskiren exposure and plasma concentrations. |
| VENETOCLAX -- P-GP SUBSTRATES |  Major | Fair | Concurrent use of ALISKIREN and CYCLOSPORINE may result in increased aliskiren exposure and plasma concentrations. |
| SIMEPREVIR -- P-GLYCOPROTEIN SUBSTRATES |  Major | Fair | Concurrent use of VENETOCLAX and P-GP SUBSTRATES may result in increased exposure of P-gp substrate. |
| | | | Concurrent use of SIMEPREVIR and P-GLYCOPROTEIN SUBSTRATES may result in |

| | | | |
|---|---|-------------|---|
| LASMIDITAN -- P-GP SUBSTRATES |  Major | Fair | increased exposure of P-glycoprotein substrate. Concurrent use of LASMIDITAN and P-GP SUBSTRATES may result in Increased exposure of P-gp substrate. |
| FUROSEMIDE [Systemic] -- ALISKIREN [Systemic] |  Moderate | Good | Concurrent use of ALISKIREN and FUROSEMIDE may result in decreased furosemide exposure. |
| RIFAMPIN [Systemic] -- ALISKIREN [Systemic] |  Moderate | Good | Concurrent use of ALISKIREN and RIFAMPIN may result in reduced aliskiren plasma concentrations and exposure. |
| ALISKIREN -- POTASSIUM-SPARING DIURETICS |  Moderate | Fair | Concurrent use of ALISKIREN and POTASSIUM-SPARING DIURETICS may result in hyperkalemia. |
| interact(s) with: 相互作用物质 | | | |
| POTASSIUM [Systemic] -- ALISKIREN [Systemic] |  Moderate | Fair | Concurrent use of ALISKIREN and POTASSIUM may result in hyperkalemia. |

Drug-过敏 相互作用 (未找到)**Drug-食物 相互作用 (1)**

| 药物: | 严重性: | 文档: | 综述: |
|--|---|------------------|---|
| ALISKIREN -- GRAPEFRUIT JUICE [All Routes] |  Moderate | Excellent | Concurrent use of ALISKIREN and GRAPEFRUIT JUICE may result in reduced bioavailability of aliskiren . |

Drug-乙醇 相互作用 (未找到)**Drug-化验室 相互作用 (未找到)****Drug-抽烟 相互作用 (未找到)****Drug-怀孕 相互作用 (1)**

| 药物: | 严重性: | 文档: | 综述: |
|-----------------------------------|---|----------------|--|
| PREGNANCY -- ALISKIREN [Systemic] |  Moderate | Unknown | No US FDA rating is available for Aliskiren. |

Drug-哺乳期 相互作用 (1)

| 药物: | 严重性: | 文档: | 综述: |
|-----------------------------------|--|----------------|--|
| LACTATION -- ALISKIREN [Systemic] |  Major | Unknown | Infant risk cannot be ruled out: Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when Aliskiren is used during breast-feeding. Weigh the potential benefits of treatment against |

potential risks before prescribing Aliskiren during breast-feeding.

定义

Severity:



禁忌

禁止同时使用这些药物。



严重

这种相互作用可能危及生命和/或需要医疗干预以尽量减少或避免严重的不良影响。



中等

这种相互作用可能导致加重患者的病情和/或需要在治疗中发生改变。



较弱

这种相互作用将限制临床效果。表现可能包括增加副作用的频率或严重程度，但一般不需要在治疗中发生重大改变。



未知

未知。

Documentation:

卓越

对照研究明确确立了相互作用的存在。

良好

文档强烈建议相互作用的存在，但缺乏良好对照研究。

一般

可用文档不佳，但药理考虑引导临床医生怀疑相互作用的存在性；或从药理学讲，文档可很好地用于类似的药物。

未知

未知。

IV 相容性 (单一)

No results available

Pregnancy Category

- [Fetal risk has been demonstrated.](#) (TH)

Breast Feeding

- [Micromedex: Infant risk cannot be ruled out.](#)

Monitoring

- hypertension: a decrease in blood pressure is indicative of clinical response
- renal function; periodically in all patients, particularly if risk for developing acute renal failure (eg, renal arterial stenosis, severe heart failure, post myocardial infarction, volume depletion, concomitant angiotensin receptor blockers, ACE inhibitors, or NSAIDs) [8]
- serum potassium; periodically in all patients, especially in patients with risk factors for developing hyperkalemia (eg, concomitant angiotensin receptor blockers, ACE inhibitors, NSAIDs, potassium supplements, or potassium-sparing diuretics, those with preexisting renal insufficiency, or diabetes) [8]

Do Not Confuse

无可用结果

MECHANISM OF ACTION

Mechanism of Action

- Aliskiren directly inhibits renin which decreases plasma renin activity (PRA) and inhibits the conversion of angiotensinogen to angiotensin I (Ang I). Unlike angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs) which indirectly increase levels of PRA, aliskiren reduces PRA, Ang I, and Angiotensin II (Ang II) by directly inhibiting renin. These reductions occur whether or not aliskiren is used as monotherapy or concomitantly with other antihypertensive agents. It is unknown if aliskiren has an effect on other renin-angiotensin-aldosterone system (RAAS) components [12].

PHARMACOKINETICS

Pharmacokinetics

Absorption

- Tmax, ESRD, Oral: 2.68 hours (hemodialysis 48 hours postdose); 3.54 hours (hemodialysis 1 hour postdose) [13]
- Tmax, Pediatric, Oral: 1 hour (2 mg/kg); 1.5 to 2 hours (6 mg/kg) [14]
- Oral: rapidly absorbed [15]
- Bioavailability: (oral, tablet), 2.5% [12]
- Effect of food: high fat food decreased AUC and Cmax by 71% and 85%, respectively; not found to be clinically relevant [15]

Distribution

- Vd: 135 L [16]
- Protein binding: 47% to 51% [15][16]

Metabolism

- Hepatic: in vitro via P450 CYP3A4, minor extent [15].

Excretion

- Fecal/Biliary: 91%, 77.5% unchanged [15]
- Renal: 0.6%, 0.4% unchanged [15]
- Hemodialysis: No, 10% to 12% [13]
- Total body clearance, Pediatric: 3539 to 3905 mL/hr/kg (6 mg/kg; 6 to 17 years); 5388.1 mL/hr/kg (2 mg/kg; 12 to 17 years); 9694 mL/hr/kg (2 mg/kg; 6 to 11 years) [14]

Elimination Half Life

- approximately 40 hours [15]
- ESRD: 38 hours (hemodialysis 1 hour postdose); 42 hours (hemodialysis 48 hours postdose) [13]
- Pediatric: 38.8 to 39.2 hours (2 mg/kg); 42.9 to 45.1 hours (6 mg/kg) [14]

PATIENT EDUCATION

Medication Counseling

- Tell patient to report symptoms of lightheadedness or syncope [6]
- Side effects may include diarrhea, abdominal pain, dyspepsia, gastroesophageal reflux, and cough [6].
- Instruct patient to take oral pellets by emptying capsule contents into a spoon and then administering by mouth, followed with milk (dairy or soy-based) or water immediately without crushing or chewing. Alternatively, oral pellets may be taken by mixing capsule contents with 1 teaspoon of one of the following dosing vehicles: milk- or soy-based vanilla pudding, milk- or soy-based vanilla ice cream, dairy or soy-based milk, or water [6].
- Tell patient to avoid potassium supplements or salt substitutes containing potassium [6].

Patient Handouts

[Aliskiren \(Oral route, Pellet, Tablet\)](#)

TOXICOLOGY

Clinical Effects

ALISKIREN

- USES: Aliskiren is used alone or in combination with other agents to treat hypertension. PHARMACOLOGY: Aliskiren directly inhibits renin which decreases plasma renin activity (PRA) and inhibits the conversion of angiotensinogen to angiotensin I (Ang I). Unlike

angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs) which indirectly increase levels of PRA, aliskiren reduces PRA, Ang I, and Angiotensin II (Ang II) by directly inhibiting renin. These reductions occur whether or not aliskiren is used as monotherapy or concomitantly with other antihypertensive agents. It is unknown if aliskiren has an effect on other renin-angiotensin-aldosterone system (RAAS) components. **EPIDEMIOLOGY:** Overdose is rare. **OVERDOSE:** Overdose effects are anticipated to be an extension of adverse effects following therapeutic doses. The main effect expected with aliskiren overdose would be hypotension. **ADVERSE EFFECTS:** Aliskiren is generally well tolerated by most patients. Adverse effects reported with aliskiren therapy include hypotension (rare), diarrhea, abdominal pain, dyspepsia, gastrointestinal reflux disease, dizziness, headache, and decreased hemoglobin and hematocrit. Most symptoms were dose-related, mild, and rarely led to discontinuation of therapy.

Range of Toxicity

ALISKIREN

- **TOXICITY:** A toxic dose has not been established. Doses up to 600 mg/day have been used in adults in therapeutic trials with minimal adverse effects. An accidental ingestion of a single 300 mg aliskiren tablet by a 12-year-old boy (77.2 kg) resulted in a significant drop in systolic and diastolic pressure with the nadir occurring approximately 7 hours post-ingestion; his blood pressure gradually improved. **THERAPEUTIC DOSE: ADULT:** Initial, 150 mg orally once daily; may be increased to 300 mg orally once daily if BP is not adequately controlled.

Treatment

ALISKIREN

- **Support: MANAGEMENT OF MILD TO MODERATE TOXICITY:** Treatment is symptomatic and supportive. Manage mild hypotension with IV fluids. **MANAGEMENT OF SEVERE TOXICITY:** Treatment is symptomatic and supportive. Treat severe hypotension with IV 0.9% NaCl at 10 to 20 mL/kg. Add dopamine or norepinephrine if unresponsive to fluids. Correct any significant serum electrolyte abnormalities in patients with severe vomiting and/or diarrhea.
- **Decontamination: PREHOSPITAL:** Consider activated charcoal if the overdose is recent, the patient is not vomiting, and is able to maintain airway. **HOSPITAL:** Consider activated charcoal if the overdose is recent, the patient is not vomiting, and is able to maintain airway.
- **Airway management:** Airway management is very unlikely to be necessary unless more toxic agents are involved. Ensure adequate ventilation and perform endotracheal intubation early in patients with hemodynamic instability.
- **Antidote:** None
- **Monitoring of patient:** Plasma concentrations are not readily available or clinically useful in the management of overdose. Monitor vital signs after significant overdose. Monitor serum electrolytes in patients with significant vomiting and/or diarrhea.
- **Enhanced elimination procedure:** Aliskiren is moderately bound to plasma proteins (49.5%) and has a volume of distribution of 135 L. Hemodialysis is unlikely to be useful in overdose.
- **Patient disposition: HOME CRITERIA:** A specific toxic dose has not been established. Doses up to 600 mg/day have been used in adults in therapeutic trials with minimal adverse effects. An accidental ingestion of a single 300 mg aliskiren tablet by a 12-year-old boy (77.2 kg) resulted in a significant drop in systolic and diastolic pressure with the nadir occurring approximately 7 hours post-ingestion (77/47 mm Hg; greater than 45% drop). No symptoms associated with hypotension (dizziness, mental status change, light-headedness) were reported, and his blood pressure gradually improved. A patient with an inadvertent exposure, that remains asymptomatic, can be managed at home. **OBSERVATION CRITERIA:** Patients who are symptomatic and patients with deliberate overdose should be observed with frequent monitoring of vital signs. Patients that remain asymptomatic can be discharged. Deliberate overdose patients require psychiatric evaluation prior to discharge. **ADMISSION CRITERIA:** Patients who remain symptomatic despite treatment should be admitted. **CONSULT CRITERIA:** Consult a local poison center or medical toxicologist for assistance in managing patients with severe toxicity or in whom the diagnosis is not clear.

ABOUT

How Supplied

Generic

- Oral Tablet: 150 MG, 300 MG

Tekturna

- Oral Tablet: 150 MG, 300 MG

Drug Properties

无可用结果

Storage & Stability

无可用结果

Trade Names

- Tekturna

[All Trade Names](#)

Regulatory Status

- RX

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