

MEDICATION GUIDE
ATZUMI™ (at zoo' mee)
(dihydroergotamine)
nasal powder

What is the most important information I should know about ATZUMI?

ATZUMI can cause serious side effects, including:

- **Serious problems with blood circulation to your legs and feet (peripheral ischemia).** ATZUMI can cause peripheral ischemia when you take it with certain medicines known as CYP3A4 inhibitors. Peripheral ischemia may lead to a stroke and death. Stop taking ATZUMI and get emergency medical help right away if you have any of the following symptoms:
 - cramping and pain in your legs or hips
 - feeling of heaviness or tightness in your leg muscles
 - burning or aching pain in your feet or toes while resting
 - numbness, tingling, or weakness in your legs
 - cold feeling or color changes in 1 or both legs or feet
 - slurred speech
 - sudden weakness

Do not take medicines known as strong CYP3A4 inhibitors, such as:

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|--------------|------------------|----------------|
| ○ ritonavir | ○ erythromycin | ○ ketoconazole |
| ○ nelfinavir | ○ clarithromycin | ○ itraconazole |

These are not all of the medicines that could affect how ATZUMI works. Your healthcare provider can tell you if it is safe to take ATZUMI with other medicines.

What is ATZUMI?

ATZUMI is a prescription medicine used for the acute treatment of migraine with or without aura in adults.

- ATZUMI is not used to prevent migraine.
- ATZUMI is not used to treat other types of headaches such as hemiplegic (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines.

It is not known if ATZUMI is safe and effective in children.

Who should not take ATZUMI?

Do not take ATZUMI if you:

- are taking medicines known as strong CYP3A4 inhibitors.
- have heart problems or a history of heart problems.
- have uncontrolled high blood pressure.
- have narrowing of blood vessels in your legs, arms, stomach, or kidneys (peripheral vascular disease).
- have sepsis.
- have had vascular surgery.
- have severe liver problems.
- have severe kidney problems.
- are allergic to dihydroergotamine, ergot alkaloids, or any of the ingredients in ATZUMI. See the end of this Medication Guide for a complete list of ingredients in ATZUMI.
- have taken any of the following medicines in the last 24 hours:
 - sumatriptan
 - almotriptan
 - eletriptan
 - frovatriptan
 - naratriptan
 - rizatriptan
 - zolmitriptan
 - ergotamine or ergotamine-type medicines
- have taken any medicines that constrict your blood vessels or raise your blood pressure.

Ask your healthcare provider if you are not sure if you are taking any of these medicines.

Your healthcare provider can tell you if it is safe to take ATZUMI with other medicines.

Before you take ATZUMI, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure.
- have liver problems.
- have kidney problems.
- have risk factors for heart disease. You have a higher risk for heart disease if you:
 - have high blood pressure
 - have high cholesterol levels
 - smoke
 - are overweight
 - have diabetes
 - have a family history of heart disease
- are taking medicines known as strong CYP3A4 inhibitors.
- are pregnant or plan to become pregnant. ATZUMI may cause preterm labor. ATZUMI should be avoided during pregnancy. Talk to your healthcare provider right away if you are pregnant or want to become pregnant.
- are breastfeeding or plan to breastfeed. ATZUMI may reduce breast milk supply and pass into your breast milk. ATZUMI may be harmful to your baby. Do not breastfeed your baby while taking ATZUMI and for 3 days after you use ATZUMI. Talk with your healthcare provider about the best way to feed your baby if you take ATZUMI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider will decide if you can take ATZUMI with your other medicines.

How should I take ATZUMI?

- ATZUMI is for nasal use only (use in the nose).
- Certain people should take their first dose of ATZUMI in their healthcare provider's office or in another medical setting. Ask your healthcare provider if you should take your first dose in a medical setting.
- Use ATZUMI exactly as your healthcare provider tells you to use it. Read and follow the instructions in the Instructions for Use or use the Quick Reference Guide located on the ATZUMI protective foil pouch.
- If your headache comes back after the first complete dose or you only get some relief from your headache, you can use a second dose 1 hour after the first complete dose. Use a new ATZUMI nasal powder device for the second dose, if needed.
- Do not take more than 2 doses of ATZUMI within a 24-hour period. It is not known if it is safe to take more than 4 doses of ATZUMI in a 7-day period or 12 doses in a 30-day period.
- Taking ATZUMI for 10 or more days in 1 month may make your headaches worse. You should write down when you have headaches and when you take ATZUMI so that you can talk with your healthcare provider about how ATZUMI is working for you. See "What are the possible side effects of ATZUMI?"

If you use too much ATZUMI, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of ATZUMI?

ATZUMI can cause serious side effects, including:

See "What is the most important information I should know about ATZUMI?"

- **Heart attack and other heart problems.** Heart problems may lead to death. Stop taking ATZUMI and get emergency medical help right away if you have any of the following symptoms of a heart attack:
 - discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
 - severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
 - pain or discomfort in your arms, back, neck, jaw, or stomach
 - shortness of breath with or without chest discomfort
 - breaking out in a cold sweat
 - feeling lightheaded
 - nausea or vomiting

ATZUMI is not for people with risk factors for heart disease unless a heart exam is done and shows no problem.

See "**Before you take ATZUMI, tell your healthcare provider about all of your medical conditions, including if you:**" for the risk factors for heart disease.

- **Stroke.** Stop taking ATZUMI and get emergency medical help right away if you have any of the following symptoms of a stroke:
 - face drooping

- unusual weakness or numbness
- slurred speech
- **Changes in color or sensation in your fingers and toes (Raynaud's syndrome).**
- **Stomach and intestinal problems** (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include:
 - sudden or severe stomach pain
 - constipation or diarrhea
 - stomach pain after meals
 - bloody diarrhea
 - weight loss
 - fever
 - nausea or vomiting
- **Increased blood pressure.**
- **Medicine overuse headache.** Some people who use too much ATZUMI may make their headaches worse (medicine overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with ATZUMI.
- **Preterm labor.**
- **Tissue changes (fibrotic complications).** Inflammation and fiber-like tissue that is not normal (fibrosis) can occur around the lungs and stomach.
- **Nose irritation.** Discomfort in your nose, change in taste, stuffy nose, and cold-type symptoms, (such as, runny nose, sneezing, and cough) can occur.

The most common side effects of ATZUMI include:

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|------------------|------------------------------|---------------|
| ● runny nose | ● application site reactions | ● sleepiness |
| ● nausea | ● dizziness | ● sore throat |
| ● abnormal taste | ● vomiting | ● diarrhea |

These are not all of the possible side effects of ATZUMI.

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 ATZUMI?

- Store ATZUMI at room temperature between 68°F to 77°F (20°C to 25°C).
- Store ATZUMI in its protective foil pouch until ready to use.

Keep ATZUMI and all medicines out of the reach of children.

General information about the safe and effective use of ATZUMI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ATZUMI for a condition for which it was not prescribed. Do not give ATZUMI to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ATZUMI that is written for health professionals.

What are the ingredients in ATZUMI?

Active ingredient: Dihydroergotamine

Inactive ingredients: Hypromellose, mannitol, and microcrystalline cellulose

ATZUMI is a trademark of Satsuma Pharmaceuticals, Inc.

Manufactured for Satsuma Pharmaceuticals, Inc., Durham, NC 27703

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For more information, go to www.atzumi.com or call 1-888-273-2480.