



Patient Information Sheet

Almotriptan malate (marketed as Axert)

This is a summary of the most important information about Axert. For details, talk to your healthcare professional.

FDA ALERT [07/2006] – Possible Life-Threatening Serotonin Syndrome When Used With SSRI or SNRI Medicines

A life-threatening condition called serotonin syndrome can happen when medicines called 5-hydroxytryptamine receptor agonists (triptans), such as Axert, and medicines used to treat depression and mood disorders called selective serotonin reuptake inhibitors (SSRIs) or selective serotonin/norepinephrine reuptake inhibitors (SNRIs), are used together. Signs and symptoms of serotonin syndrome include the following:

- restlessness
- hallucinations
- loss of coordination
- fast heart beat
- increased body temperature
- fast changes in blood pressure
- overactive reflexes
- diarrhea
- coma
- nausea
- vomiting

Serotonin syndrome may be more likely to occur when starting or increasing the dose of a triptan, SSRI, or SNRI. This information comes from reports sent to FDA and knowledge of how these medicines work. If you take medicines for depression or mood disorders, ask your healthcare professional if your medicine is an SSRI or SNRI.

Before you take Axert and an SSRI or SNRI together, talk to your healthcare professional. If you must take these medicines together, be aware of the possibility of serotonin syndrome, and get medical care right away if you think serotonin syndrome is happening to you.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update

this sheet when additional information or analyses become available.

What is Axert?

Axert is used for the short term treatment of most types of migraine attacks in adults. Axert is not used to prevent migraines, or to decrease the number of migraine attacks. Axert has not been shown to treat cluster headaches.

Who Should Not Take Axert?

You should not take Axert if you have (or have had) any of following conditions:

- uncontrolled high blood pressure
- heart disease or a history of heart disease
- hemiplegic or basilar migraine (if you are not sure about this, ask your healthcare professional)
- stroke
- circulation (blood flow) problems to your arms, legs, and bowels
- have taken another migraine medicine in the same drug class as Axert or other migraine medicines that contain ergotamine, dihydroergotamine, or methylsergide in the last 24 hours (ask your healthcare professional for a list of these medicines if you are unsure)

What are The Risks?

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

Some signs of rare but serious side effects include:

- **Possible life-threatening serotonin syndrome when used with SSRI or SNRI medicines: See FDA Alert [07/2006] above.**
- Pain, pressure or tightness in the chest or throat. If severe, or does not go away, call





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your healthcare professional right away. If this happens at all, discuss with your healthcare professional before taking any more Axert.

- Rarely, people have a serious allergic reaction to Axert. This could cause shortness of breath, wheeziness, heart throbbing, swelling of eyelids, face, or lips, or a skin rash, lumps or hives. If this happens, tell your healthcare professional right away.

Other side effects may include:

- Nausea
- Sleepiness
- Tingling or burning feeling
- Headache
- Dry mouth

What Should I Tell My Healthcare Professional?

Before you start taking Axert, tell your healthcare professional if you:

- are trying to become pregnant, are already pregnant, or are breastfeeding
- have risk factors for heart disease including:
 - high cholesterol
 - high blood pressure
 - obesity
 - diabetes
 - smoking
 - strong family history of heart disease
 - postmenopausal female,
 - or a male over 40

Can Other Medicines Or Food Affect Axert?

Axert 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. Some medicines may affect how Axert works or Axert may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Especially tell your healthcare professional if you:

- take a SSRI or SNRI medicine
- have taken another migraine medicine in the same drug class as Axert or other migraine medicines that contain ergotamine, dihydroergotamine, or methylsergide in the last 24 hours
- take ketoconazole (Nizoral) or itraconazole (Sporanox)
- take nefazodone (Serzone)
- take troleandomycin (TAO)
- take clarithromycin (Biaxin)
- take ritonavir (Norvir) or nelfinavir (Viracept)

Ask your healthcare professional if you are not sure about the types of medicines you take.

Date this drug approved 05/2001
Patient Information Sheet Revised 07/2006

