Information on the treatment of ADHD with Intuniv® (guanfacin)

PATIENT INFORMATION – If your child or adolescent has been prescribed INTUNIV



This brochure is provided by your doctor.

This brochure is for you if your child or adolescent has been prescribed INTUNIV.

INTUNIV is a drug for the treatment of ADHD (Attention Deficit Hyperactivity Disorder) in children and adolescents aged 6-17 for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. INTUNIV is used as part of a treatment programme typically including psychological, educational and social measures.

Also carefully read the information in the patient information leaflet, included in the INTUNIV pack.

What is ADHD?

ADHD is considered a neuropsychiatric condition with both biological and psychological causes. The causes are not fully known, but the neurotransmitters dopamine and noradrenaline have been found to be involved. One theory is that a lack of or an imbalance in these neurotransmitters can cause the brain to work slightly differently. This can lead to difficulties with certain behaviours, such as maintaining attention and sitting still. The condition can also make children more intense, more inventive and faster, which can be an asset in their development in some situations. Drugs that raise the levels of these neurotransmitters have been shown to have a positive effect on people with ADHD.

Although ADHD is generally associated with childhood, symptoms may continue into adult age.

Facts for this patient brochure have been taken from:

1. *Kort om ADHD hos barn och vuxna – en sammanfattning av Socialstyrelsens kunskapsöversikt.* (Briefly about ADHD in children and adults – a summary of the Swedish National Board of Health and Welfare's knowledge overview.) Article no. 2004-110-7. ISBN 91-7201-854-2.

2. INTUNIV patient information leaflet and product summary. www.fass.se.

Content fact-checked by Marcus Westin, specialist in child and adolescent psychiatry, Uppsala.

ADHD - facts in brief

- > ADHD stands for **Attention Deficit Hyperactivity Disorder**.
- > ADHD is a condition that affects parts of the brain that regulate **attention, activity and impulsivity**.
- The core symptoms of ADHD are attention difficulties, hyperactivity and impulsivity.
- An ADHD diagnosis always requires a thorough assessment by a specialist,
- > and there must be clear evidence of long-term issues.
- > ADHD is **not a rare condition**. It affects between about 3 and 5% of children of school age.
- > ADHD is a **neuropsychiatric disorder**. It acknowledges that the child's behaviour is not always volitional.

Why drug treatment?

In Sweden, roughly 3–5% of children of school age are affected by ADHD. Many of these children have significant problems at home and at school, despite adaptation and special support. They may therefore benefit from treatment with ADHD medication.

The main aim of treatment is to increase attentiveness, increase concentration, and to reduce motor anxiety (restlessness) and involuntary impulsiveness. INTUNIV can help to improve the ability to concentrate, and reduce hyperactivity and impulsivity. This improves the child's ability to function (way of functioning).



Your child has been prescribed INTUNIV

This leaflet provides information on what INTUNIV is, how to take it, and how it can help to control symptoms of ADHD. Before your child begins treatment, please read the leaflet inside the INTUNIV pack.

What is INTUNIV and how does it work?

INTUNIV is a non-stimulant medication for treating ADHD in children and adolescents aged 6–17. INTUNIV is used as part of a treatment programme, typically including psychological (psychotherapy), educational and support measures.

In people with ADHD, certain parts of the brain are affected. The parts that help the person be attentive, remember details and plan their daily life can be affected to different degrees. ADHD also affects social functioning.

INTUNIV can help to improve attentiveness and concentration, to make the child less impulsive and hyperactive.

INTUNIV is not classed as an addictive drug.



How does INTUNIV affect your child?

INTUNIV is a long-acting drug that is taken once daily, either morning or evening.

INTUNIV can help make everyday life easier, from dressing in the morning and concentrating on school work, to leisure time and evenings spent with friends and family.

How do you take INTUNIV?

INTUNIV must always be taken as prescribed by a doctor.

If you are ever unsure, contact the child's doctor or a pharmacy.

INTUNIV is available in four different strengths (1, 2, 3 and 4 mg). The recommended starting dose of INTUNIV is 1 mg. The child's doctor may then increase the dose to find the right level for your child. The daily dose will be between 1 and 7 mg.

Make sure that your child takes INTUNIV at the same time every day, either in the morning or evening. Do not let the child stop taking the medicine without first consulting the child's doctor.



- > INTUNIV is taken once a day.
- > INTUNIV can be taken with or without food. If taken with food: avoid foods with a high fat content.
- Swallow the tablet whole with a glass of water or other drink (but not grapefruit juice).
- > Do not break, crush or chew the tablet as this affects the drug's efficacy.

If the child forgets to take INTUNIV, wait until the next day to take a normal dose. Never take a double dose to compensate for the missed one. If the child forgets to take the medicine on two or more consecutive days, consult your doctor. If your child takes too high a dose of INTUNIV, contact a doctor or go to the hospital immediately. Take the medicine packaging with you and tell them how much your child has taken.



What you can expect

Before your child starts treatment with INTUNIV, your doctor will assess your child to find out whether he/she is suitable for treatment and will benefit from it. Your child will have regular check-ups during treatment, and slightly more frequently when the dose is adjusted. Be patient. You may not notice an immediate effect when treatment begins. Some patients may notice an improvement after the first week, but it may take longer. As a rule, the doctor will initially prescribe the lowest dose of INTUNIV, and then gradually fine-tune the dose up to the right level over subsequent weeks based on bodyweight and the child's response to INTUNIV. The drug will only begin controlling the symptoms of ADHD once the right dose for your child has been found.

The length of time before noticing an improvement depends on the child's weight and how quickly the body responds to the treatment. Paying attention to how your child is feeling and noticing any side effects can help the doctor to find the right dose.

Possible side effects

Side effects are unwanted effects of a drug. Just like other drugs, INTUNIV may produce side effects, although not everybody will have them. The doctor will tell you more about these side effects.

The most common side effects (affecting more than 1 in 10 people) are drowsiness (somnolence), tiredness, headache and stomach pain. The patient may also feel other kinds of side effects. If your child experiences side effects of any kind, you should contact the child's doctor.

Important to remember

- > Tell the child's doctor if your child is taking any other medication.
- > The tablet should be swallowed whole and should not be broken, crushed or chewed.
- > Make sure that your child takes in enough fluid, although not grapefruit juice.
- > Don't let your child take INTUNIV together with high-fat foods.
- Don't let your child stop taking the medication on his/her own initiative.
- Taking INTUNIV may cause dizziness and drowsiness, especially in the early stages of treatment. If your child experiences side effects of any kind, you should contact the child's doctor.
- The patient must not drink alcohol while being treated with INTUNIV.
- There is limited study data on using guanfacine in pregnancy. INTUNIV is not recommended in pregnancy.

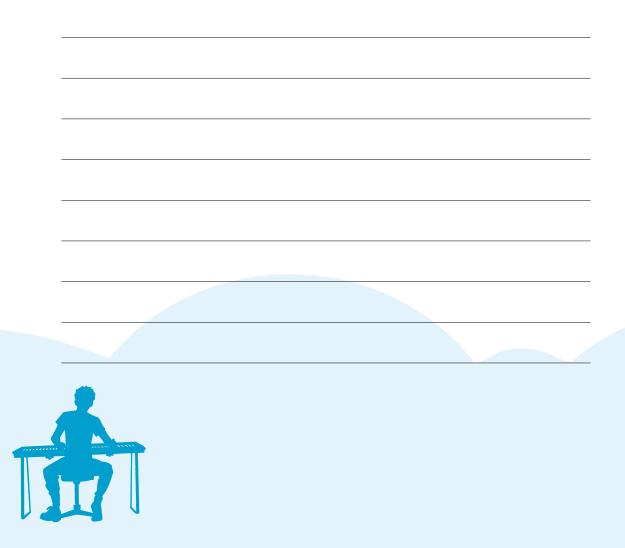
You can find more detailed information about INTUNIV in the patient information leaflet or at fass.se.

If you notice any unexpected change, it is vital that you contact your doctor. There is a more detailed list of possible side effects in the patient information leaflet included in the pack.

Please read the information thoroughly.

Notes

Use this space to write down questions for the doctor or nurse:





INTUNIV is only subsidised when the response to previous treatment with stimulants and atomoxetine is deemed clinically insufficient, or where treatment with these is unsuitable.

This medicine is subject to extended monitoring. This will make it possible to quickly identify new safety information. Healthcare staff are urged to report all suspected side effects to: Swedish Medical Products Agency, Box 26, SE-751 03 Uppsala, www.lakemedelsverket.se.

INTUNIV[®] (guanfacine) 1 mg, 2 mg, 3 mg, 4 mg prolonged-release tablets. Prescription medication. This medication is used to treat ADHD in children and adolescents aged 6–17 for whom current stimulant medications are not suitable and/or where the existing medication does not provide sufficient control of the ADHD symptoms. INTUNIV is used as part of a comprehensive ADHD treatment programme typically including psychological, educational and social measures. You must tell your doctor if you do not feel better or if you feel worse and feel very sleepy or drowsy after taking the medicine for about 6 weeks. If you get sleepy or drowsy, do not drive a vehicle or operate machinery. Do not stop taking INTUNIV without medical advice. If you suddenly stop taking INTUNIV, you may experience withdrawal symptoms in the form of an increased heart rate and high blood pressure. Carefully read the patient information leaflet before starting to take the medicine. INTUNIV must always be taken as prescribed by a doctor. Abridged information based on the patient information heaflet dated **6/2020. For full information** on contraindications, side effects, dosage and price, go to fass.se. Takeda Pharma AB, www.takeda.se.

