

PART III: CONSUMER INFORMATION

PrINTUNIV XR®*

guanfacine hydrochloride extended-release tablets

This leaflet is part III of a three-part "Product Monograph" published when INTUNIV XR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INTUNIV XR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- INTUNIV XR may be a part of the patient's overall treatment of ADHD. The doctor may also recommend that you/your child have/has counselling or other therapy.
- INTUNIV XR is a prescription medicine, specifically a selective alpha_{2A}-adrenergic receptor agonist. It contains guanfacine hydrochloride which is used to treat the symptoms of Attention Deficit Hyperactivity Disorder (ADHD) in children 6-17 years of age.

What it does:

INTUNIV XR helps increase attention (including the ability to follow directions and finish tasks) and decrease impulsiveness and hyperactivity in patients with ADHD.

When it should not be used:

INTUNIV XR should not be taken if

- You/your child are/is allergic to guanfacine or any other non-medicinal ingredients in INTUNIV XR. (see What the non-medicinal ingredients are)
- Your child is younger than 6 years old.

What the medicinal ingredient is:

guanfacine hydrochloride

What the non-medicinal ingredients are:

Crospovidone, fumaric acid, glyceryl behenate, green pigment blend PB-1763 (3mg and 4mg tablets only), hypromellose, lactose, methacrylic acid copolymer, microcrystalline cellulose, and povidone.

What dosage forms it comes in:

Tablets; 1mg, 2mg, 3mg, and 4mg guanfacine as guanfacine hydrochloride

WARNINGS AND PRECAUTIONS

The following have been reported with use of medicines used to treat ADHD such as INTUNIV XR:

Mental (Psychiatric) problems:

- New or worse thoughts or feelings related to suicide (thinking about or feeling like killing yourself) and suicide actions (suicide attempt, completed suicide)
- New or worse bipolar illness, characterized by extreme mood swings, with periods of mania (unusually excited, over-active or un-inhibited) alternating with periods of depression (feelings of sadness, worthlessness or hopelessness)
- New or worse aggressive behavior or hostility
- New psychosis (such as hearing voices, believing things that are not true, are suspicious) or new mania (unusually excited, over-active or un-inhibited).

These new or worse mental problems may be more likely to occur if your child has mental disorders that you may or may not know about. Tell your child's doctor about any mental problems your child has, or about any personal or family history of suicide, bipolar illness, or depression.

A small number of patients taking ADHD drugs may experience unusual feelings of agitation, hostility or anxiety, or have impulsive or disturbing thoughts such as thoughts of suicide, self-harm or harm to others. Those suicidal thoughts or behaviors may occur at any time *during* treatment, particularly at the start or during dose changes, and also *after stopping* INTUNIV XR. **Should this happen to your child, talk to your child's doctor immediately. Close observation by a doctor is necessary in this situation.**

Call your child's doctor right away if your child has any new or worsening mental symptoms while taking INTUNIV XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

BEFORE you/your child uses INTUNIV XR, talk to your doctor or your child's doctor or pharmacist if you/your child:

- Have/has a heart problem (e.g., very low heart rate (pulse), heart rhythm problem)
- Have/has already fainted in the past (or have/has a history of fainting)
- Have/has low or high blood pressure
- Have/has liver or kidney problems
- Have/has mental problems or a family history of mental problems including psychosis, mania, bipolar illness, depression, or suicide

- Have/has any other medical condition
- Are/ is pregnant
- Are/is breast-feeding or plans to breast-feed

While on INTUNIV XR, you/your child should avoid becoming dehydrated or overheated.

Talk to your doctor or your child's doctor or pharmacist about any problem with weight while taking INTUNIV XR.

Do not drive, operate heavy machinery, or do other dangerous activities until you know how INTUNIV XR affects you. INTUNIV XR can slow your thinking and motor skills. INTUNIV taken with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.

INTERACTIONS WITH THIS MEDICATION

It is important to tell your doctor or your child's doctor or pharmacist about all medicines that you/your child are/ is taking, including medicines prescribed by other doctors, medicines or vitamins that you buy without a prescription, and any other alternative medicines and herbal remedies. While on INTUNIV XR, do not take/give your child a new medicine or herbal remedy before checking with your doctor or your child's doctor.

It is especially important to inform your doctor or your child's doctor if you or your child takes the following medication:

- Medicines that can affect enzyme metabolism (such as ketoconazole, rifampin)
- Valproic acid
- Medicines that affect heart functioning (e.g., QT interval-prolongation, pulse and blood pressure)
- Drugs causing sleepiness (sedatives)
- Drugs inducing sleep in surgical anesthesia or in the treatment of insomnia (hypnotics)
- Drugs used as tranquilizer (benzodiazepines)
- Drugs used as central nervous system depressants (barbiturates)
- Medication used to manage psychosis (antipsychotics)
- Alcohol
- Other medicines for ADHD
- Any drug that may cause heart valve problems

Know the medicines that you/your child takes. Keep a list of you/your child's medicines with you to show the doctor and pharmacist each time you/your child have/has an appointment.

PROPER USE OF THIS MEDICATION

- You/your child should take INTUNIV XR exactly as your doctor or your child's doctor prescribes.
- You/your child should not stop taking INTUNIV XR without talking to your doctor or your child's doctor.
- INTUNIV XR should be taken once a day, either alone or with an ADHD psychostimulant medication prescribed by your doctor or your child's doctor. This doctor will tell you when you/your child should take INTUNIV XR and when to take your/his/her ADHD psychostimulant medication.
- Do not take INTUNIV XR with a high-fat meal.

Usual dose:

The recommended starting dose is 1mg tablet once a day. To be swallowed whole with a small amount of liquid. Should not be crushed, chewed, broken or divided prior to swallowing-

The increments of dosage should be no more than 1mg per week. Total daily dose between 1-7mg.

In order to receive the most benefit from INTUNIV XR, it is important that INTUNIV XR be taken only as directed by your doctor or your child's doctor. The doctor may adjust the amount of drug taken until it is right for you/your child.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Possible symptoms of an overdose include: low blood pressure, initial high blood pressure, slowing of heart rhythm (bradycardia), sleepiness (lethargy), and difficulty breathing (respiratory depression).

Children/adolescents who develop lethargy should be observed for the development of more serious symptoms including, slowing of heart rhythm and low blood pressure due to the possibility of delayed onset of these symptoms.

Missed Dose:

If two or more consecutive doses are missed, talk to your doctor or your child's doctor. It is recommended to have your doctor or your child's doctor restart you/your child on the lowest possible dose.

Discontinuation:

You/your child should not stop taking INTUNIV XR without talking to your doctor or your child's doctor about how to stop the medicine. Sudden discontinuation of INTUNIV XR may lead to serious increase in blood pressure and heart rate (pulse).

Withdrawal symptoms of high blood pressure and increased heart rate after suddenly stopping INTUNIV XR may occur within a few days or after a few weeks and may be accompanied by headaches, feeling confused, nervousness, agitation, and tremors; and may require immediate medical assistance.

These effects on blood pressure and heart rate may be more important if you/your child are taking a psychostimulant in addition to INTUNIV XR.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its desired effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur, talk to your doctor or your child's doctor.

The most common side effects include:

- Sleepiness, trouble sleeping
- Tiredness, dizziness
- Headache
- Nausea, stomach pain
- Decreased appetite

You/your child should avoid performing tasks which may require special attention, such as driving, riding a bike, operating machinery or doing other dangerous activities until you/they are certain that INTUNIV XR does not adversely affect you/them.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist right away		Seek immediate medical help
		Only if severe	In all cases	
Common	Low blood pressure Sleepiness		√	
Uncommon	Low heart rate (pulse) Fainting Convulsion		√ √ √	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist right away		Seek immediate medical help
Unknown	Allergic reaction: rash, itching, hives, swelling of the face, nose, lips or tongue, difficulty breathing or swallowing, dizziness			√
	New Psychotic or Manic Symptoms: -Paranoia, delusions Hallucinations: seeing, feeling or hearing things that are not real Mania: feeling unusually excited, over-active, or uninhibited (see Warnings and Precautions)		√ √	
	Aggressive Behavior or Hostility		√	
	Suicidal Behavior: Thoughts or actions about hurting or killing yourself. (see Warnings and Precautions)			√
	High Blood Pressure after suddenly stopping INTUNIV XR: headaches, feeling confused, nervousness, agitation, tremors			√

This is not a complete list of side effects. For any unexpected effects while taking INTUNIV XR, contact your doctor or your child's doctor or pharmacist.

HOW TO STORE IT

Store at 25°C (77°F); excursions permitted from 15° to 30°C (59° to 86°F). Keep out of sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION**If you want more information about INTUNIV XR:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website <http://hc-sc.gc.ca>, the manufacturer's website www.shirecanada.com, or by calling 1-800-268-2772.

This leaflet was prepared by Shire Pharma Canada ULC
22 Adelaide St. West, Suite 3800
Toronto, Ontario M5H 4E3

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