INTUNIV®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using INTUNIV?

INTUNIV contains the active ingredient guanfacine hydrochloride. INTUNIV is used to treat the symptoms of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents.

For more information, see Section 1. Why am I using INTUNIV? in the full CMI.

2. What should I know before I use INTUNIV?

Do not use if you have ever had an allergic reaction to INTUNIV or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, have history or current mental health problems, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use INTUNIV? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INTUNIV and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use INTUNIV?

- Your doctor will tell you what dose to take each day based on your/your child's body weight and the dose if it is used together with a stimulant medicine.
- Swallow the tablet whole with a full glass of water. Do not break, crush or chew the tablet. Follow all directions given to you by your doctor or pharmacist carefully.

More instructions can be found in Section 4. How do I use INTUNIV? in the full CMI.

5. What should I know while using INTUNIV? ('You' means either yourself or your child)

Things you should do	• Remind any doctor or dentist whom you visit that you are using

	INTUNIV. If you become pregnant while using this medicine, tell the doctor immediately.
Things you should not do	• Do not stop using this medicine or change dosage without checking with your doctor.
Driving or using machines	• Be careful driving or operating machinery until you know how INTUNIV affects you.
Drinking alcohol	• Be careful when drinking alcohol while taking INTUNIV because it could make you sleepy and drowsy.
Looking after your medicine	• Store INTUNIV in a cool dry place where the temperature is below 25°C.

For more information, see Section 5. What should I know while using INTUNIV? in the full CMI.

6. Are there any side effects?

Common side effects include feeling drowsy, headache, restless, trouble sleeping, weight gain, loss of appetite, dry mouth, diarrhoea, constipation. Serious side effects

include allergic reaction, chest pain, seizures, loss of strength, need to urinate frequently, itchy skin, high blood pressure, irregular heart rhythms.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

INTUNIV®

Active ingredient(s): guanfacine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using INTUNIV. It does not take the place of talking to your doctor or pharmacist. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INTUNIV.** The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.takeda.com/en-au. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

1. Why am I using INTUNIV?
2. What should I know before I use INTUNIV?
3. What if I am taking other medicines?
4. How do I use INTUNIV?
5. What should I know while using INTUNIV?
6. Are there any side effects?
7. Product details

1. Why am I using INTUNIV?

INTUNIV contains the active ingredient guanfacine hydrochloride. INTUNIV is a medicine used to treat the symptoms of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents 6-17 years old. It can be used alone or with another medicine called a psychostimulant. INTUNIV 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.

This medicine is not addictive.

2. What should I know before I use INTUNIV?

Warnings

Do not use INTUNIV if:

1. you are allergic to guanfacine hydrochloride, or any of the ingredients listed at the end of this leaflet.
2. Always check the ingredients to make sure you can use this medicine.
3. Do not give this medicine to a child under the age of 6 years. Do not use if you are an adult or are elderly. Safety and effectiveness in children younger than

6 years, and adults and the elderly have not been established.

Check with your doctor if you/your child:

- have heart problems or a low heart rate
- have fainted
- have low blood pressure
- have history or current suicidal thoughts or behaviour
- have liver or kidney problems
- have any other medical conditions or take any medicines for any other condition

During treatment, you/your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you/your child are pregnant or intend to become pregnant.

Talk to your doctor if you/your child are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some 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. 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

• medicines that contain metformin (used for treatment of type 2 diabetes).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INTUNIV.

4. How do I use INTUNIV?

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.
- Follow the instructions provided and use INTUNIV until your doctor tells you to stop.

When to take INTUNIV

- Take INTUNIV once a day either in the morning or evening.

How to take INTUNIV

- INTUNIV can be taken with or without food. Swallow the tablet whole with a full glass of water. Do not break, crush or chew the tablet.
- Do not take INTUNIV with fatty foods
- 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.

If you/your child forget(s) to use INTUNIV

INTUNIV should be used regularly at the same time each day. If you/your child miss(es) a dose, wait until the next day and take the usual dose.

Do not take a double dose to make up for the dose you/your child missed.

If you use too much INTUNIV

If you think that you/your child have/has used too much INTUNIV, you/your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre
  Australia: 13 11 26
  New Zealand: 0800 POISON or 0800 764 766
  or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Some of the signs and symptoms of an overdose may include high blood pressure at the beginning turning into low blood pressure, slow heart rate, lack of energy, difficulty breathing.

5. What should I know while using INTUNIV?

Things you should do

- Make sure that all of your doctors, dentists, and pharmacists know you/your child are taking INTUNIV. Remind them if any new medicines are about to be started.
- 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.
- All thoughts of suicide must be taken seriously. Talk to your doctor or mental health professional if you/ your child have thoughts or talk about death or suicide; or thoughts or talk about self-harm or doing harm to others.
- 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 should not do

- Do not stop using this medicine suddenly 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.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

Keep INTUNIV tablets in the pack until it is time to take them. Store INTUNIV in a cool dry place where the temperature stays below 25°C.

Do not store it in the bathroom or near a sink, or in the car or on windowsill.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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 • new or worse aggressive behaviour, hostility • weight gain • loss of appetite • have a dry mouth • wetting yourself • feeling or being sick • diarrhoea, indigestion (upset stomach) or constipation • slow heartbeat	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• asthma • rash • feeling dizzy or faint	

Serious side effects

Serious side effects	What to do
• 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 • fainting • trouble breathing • low blood pressure or feeling dizzy when standing up • pale skin colour • high blood pressure or an unusual heart rhythm	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• fast and/or irregular heartbeat • itchy skin • need to urinate frequently • feeling agitated • hallucinations • sleeping more than normal • changes in liver blood test results • loss of strength • suicidal thoughts or behaviour	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you/your child experience, you can report side effects to:

In Australia: The Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems

In New Zealand: Medsafe online at https://pophealth.my.site.com/carmreportnz/s/

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What INTUNIV contains

Active ingredient (main ingredient)	Guanfacine hydrochloride
Other ingredients (inactive 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 (in 3 mg and 4 mg tablets)

	and iron oxide yellow (in 3 mg and 4 mg tablets)

Do not take this medicine if you are allergic to any of these ingredients.

What INTUNIV looks like

INTUNIV 1 mg tablet: Round and white to off-white, hard tablets, debossed with 1MG on one side and 503 on the other side.

INTUNIV 2 mg tablet: Oblong shaped and white to off-white, hard tablets, debossed with 2MG on one side and 503 on the other side.

INTUNIV 3 mg tablet: Round and green, hard tablets, debossed with 3MG on one side and 503 on the other side.

INTUNIV 4 mg tablet: Oblong shaped and green, hard tablets, debossed with 4MG on one side and 503 on the other side.

INTUNIV is supplied as a 28 tablets pack size.

Who distributes INTUNIV

INTUNIV is supplied in Australia by:

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Australia

Phone: 1800 012 612

www.takeda.com/en-au

Australian Registration Number:

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 supplied in New Zealand by:

Takeda New Zealand Limited

Private Bag 92518

Auckland 1141

New Zealand

Telephone: 0508 169 077

www.takeda.com/en-nz

This leaflet was prepared in September 2026.

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