

Patient Information
INTUNIV™ (in-TOO-niv)
(guanfacine)
Extended-Release Tablets

Read the Patient Information that comes with INTUNIV™ before you start taking it and each time you get a refill. There may be new information. **This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.**

What is INTUNIV™?

INTUNIV™ is a prescription medicine used to treat the symptoms of attention deficit/hyperactivity disorder (ADHD).

INTUNIV™ is not a central nervous system (CNS) stimulant.

INTUNIV™ should be used as a part of a total treatment program for ADHD that may include counselling or other therapies.

It is not known if INTUNIV™ is effective:

- for use longer than 9 weeks

It is not known if INTUNIV™ is safe or effective:

- in children younger than 6 years old
- in adults

What should I tell my doctor before taking INTUNIV™?

Before you take INTUNIV™, tell your doctor if you:

- have heart problems or a low heart rate
- have fainted
- have low blood pressure
- have liver or kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if INTUNIV™ will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed. It is not known if INTUNIV™ passes into your breast milk. You and your doctor should decide if you will take INTUNIV™ or breastfeed.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

INTUNIV™ may affect the way other medicines work, and other medicines may affect how INTUNIV™ works.

Especially tell your doctor if you take:

- ketoconazole
- medicines that can affect enzyme metabolism
- valproic acid
- high blood pressure medicine
- sedatives
- benzodiazepines
- barbiturates
- antipsychotics

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take INTUNIV™?

- Take INTUNIV™ exactly as your doctor tells you.
- Your doctor may change your dose. Do not change your dose of INTUNIV™ without talking to your doctor.
- Do not stop taking INTUNIV™ without talking to your doctor.
- INTUNIV™ should be taken 1 time a day.
- INTUNIV™ should be swallowed whole with a small amount of water, milk, or other liquid.
- Do not crush, chew, or break INTUNIV™. Tell your doctor if you can not swallow INTUNIV™ whole.
- Do not take INTUNIV™ with a high-fat meal.
- Your doctor will check your blood pressure and heart rate while you take INTUNIV™.
- If you take too much INTUNIV™, call your local Poison Control Center or go to the nearest emergency room right away.

What should I avoid while taking INTUNIV™?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how INTUNIV™ affects you. INTUNIV™ can slow your thinking and motor skills.
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking INTUNIV™ until you talk with your doctor. INTUNIV™ taken with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

What are the possible side effects of INTUNIV™?

INTUNIV™ may cause serious side effects including:

- low blood pressure
- low heart rate
- fainting
- sleepiness
- tiredness
- drowsiness

Get medical help right away, if you have any of the symptoms listed above.

The most common side effects of INTUNIV™ include:

- | | |
|----------------------|-----------------------------------|
| • sleepiness | • dry mouth |
| • drowsiness | • dizziness |
| • low blood pressure | • irritability |
| • headache | • constipation |
| • nausea | • not hungry (decreased appetite) |
| • stomach pain | |

Tell the doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of INTUNIV™. For more information, ask your doctor or pharmacist.

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 INTUNIV™?

- Store INTUNIV™ between 59°F to 86°F (15°C to 30°C)

Keep INTUNIV™ and all medicines out of the reach of children.

General Information about INTUNIV™

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use INTUNIV™ for a condition for which it was not prescribed. Do not give INTUNIV™ to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarizes the most important information about INTUNIV™. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about INTUNIV™ that is written for health professionals.

For more information, go to www.INTUNIV.com or call 1-800-828-2088.

What are the ingredients in INTUNIV™?

Active ingredient: guanfacine hydrochloride

Inactive ingredients: hypromellose, methacrylic acid copolymer, lactose, povidone, crospovidone, microcrystalline cellulose, fumaric acid, and glycerol behenate. In addition, the 3mg and 4mg tablets also contain green pigment blend PB-1763.

Manufactured for Shire US Inc., Wayne, PA 19087.

INTUNIV™ is a trademark of Shire LLC.

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This product is covered by US patents including 5,854,290; 6,287,599; 6,811,794.

Version: August 2009