

Package leaflet: Information for the patient

Dexatin 5 mg tablets

Dexatin 10 mg tablets

Dexatin 20 mg tablets

dexamfetamine sulfate

Read all of this leaflet carefully before you/your child starts taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have/your child has any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you/your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours/your child's.
- If you get/your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dexatin is and what it is used for
2. What you need to know before you take/your child takes Dexatin
3. How you take/your child takes Dexatin
4. Possible side effects
5. How to store Dexatin
6. Contents of the pack and other information

1. What Dexatin is and what it is used for

What Dexatin is

Dexatin contains the active substance dexamfetamine sulfate. Dexatin is a psychostimulant which improves the activity in parts of the brain. The medicinal product can help to improve attention span, concentration, and reduce impulsive behavior.

What Dexatin is used for

Dexatin is used to treat ADHD (attention deficit hyperactivity disorder).

- it is used in children and adolescents aged 6 to 17 years
- it is not indicated in all children with ADHD
- it is used only after when another medicine containing methylphenidate was not sufficiently effective
- it should be used as part of a treatment programme which typically includes psychological, educational and social measures.

Dexatin treatment must only be initiated by, and used under the supervision of a physician specialized in child and adolescent psychiatry or child and adolescent medicine.

2. What you need to know before you take/your child takes Dexatin

Do not use if you/your child

- is allergic to dexamfetaminesulfat or other amfetamine compounds or any of the other ingredients of this medicine (listed in section 6)
- have a thyroid problem
- have increased pressure in the eyes (glaucoma)
- have a tumour in the adrenal gland (phaeochromocytoma)

- have an eating problem, do/does not feel hungry or do/does not want to eat (e.g. anorexia nervosa)
- have very high blood pressure or narrowing of the blood vessels, which can cause pain in the legs and arms
- have ever had heart problems e.g., a heart attack, uneven heartbeat, pain or discomfort in the chest, heart failure, heart disease or was born with a heart problem
- have had problem with the blood vessels in the brain e.g., a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels or inflammation of the blood vessels (vasculitis)
- have mental health problems such as:
 - a psychopathic or borderline personality disorder
 - abnormal thoughts, hallucinations or schizophrenia
 - signs of a severe mood disorder like:
 - suicidal feelings
 - severe depression
 - mania
 - mood swings (from being manic to being depressed – called "bipolar disorder")
- is currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor, MAOI). See the "Other medicines and Dexatin" section below
- have ever abused alcohol, prescription medicines or "party drugs"
- have Tourette's syndrome or other motor or verbal tics (hard to control, repeated twitching of any parts of the body or repeats sounds and words)
- have porphyria.

Do not use this medicine if any of the above applies to you/your child. If you are not sure, talk to your doctor or pharmacist before you use/your child uses Dexatin, because this medicine can make these problems worse.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dexatin if you/your child

- have high blood pressure
- have a heart problem which is not mentioned in the 'Do not use Dexatin' section above
- have a mental health problem which is not in the 'Do not use Dexatin' section above. This may include mood swings, unusual aggression, hallucinations, delusions, paranoia, agitation (violent concern) and anxiety, feelings of guilt and depression.
- is hyperexcitable or have/has an unstable personality
- have had fits (seizures, convulsions, epilepsy) or any other abnormal brain scans (EEGs)
- have blood, liver, or kidney problems
- are female and have started having periods (see the 'Pregnancy and breast-feeding' section below)

Tell your doctor or pharmacist if any of the above applies to you/your child before starting treatment. This is because this medicine can make these problems worse. Your doctor would like to monitor how the medicine affects you/your child.

Checks that your doctor will make before Dexatin is used

These checks are to decide if this is the correct medicine for you/your child. Your doctor will talk to you/your child about:

- any other medicines you are/your child is taking
- whether there is any family history of sudden unexplained death
- any other medical problems (e.g. heart problems) you or your family may have
- how you are/your child is feeling, e.g. if you are/your child is feeling high or low, having strange thoughts or if you have/your child has had any of these feelings in the past

- whether there is a family history of tics (hard to control, repeated twitching of any parts of the body or repeating sounds and words)
- any mental health or behaviour problems you/your child or other family members have ever had.

Your doctor will regularly monitor your heart function.

Your doctor will discuss whether you are/your child is at risk of having mood swings (from being manic to being depressed - called bipolar disorder). They will check your/your child's mental health history. If any of your family has a history of suicide, bipolar disorder or depression will also be checked.

It is important that you provide as much information as you can. This will help your doctor decide if Dexatin is the correct medicine for you/your child. Your doctor may decide that other medical tests are needed before you start/your child starts taking this medicine.

Effect on weight/growing

Dexatin may cause reduced weight in some children and adolescents.

- There may be lack of weight gain
- Your doctor will carefully watch the height and weight of you/your child, as well as how well you are/your child is eating
- Your doctor may terminate the treatment for a short period if you/your child is not growing as expected

Having an operation

Tell your doctor if you are/your child is going to have an operation. Dexatin should not be taken on the day of surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

Drug/laboratory test interactions

This medicine may interfere with your laboratory test results.

Children and adolescents

Dexatin is not for use as a treatment for ADHD in children under 6 years of age and adults. It is not known if it is safe or of benefit for these patients.

Other medicines and Dexatin

Tell your doctor or pharmacist if you are/your child is taking, have/has recently taken or might take any other medicines. This also applies to medicines obtained without a prescription.

MAO inhibitors

Do not use this medicine if you are/your child is taking a medicine called MAOI (monoamine oxidase inhibitor) used for depression, or have/has taken an MAOI in the last 14 days. Taking an MAOI at the same time as dexamfetamine may cause a sudden increase in blood pressure.

If you are/your child is taking other medicines, Dexatin may affect how well they work or may cause side effects.

If you are/your child is taking any of the following medicines, check with your doctor or pharmacist before using Dexatin:

- other medicines for depression, e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors, and serotonin and norepinephrine reuptake inhibitors
- medicines for severe mental health problems, e.g. phenothiazines and haloperidol
- medicines for epilepsy, e.g. antiepileptics like phenobarbital, phenytoin, primidone and ethosuximide
- medicines used to reduce or increase blood pressure, e.g. guanethidine, clonidine, reserpine, or alphas-methyltyrosine, or beta-blockers such as propranolol

- some cough medicines and cold remedies that can affect blood pressure. It is important to check with your pharmacist before you buy any of these products
- medicines that thin the blood to prevent blood clots, e.g. coumarin anticoagulants
- medicines that contain glutamic acid HCl, ascorbic acid, ammonium chloride, sodium phosphate, sodium bicarbonate, acetazolamide, thiazides
- any of the following medicines: antihistamines, lithium, noradrenaline, morphine and meperidine.

If you are in any doubt about whether any medicines you are/your child is taking are included in the list above, ask your doctor or pharmacist for advice before taking this medicine.

Dexatin with alcohol

Alcohol must not be consumed while taking this medicine. Remember that some foods and medicines contain alcohol.

Pregnancy and breast-feeding

Available data from the use of Dexatin during the first three months of pregnancy do not indicate increased risk of congenital malformation in the child, but may increase the risk for pre-eclampsia (a condition usually occurring after 20 weeks of pregnancy characterized by high blood pressure and protein in the urine) and preterm birth. Newborns exposed to amphetamine during pregnancy may experience withdrawal symptoms (changes in behaviour including excessive crying, unstable or irritable mood, hyperexcitability and pronounced exhaustion) and reduced birth weight.

The use of Dexatin during pregnancy is not recommended. Women of childbearing potential should discontinue the use of Dexatin when intending to become pregnant.

If you are/your child is pregnant or breast-feeding, think you/your child may be pregnant or are/is planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Your doctor will discuss contraception.
- If you are/your child is pregnant, you/your child may have to stop taking this medicine.
- It is possible that this medicine is passed into human breast milk. Therefore, your doctor will decide whether you/your child should stop breast-feeding or stop taking this medicine, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Driving and using machines

You/your child may feel dizzy, have problems focussing, or have blurred vision when taking this medicine. If so, it may be dangerous to do things such as drive, use machines, ride a bike or horse, or climb trees.

Dexatin contains isomalt (E953)

If you have/your child has been told by your/your child's doctor that you have/your child has an intolerance to some sugars, contact your/your child's doctor before taking this medicinal product.

3. How you take/your child takes Dexatin

How much to take

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure. The normal recommended dose is between 5 mg and 20 mg.

Your doctor will usually start treatment with a low dose of 5 mg Dexatin. The dose will be increased gradually at weekly intervals, as needed, until the best dose for you/your child is reached. The lowest possible dose should always be used.

The maximum recommended daily dose is 20 mg (in rare cases, 40 mg may be needed).

How to take the medicine

- The medicinal product should be swallowed.

- Swallow the tablets together with fluids, e.g. water, preferably with or immediately after meals.
- Dexatin should be taken at the same time in relation to the meals.
- Dexatin should be taken once or twice daily. Your doctor will tell you how to take the medicine.
- The last dose of the day should not be taken too late after lunch in order to prevent sleep disturbance.

The tablets can be divided by placing it onto a hard surface with its cross-scored, smooth side downwards and then push carefully with the index finger at the centre of its top side. The tablet then breaks into four equal parts.

Long-term use

Your doctor will decide the treatment period. If you take/your child takes this medicine for more than a year, your doctor should stop treatment for a short time, e.g. during a school holiday. This will show if the medicine is still needed.

Not using Dexatin properly

If Dexatin is not used properly, it may cause abnormal behaviour. It may also mean that you start/your child starts to depend on the medicine. Tell your doctor if you/your child has ever abused or been dependent on alcohol, prescription medicines or narcotics.

If you take/your child takes more Dexatin than you/your child should

Talk to a doctor or call an ambulance straight away. Tell them how much has been taken. Show the package or this leaflet to the doctor. Over dosage of these tablets can be very serious.

Signs of overdose may include following: vomiting, aggression, convulsions leading to coma, excitement, confusion, hallucinations, delirium, sweating, mydriasis, dryness of mucous membranes, flushing, headache, chest pain, high heart rate, irregular heartbeats, high blood pressure, slow breathing, coma and shock (circulatory collapse) which can be life-threatening.

If you forget/your child forgets to take Dexatin

Do not take a double dose to make up for a forgotten dose. If you forget/your child forgets a dose, wait until it is time for the next dose.

When you stop/your child stops taking Dexatin

Your doctor will advise you/your child how to slowly reduce the dose to avoid and reduce withdrawal symptoms.

If you/your child suddenly stops taking this medicine, this can lead to extreme tiredness, depression, mood disorders, agitation, sleep disturbances, increased appetite, or involuntary movements. Talk to your doctor/your child's doctor before stopping Dexatin treatment.

If you have/your child has any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Your doctor will talk to you/your child about these side effects.

If you get any of the following symptoms, contact a doctor immediately or go to the nearest emergency:

- Hallucinations, psychosis/psychotic reactions, suicidal behaviour (Very rare: may affect up to 1 in 10 000 people)
- Serious allergic reactions which causes swelling of the face, tongue or throat; difficulties in swallowing; hives and difficulties in breathing (angioedema/anaphylaxis) (Not known: frequency cannot be estimated from the available data)
- Abnormal muscle breakdown, may manifest as unexplained muscle pain, muscle cramps or muscle weakness (rhabdomyolysis) (Not known: frequency cannot be estimated from the available data).

Other side effects

If side effects get serious, please contact your doctor or seek medical care.

Very common: may affect more than 1 in 10 people

- Decreased appetite, reduced weight gain and weight loss during long-term use in children
- Difficulties in sleeping
- Nervousness

Common: may affect up to 1 in 10 people

- Irregular or increased heartbeat, a more noticeable heartbeat
- Abdominal pain and/or cramps, nausea, vomiting, dry mouth. These effects usually occur at the beginning of treatment and may be alleviated by taking the medicine with meals.
- Changes in blood pressure and heart rate (usually increases)
- Joint pain
- A feeling of dizziness (vertigo) or “spinning”, jerky or involuntary movements, headache, hyperactivity, abnormal behaviour, aggression, excitation, loss of appetite, anxiety, depression, irritability.

Rare: may affect up to 1 in 1 000 people

- Angina pectoris
- Difficulties in visual sharpening and focus, blurred vision, dilation of the pupils
- Reduced height increase during long-term use in children
- Fatigue
- Rash, hives

Very rare: may affect up to 1 in 10 000 people

- Itchy red skin lesions (erythema multiforme) or scaly skin patches (exfoliative dermatitis)
- Inflammation and/or occlusion of the blood vessels of the spinal cord and brain (cerebral vasculitis)
- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness, changes in blood cell counts (leukopenia, thrombocytopenia, thrombocytopenic purpura)
- Cardiac arrest
- Tourette’s syndrome
- Abnormal liver function
- Muscle cramps, involuntary movements (choreoathetoid movements), bleeding inside the skull (intracranial haemorrhage cases of neuroleptic malignant syndrome)
- Suicide
- Tics, worsening of preexisting tics
- Recurring rash, which happens in the same place each time the medicine is taken (fixed drug eruption)

Not known: frequency cannot be estimated from the available data

- Heart muscle disease (cardiomyopathy), heart attack
- Increased body temperature
- Stroke
- Dependence, obsessive-compulsive behaviour, panic states, paranoia
- Inflammation of parts of the large intestine when the blood flow is reduced (ischaemic colitis)

- Chest pain, sudden death
- Disturbed acid-base balance in the body (acidosis)
- Difficulty controlling movements (ataxia), dizziness, abnormal or impaired sense of taste, concentration difficulties, hyperreflexia (abnormally increased reflexibility), shaking (tremor)
- Confusion, dysphoria, emotional lability, euphoria, impaired cognitive ability (rational thinking), altered libido, nightmares, restlessness
- Renal damage
- Impotence
- Sweating, alopecia
- Diarrhoea
- Circulatory failure
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexatin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Blister:

5 mg and 20 mg: Do not store above 30 °C.

10 mg: Do not store above 25 °C.

HDPE container:

All strengths: Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dexatin contains

The active substance is dexamfetamine sulfate. One tablet contains 5, 10 or 20 mg dexamfetamine sulfate.

The other ingredients are

Isomalt (E953), magnesium stearate (E470b)

What Dexatin looks like and contents of the pack

Dexatin 5 mg tablet

White, round, cloverleaf-shaped tablets of 8.5 mm diameter with a notched, cross-scored line on the one side and a cross-scored line embossed with "S" on each quarter on the other side.

Dexatin 10 mg tablet

White, octagonal tablets of 8.1 mm diameter with a notched, cross-scored line on the one side and a cross-scored line embossed with "M" on each quarter on the other side.

Dexatin 20 mg tablet

White, round tablets of 8.5 mm diameter with a notched, cross-scored line on the one side and a cross scored line embossed with "L" on each quarter on the other side.

All tablets can be divided into four equal parts.

Pack sizes, all strengths (blister): 10, 20, 30, 50 or 100 tablets.

Pack sizes, all strengths (HDPE-bottles): 28, 30, 50, 98 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

<to be completed nationally>

This leaflet was last revised in 2026-06-24