**PATIENT INFORMATION**
**Axitinib** (ax i′ ti nib) **Tablets**

**What are axitinib tablets?**

Axitinib tablets are a prescription medicine used to treat kidney cancer that has spread or cannot be removed by surgery (advanced renal cell carcinoma or RCC):

- alone when 1 prior drug treatment regimen for your RCC has not worked.

It is not known if axitinib tablets are safe and effective in children.

**Before taking axitinib tablets, tell your healthcare provider about all of your medical conditions, including if you:**

- have high blood pressure
- have thyroid problems
- have liver problems
- have a history of blood clots in your veins or arteries (types of blood vessels), including stroke, heart attack, or change in vision
- have any bleeding problems
- have a history of heart problems, including heart failure
- have an unhealed wound
- plan to have surgery or have had a recent surgery. You should stop taking axitinib tablets for at least 2 days before planned surgery. See **"What are the possible side effects of axitinib tablets?"**

**For females, tell your healthcare provider if you:**

- are pregnant or plan to become pregnant. Taking axitinib tablets during pregnancy can harm your unborn baby. You should not become pregnant during treatment with axitinib tablets.
- are able to become pregnant. You should have a pregnancy test before you start treatment with axitinib tablets. Use effective birth control during treatment and for 1 week after your last dose of axitinib tablets. Talk to your healthcare provider about birth control methods that you can use to prevent pregnancy during this time.
- are breastfeeding or plan to breastfeed. It is not known if axitinib passes into your breast milk. Do not breastfeed during treatment and for 2 weeks after your last dose of axitinib tablets.

**For males with female partners who are able to become pregnant:**

- Use effective birth control during treatment and for 1 week after your last dose of axitinib tablets.
- If your female partner becomes pregnant during your treatment with axitinib tablets, tell your healthcare provider right away.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Axitinib tablets and certain other medicines can affect each other causing serious side effects.

Talk with your healthcare provider before you start taking any new medicine. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take axitinib tablets?**

- Take axitinib tablets exactly as prescribed by your healthcare provider.
- Your healthcare provider may change your dose if needed.
- Axitinib tablets can be taken with or without food.
- Take axitinib tablets 2 times a day about 12 hours apart.
- Swallow axitinib tablets whole with a glass of water.
- Your healthcare provider should check your blood pressure regularly during treatment with axitinib tablets.
- If you vomit or miss a dose of axitinib tablets, take your next dose at your regular time. Do not take two doses at the same time.
- If you take too much axitinib tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

**What should I avoid while taking axitinib tablets?**

- Do not drink grapefruit juice or eat grapefruit. Grapefruit may increase the amount of axitinib tablets in your blood.

**What are the possible side effects of axitinib tablets?**

**Axitinib tablets may cause serious side effects, including:**

- **High blood pressure (hypertension). High blood pressure is common with axitinib tablets and may sometimes be severe.** Your healthcare provider should check your blood pressure regularly during treatment with axitinib tablets. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure, lower your dose, or stop your treatment with axitinib tablets.
- **Blood clots in your veins or arteries.** Axitinib tablets can cause blood clots which can be serious, and sometimes lead to death. Get emergency help and call your healthcare provider if you get any of the following symptoms:
  - chest pain or pressure
  - pain in your arms, back, neck or jaw
  - shortness of breath
  - numbness or weakness on one side of your body
  - trouble talking
  - headache
  - vision changes
- **Bleeding.** Axitinib tablets can cause bleeding which can be serious, and sometimes lead to death. Call your healthcare provider right away or get medical help if you develop any of the following signs or symptoms:
  - unexpected bleeding or bleeding that lasts a long time, such as:
    - unusual bleeding from the gums
    - menstrual bleeding or vaginal bleeding that is heavier than normal
    - bleeding that is severe or you cannot control
    - pink or brown urine
    - red or black stools (looks like tar)
    - bruises that happen without a known cause or get larger
    - cough up blood or blood clots
    - vomit blood or your vomit looks like “coffee grounds”
  - unexpected pain, swelling, or joint pain
  - headaches, feeling dizzy or weak
- **Heart failure.** Your healthcare provider should check you for signs or symptoms of heart failure regularly during treatment with axitinib tablets. Heart failure can be serious and can sometimes lead to death. Tell your healthcare provider if you have any of the following symptoms during your treatment with axitinib tablets:
  - tiredness
  - swelling of your stomach-area (abdomen), legs or ankles
  - shortness of breath
  - protruding neck veins
- **Tear in your stomach or intestinal wall (perforation).** A tear in your stomach or intestinal wall can be serious and can sometimes lead to death. Get medical help right away if you get the following symptoms:
  - severe stomach-area (abdominal) pain or stomach-area pain that does not go away
  - vomit blood
  - red or black stools
- **Thyroid gland problems.** Your healthcare provider should do blood tests to check your thyroid gland function before and during your treatment with axitinib tablets. Tell your healthcare provider if you have any of the following symptoms during your treatment with axitinib tablets:
  - tiredness that worsens or that does not go away
  - feeling hot or cold
  - your voice deepens
  - weight gain or weight loss
  - hair loss
  - muscle cramps and aches
- **Risk of wound healing problems.** Wounds may not heal properly during axitinib tablets treatment. Tell your healthcare provider if you plan to have any surgery before starting or during treatment with axitinib tablets.
  - You should stop taking axitinib tablets at least 2 days before planned surgery.
  - Your healthcare provider should tell you when you may start taking axitinib tablets again after surgery.

- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** A condition called reversible posterior leukoencephalopathy syndrome (RPLS) can happen during treatment with axitinib tablets. Call your healthcare provider right away if you get:
  - headache
  - seizures
  - weakness
  - confusion
  - high blood pressure
  - blindness or change in vision
  - problems thinking
- **Protein in your urine.** Your healthcare provider should check your urine for protein before and during your treatment with axitinib tablets. If you develop protein in your urine, your healthcare provider may decrease your dose of axitinib tablets or stop your treatment.
- **Liver problems.** Your healthcare provider will do blood tests before and during your treatment with axitinib tablets. Your healthcare provider may delay or stop your treatment with axitinib tablets if you develop severe liver problems. Tell your healthcare provider right way if you have any of the following symptoms:
  - yellowing of your skin or the whites of your eyes
  - severe nausea or vomiting
  - pain on the right side of your stomach area (abdomen)
  - dark urine (tea colored)
  - bleeding or bruising more easily than normal

**The most common side effects of axitinib tablets when used alone include:**

- diarrhea
- high blood pressure
- feeling tired or weak
- decreased appetite
- nausea
- hoarseness
- rash, redness, itching or peeling of your skin on your hands and feet
- decreased weight
- vomiting
- constipation

Axitinib tablets may cause fertility problems in males and females, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of axitinib tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store axitinib tablets?**
Store axitinib tablets at room temperature between 68°F to 77°F (20°C to 25°C).
**Keep axitinib tablets and all medicines out of the reach of children.**

**General information about the safe and effective use of axitinib tablets.**
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use axitinib tablets for a condition for which it was not prescribed. Do not give axitinib tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about axitinib tablets that is written for health professionals.

**What are the ingredients in axitinib tablets?**
**Active ingredient**: axitinib
**Inactive ingredients**: croscarmellose sodium, ethylcellulose, magnesium stearate, and microcrystalline cellulose. The film coating contains hypromellose, iron oxide red, titanium dioxide, and triacetin.

For more information, go to www.apotex.com or call 1-800-706-5575

This product's labeling may have been updated. For the most recent prescribing information, please visit www.apotex.com.

**Rx only**
**AXITINIB TABLETS**
**1 mg and 5 mg**

**Manufactured By:**
Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

**Manufactured For:**
Apotex Corp.
Weston, Florida
33326

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This Patient Information has been approved by the U.S. Food and Drug Administration.