

INTUNIV®

guanfacine hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet before you/your child start taking INTUNIV.

This leaflet answers some common questions about INTUNIV. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you/your child taking INTUNIV against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What INTUNIV is used for

INTUNIV is a medicine used to treat the symptoms of Attention Deficit Hyperactivity Disorder (ADHD). INTUNIV is a medicine that can help improve your attention, concentration and make you less impulsive and hyperactive.

INTUNIV should be used as part of a comprehensive treatment program which usually includes psychological, educational and social therapy.

The main ingredient in INTUNIV is guanfacine hydrochloride.

Ask your doctor if you have any questions about why this medicine has been prescribed for you/your child.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription

Before you take INTUNIV

When you must not take it

Do not take INTUNIV if you/your child have an allergy to:

- any medicine containing guanfacine hydrochloride
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not give this medicine to a child under the age of 6 years.

Safety and effectiveness in children younger than 6 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you/your child should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you/your child have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you/your child have or have had any of the following medical conditions:

- have heart problems or a low heart rate
- have fainted
- have low blood pressure
- have liver or kidney problems
- any other medical conditions

Tell your doctor if you/your child are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you/your child start taking INTUNIV.

Taking other medicines

Tell your doctor or pharmacist if you/your child are taking any other medicines, including any that are available without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and INTUNIV may interfere with each other. These include:

- medicines that lower blood pressure (antihypertensives)
- medicines used to treat epilepsy such as valproic acid
- medicines that make you sleepy
- medicines for mental health problems such as sedatives,

- benzodiazepines, barbiturates and antipsychotics
- medicines that can affect liver metabolism such as ketoconazole, rifampin
- medicines that can affect enzyme metabolism

These medicines may be affected by INTUNIV or may affect how well INTUNIV works. You/your child may need different amounts of your medicines, or you/your child may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take INTUNIV

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor will normally start you/your child on a low dose. Your doctor will increase the dose based on your/your child's body weight and how INTUNIV is working for you/your child. Your doctor will tell you what dose to take each day and will calculate the dose based on your/your child's body weight.

The daily dose will be between 1-7 mg, but not more than 7 mg. When used together with a stimulant, the usual daily recommended dose is not more than 4 mg.

How to take it

- Take INTUNIV exactly as prescribed. INTUNIV comes in 4 different strength tablets
- Take INTUNIV once a day either in the morning or evening

- INTUNIV can be taken with or without food
- Do not take INTUNIV with fatty foods

Swallow the tablets whole with a full glass of water. Do not break, crush or chew the tablet. This will affect how INTUNIV works.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If you/your child forget a dose, wait until the next day and take the usual dose.

Do not take a double dose to make up for the missed dose.

If you/your child have missed two or more doses talk to your doctor or pharmacist.

If you/your child have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you/your child take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much INTUNIV. Do this even if there are no signs of discomfort or poisoning.

You/your child may need urgent medical attention.

If you/your child take too much INTUNIV you/your child may experience symptoms such as slow heart rate, slow breathing rate, low or high blood pressure, feeling tired or exhausted.

While you/your child are using INTUNIV

Things you must do

If you/your child are about to be started on any new medicine, remind your doctor and pharmacist that you/your child are taking INTUNIV.

Tell any other doctors, dentists, and pharmacists who treat you/your child that you/your child are taking this medicine.

If you/your child become pregnant while taking this medicine, tell your doctor immediately.

If you/your child have a gastrointestinal illness that leads to vomiting tell your doctor. This can be like missing doses which could lead to an increase in blood pressure or heart rate.

Keep all of your/your child's doctor's appointments so that your/your/child's progress can be checked.

Your doctor will want to check your/your child's height and weight, and blood pressure and heart rate at least once a year or when your/your child's dose is changed or stopped to make sure the medicine is working and to prevent unwanted side effects.

Things you/your child must not do

Do not take INTUNIV to treat any other complaints unless your doctor tells you to.

Do not give INTUNIV to anyone else, even if they have the same condition as you/your child.

Do not stop taking INTUNIV or lower the dosage without checking with your doctor.

If INTUNIV is stopped suddenly, your/your child's condition may worsen or your/your child's blood pressure and heart rate may increase.

Things to be careful of

Do not eat or drink products and juices containing grapefruit while you/your child are being treated with INTUNIV.

It may interact with INTUNIV and affect how INTUNIV works in the body.

Be careful driving or operating machinery until you know how INTUNIV affects you.

This medicine may cause dizziness, light-headedness, tiredness, drowsiness in some people. If you/your child have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Be careful when drinking alcohol while taking INTUNIV because it could make you/your child sleepy and drowsy.

Side effects

Tell your doctor or pharmacist as soon as possible if you/your child do not feel well while you/your child are taking INTUNIV.

Like all medicines, INTUNIV can cause some side effects. Sometimes they are serious, most of the time they are not. You/your child may need medical attention if you/your child get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects (if there is an increased risk of side effects in the elderly).

Do not be alarmed by the following lists of side effects. You/your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you/your child notice any of the following and they worry you:

- feeling sleepy or very drowsy
- feeling tired or weary
- headache
- stomach pain
- feeling restless or irritable
- trouble sleeping or broken sleep or nightmares
- feeling depressed, worried or having mood swings
- weight gain
- loss of appetite
- have a dry mouth
- wetting yourself
- feeling or being sick
- diarrhoea, indigestion (upset stomach) or constipation
- slow heart beat
- feeling dizzy or faint
- fainting
- trouble breathing or asthma
- increased blood pressure
- low blood pressure or feeling dizzy when standing up
- rash

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- allergic reaction which may result in a rash or more rarely to a sharp drop in blood pressure, difficulty breathing, and hives/itching (anaphylactic reaction)
- chest pain
- seizures (fits) or convulsions
- loss of strength
- pale skin colour
- need to urinate frequently
- feeling agitated
- sleeping more than normal
- changes in liver blood test results
- high blood pressure or an unusual heart rhythm
- fast heart beat
- itchy skin

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you/your child feel unwell.

Other side effects not listed above may also occur in some people.

After using INTUNIV

Storage

Keep INTUNIV tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep INTUNIV tablets in a cool dry place where the temperature stays below 25°C.

Do not store INTUNIV or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What INTUNIV looks like

INTUNIV 1 mg tablets are round and white to off-white, hard tablets, debossed with IMG on one side and 503 on the other side.

INTUNIV 2 mg tablets are oblong shaped and white to off-white, hard

tablets, debossed with 2MG on one side and 503 on the other side.

INTUNIV 3 mg tablets are round and green, hard tablets, debossed with 3MG on one side and 503 on the other side.

INTUNIV 4 mg tablets are oblong shaped and green, hard tablets, debossed with 4MG on one side and 503 on the other side.

INTUNIV 1 mg AUST R 275278

INTUNIV 2 mg AUST R 275313

INTUNIV 3 mg AUST R 275314

INTUNIV 4 mg AUST R 275315

INTUNIV® is a registered trademark of Shire Pharmaceuticals Ireland Limited.

Ingredients

Active ingredient

INTUNIV contains guanfacine hydrochloride as the active ingredient.

Other ingredients

- methacrylic acid - ethyl acrylate copolymer (1:1)
- sodium lauryl sulfate
- polysorbate 80
- hypromellose
- lactose
- povidone
- crospovidone
- silicified microcrystalline cellulose
- fumaric acid
- glycerol dibehenate
- indigo carmine aluminium lake (3 and 4 mg)
- iron oxide yellow (3 and 4 mg)

This medicine contains lactose.

Sponsor

Shire Australia Pty Ltd

Shire is now part of Takeda

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