

## Dexamfetamine Sulfate 1 mg/ml Oral Solution dexamfetamine sulfate

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- Throughout this leaflet Dexamfetamine Sulfate 1 mg/ml Oral Solution will be referred to as 'Dexamfetamine Solution'.

**What is in this leaflet:**

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

### 1. What Dexamfetamine Solution is and what it is used for

Dexamfetamine Solution contains dexamfetamine, which belongs to a group of medicines called stimulants. These work by increasing activity in the brain. Dexamfetamine works by affecting some of the natural chemicals that are found in the brain. In particular, it increases the activity of chemicals called dopamine and noradrenaline in areas of the brain that play a part in controlling attention and behaviour.

Dexamfetamine stimulates activity in the brain, helping to keep people alert and active during the day.

Dexamfetamine Solution is used to treat attention-deficit/hyperactivity disorder (ADHD).

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

Dexamfetamine Solution treatment must only be initiated by and used under the supervision of a specialist in childhood or adolescent behavioural disorders.

Dexamfetamine Solution is also used:

- To treat narcolepsy (being unable to stop yourself falling asleep).

You must talk to a doctor if you or your child do not feel better or feel worse after a month. The doctor may decide that a different treatment is needed.

### 2. What you need to know before you take Dexamfetamine Solution

**Do NOT take Dexamfetamine Solution if you or your child:**

- are allergic (hypersensitive) to dexamfetamine 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 of the adrenal gland (phaeochromocytoma)
- have an eating problem, do not feel hungry or do 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 arms and legs
- have advanced arteriosclerosis
- have ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease, or were born with a heart problem
- have had a problem with the blood vessels in the brain - such as 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 or visions or schizophrenia
  - signs of a severe mood disorder like:
    - suicidal feelings
    - severe depression
    - mania
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) - see 'Other medicines and Dexamfetamine Solution' section below
- have ever abused alcohol, prescription medicines, or street drugs or anyone in your family has Tourette's syndrome or other motor or verbal tics
- have hard-to-control, repeated twitching of any parts of the body or repeats sounds and words
- have porphyria.

If any of the above applies to you do not take Dexamfetamine Solution and talk to your doctor or pharmacist. This is because this medicine can make these problems worse.

**Warnings and precautions**

Talk to your doctor before taking Dexamfetamine Solution if you or your child:

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

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

**Checks that your doctor will make before Dexamfetamine Solution is used**

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

- any other medicines you or your child are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how you or your child are feeling, such as feeling high or low, having strange thoughts or if you or 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 or other family members have ever had.

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

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

**Effect on weight/growing**

Dexamfetamine Solution may cause reduced weight in some children and adolescents.

- There may be a lack of weight gain.
- Your doctor will carefully watch the height and weight of your child, as well as how well your child is eating.
- If your child is not growing as expected, then your doctor may stop treatment with Dexamfetamine Solution for a short time.

**Having an operation**

Tell your doctor if you or your child are going to have an operation. Dexamfetamine Solution 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. This includes testing used in sports.

**Children and adolescents**

Dexamfetamine Solution 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 people.

Dexamfetamine Solution is not for use as a treatment for narcolepsy in children and adolescents. It is not known if it is safe or of benefit to them.

**Other medicines and Dexamfetamine Solution**

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

**Monoamine oxidase inhibitors**

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

If you or your child are taking other medicines, this medicine may affect how well they work or may cause side effects. If you or your child are taking any of the following medicines, check with your doctor or pharmacist before using Dexamfetamine Solution:

- other medicines for depression, e.g. tricyclic antidepressants and selective serotonin reuptake inhibitors
- medicines for severe mental health problems, e.g. phenothiazines and haloperidol
- medicines for epilepsy, e.g. anticonvulsants like phenobarbital, phenytoin, primidone and ethosuximide
- medicinal products that help to give up alcohol, e.g. disulfiram
- medicines used to reduce or increase blood pressure, e.g. guanethidine, clonidine, reserpine, or alpha-methyltyrosine, or beta-blockers such as propranolol
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- medicines that thin the blood to prevent blood clots, e.g. coumarin anticoagulants
- any medicines that contain glutamic acid HCl, ascorbic acid, ammonium chloride, sodium acid phosphate, sodium bicarbonate, acetazolamide, thiazides
- any of the following medicines: beta-blockers, antihistamines, lithium, noradrenaline, morphine and meperidine.

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

**Dexamfetamine Solution with alcohol**

Alcohol must not be consumed while taking this medicine.

Remember that some foods and medicines contain alcohol.

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## Information for children / young people with ADHD and their carers

This information is to help you learn the main things about Attention Deficit Hyperactivity Disorder (ADHD) and about your or your child's medicine called Dexamfetamine Solution.

Some people don't enjoy reading, however it is very important to read this information. It may help if you read small bits at a time. If you don't enjoy reading, it may help if someone else reads it for you and answers any questions.

**What is ADHD?**

ADHD is a condition which affects behaviour of children or young people.

ADHD can make you:

- run about too much
- not be able to pay attention
- act quickly without thinking about what will happen next (impulsive).

It affects learning, making friends and how you think about yourself. **It is not your fault.**

**What is Dexamfetamine Solution?**

Dexamfetamine Solution is a medicine which helps to keep people alert and active during the day.

This medicine can help children and young people with ADHD.

It is used in children and young people aged 6- 17 years with ADHD, however not everyone with ADHD may take this medicine.

**Some people cannot have this medicine**

You/your child **may not be able to have** this medicine if:

- you (or your child) have a problem with your heart
- you (or your child) feel very unhappy, depressed or have a certain type of mental illness.

**Some people need to talk to their doctor before they start having this medicine**

You **need to talk to your doctor** if:

- you (or your child) have epilepsy (fits)
- you (or your child) are pregnant or breast-feeding
- you (or your child) are taking other medicines – your doctor needs to know about all the medicines you (or your child) are taking.

**Before you (or your child) will start taking this medicine**

Your doctor will first check whether this medicine is right for you/ your child.

Your doctor will check :

- whether you (or your child) have or ever had heart problems
- whether you (or your child) have been unhappy, depressed or have had a mental illness
- whether you (or your child) have ever had a problem with alcohol or other drugs

Your doctor will ask you/your child questions and it is important that you/your child provide as much information as you can. Your doctor may decide that other medical tests are needed, which the doctor will explain to you. This will help your doctor to decide if this medicine is the correct medicine for you/your child.

Your doctor will then decide how much of the medicine you/your child need to take and how long you/your child will need to take it for.

**While you (or your child) are taking this medicine**

As well as taking this medicine, you (or your child) will also get help with ways to cope with ADHD, such as talking to ADHD specialists.

This medicine should help you/your child. But it does not cure ADHD.

It is very important that you/your child go to your doctor several times a year for check-ups, or as your doctor requests. This is to make sure the medicine is working and that you (or your child) are growing as you (or your child) should.

Your doctor will regularly check:

- that your (or your child's) heart is healthy
- that your (or your child's) height and weight is as it should be for your/your child's age
- how any changes in mood or appetite.

**How do I (my child) take this medicine?**

Your doctor will tell you how much of this medicine you/your child need to take, how to take it and how many times a day to take it.

Do not stop taking the medicine without talking to your doctor first.



### **Pregnancy and breast-feeding**

Available data from the use of Dexamfetamine Solution 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 behavior including excessive crying, unstable or irritable mood, hyperexcitability and pronounced exhaustion).

If you or your daughter are pregnant or breast-feeding, may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- Your doctor will discuss contraception.
- If you or your daughter are pregnant you/she 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 or your daughter should stop breast-feeding or stop taking this medicine.

### **Driving and using machines**

You or your child may feel dizzy, have problems focusing, 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.

### **Dexamfetamine Solution contains Liquid maltitol**

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

### **Dexamfetamine Solution contains Benzoic acid**

This medicine contains 0.6 mg benzoic acid in each ml. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

## **3. How to take Dexamfetamine Solution**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### **The recommended dose is:**

#### **For narcolepsy in adults:**

- The usual starting dose is 10 mg a day in divided doses.
- Your doctor may increase your dose each week up to a maximum of 60 mg a day if necessary.

#### **For narcolepsy in the elderly:**

- The usual starting dose is 5 mg a day.
- Your doctor may increase your dose by 5 mg each week.

#### **For ADHD in children aged 6 years and over:**

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The normal recommended dose is between 5 mg and 20 mg.

- Your doctor will usually start treatment with a low dose of 5 mg of Dexamfetamine Solution. This will be increased gradually by 5 mg at weekly intervals, as required.
- The maximum daily dose is 20 mg (in rare cases, 40 mg may be needed).

### **How to take**

The medicinal product is intended for oral use.

Your child should take Dexamfetamine Solution with a drink of water, preferably with or immediately after meals.

Dexamfetamine Solution should be taken at the same time in relation to the meals. The last dose should, in general, not be given too late after lunch in order to prevent disturbances in falling asleep.

If your child does not feel better, tell your doctor. They may decide a different treatment is needed.

### **Long-term treatment**

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

### **Not using Dexamfetamine Solution properly**

If Dexamfetamine Solution is not used properly, it may cause abnormal behaviour. It may also mean that you or your child starts to depend on the medicine. Tell your doctor if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.

This medicine is only for you or your child. Do not give this medicine to anyone else, even if their symptoms seem similar.

### **Medical check-ups in children**

Your doctor will check the height and weight of your child whilst they are taking Dexamfetamine Solution.

### **If you or your child take more Dexamfetamine Solution than you should**

If you or your child take more solution than you should, you might experience excitement, hallucinations, convulsions leading to coma, irregular and rapid heartbeat and reduced breathing.

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining solution with you so that people can see what you have taken.
3. Do this even if you feel well.

### **If you or your child forget to take Dexamfetamine Solution**

If you or your child forget to take a dose, take it as soon as you remember, but if it is almost time for your next dose, skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Dexamfetamine Solution**

Do not stop taking Dexamfetamine Solution without first talking to your doctor.

Suddenly stopping taking Dexamfetamine Solution can lead to extreme tiredness and depression, mood disorders, agitation, sleep disturbances, increased appetite, or involuntary movements. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Your doctor will stop the treatment gradually.

If you have any further questions about 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 about these side effects.



### **Possible side effects**

Side effects are the unwanted things that can happen when you (or your child) take a medicine. If any of the following happen, tell an adult you trust (or your doctor) straight away.

The main things that could affect you (or your child) are:

- feeling worried or nervous
- feeling dizzy, or getting headaches
- being very depressed and unhappy or wanting to hurt yourself
- having different moods than usual, not being able to get to sleep or sleeping too much
- skin rashes, bruising easily, getting out of breath
- the medicine can also make you (or your child) feel sleepy. If this happens, it is important not to do outdoor sports like riding a horse or bike, swimming or climbing trees. You could hurt yourself and others
- your (or your child's) heart beating faster than usual

**If you (or your child) feel unwell in any way while taking this medicine, please tell a doctor, nurse or a pharmacist straight away.**

### **Other things to remember:**

Make sure you keep your (or your child's) medicine in a safe place so that no one else takes it, especially younger brothers or sisters.

The medicine is special for the person it was prescribed for - do not let anyone else have it. It may help you (or your child), but it could hurt someone else.

### **Tell a doctor, nurse or a pharmacist if:**

- anyone asked you (or your child) to give them your (or your child's) medicine
- anyone told you (or your child) they want to take your (or your child's) medicine.

Always take your medicine as your doctor told you to. This is very important because if this medicine is not taken correctly, it could cause an abnormal behaviour – for example dependency on your medication (feeling that you want or need to take more of your medication).

### **Very common: may affect more than 1 in 10 people**

- decreased appetite, reduced weight gain and weight loss during prolonged use in children
- difficulty in sleeping
- nervousness

### **Common: may affect up to 1 in 100 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 or “spinning”, jerky or involuntary movements, headache, hyperactivity
- abnormal behaviour, aggression, excitation, anorexia, 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 prolonged use in children
- fatigue
- rash, hives

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

- 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 ranging from hepatic enzyme elevations to hepatic coma
  - muscle cramps
  - convulsions, involuntary movements (choreoathetoid movements), bleeding inside the skull (intracranial haemorrhage)
  - hallucinations, psychosis/psychotic reactions, suicidal behaviour or suicide, tics, worsening of pre-existing tics
  - itchy red skin lesions (erythema multiforme) or scaly skin patches (exfoliative dermatitis), recurring rash, which happens in the same place each time the medicine is taken (fixed drug eruption)
  - inflammation of the blood vessels of the spinal cord and brain (cerebral vasculitis) and/or occlusion
- Not known: frequency cannot be estimated from the available data**
- heart muscle disease (cardiomyopathy), heart attack
  - inflammation of parts of the large intestine when the blood flow is reduced (ischaemic colitis), diarrhoea
  - chest pain, growth retardation during prolonged use, increased body temperature, allergic reactions including serious allergic reaction which causes swelling of the face or throat (angioedema) and serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis), sudden death
  - disturbance of the acid-base balance of the body (acidosis)
  - abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)
  - difficulty in controlling movements (ataxia), dizziness, abnormal or impaired sense of taste, concentration difficulties, hyperreflexia, stroke, shaking (tremor)
  - confusion, dependence, dysphoria, emotional instability, euphoria, impaired cognitive test performance, altered libido, night terrors, obsessive-compulsive behaviour, panic states, paranoia, restlessness
  - renal damage
  - impotence
  - sweating, hair loss
  - 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

## **5. How to store Dexamfetamine Solution**

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

Store the bottle in an upright position.

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

Do not use after 30 days from the date of first opening.

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 Dexamfetamine Solution contains**

The active substance is dexamfetamine sulfate.

The other ingredients are benzoic acid (E210), citric acid monohydrate (E330), disodium phosphate dihydrate, liquid maltitol (E965), hypromellose, orange tangerine flavour and purified water (See end of Section 2 for further information on liquid maltitol and benzoic acid).

### **What Dexamfetamine Solution looks like and contents of the pack**

Dexamfetamine Solution is a clear colourless solution which smells of orange/tangerine.

Dexamfetamine Solution is available in a 150 ml brown glass bottle.

### **Marketing Authorisation Holder:**

Rosemont Pharmaceuticals Ltd, Leeds, LS11 9XE, UK.

### **Manufacturer:**

Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, The Netherlands.

### **This medicinal product is authorised in the Member States of the EEA and United Kingdom (Northern Ireland) under the following names:**

Norway: Dexamfetamine Taw Pharma

Iceland: Dexamfetamine Taw Pharma

United Kingdom: Dexamfetamine Sulfate 1 mg/ml Oral Solution

**This leaflet was last revised in January 2023.**

If this leaflet is difficult to see or read, please contact the marketing authorisation holder for help.

### **Tell a doctor, nurse or a pharmacist if:**

- you (or your child) feel that you (or he/she) would like to take more of your (or their) medicine
- you (or your child) feel that you (or he/she) need to take more of your (or their) medicine.

If you (or your child) forget to take your (or his/her) medicine don't take two doses the next time. Just take the next dose at the next normal time.

If you (or your child) do take too much medicine, tell an adult, doctor, nurse or a pharmacist right away.

It is important not to take too much medicine or you (or your child) will get ill.

Don't stop taking your medicine until your doctor tells you to stop.

Do not drink alcohol. Alcohol may make the side effects of this medicine worse.

If you (or your child) are/is having sex, please talk to your doctor about contraception. Girls must tell their doctor straight away if they think they may be pregnant. We do not know how this medicine affects unborn babies.

### **Who should I ask if there is anything I don't (or my child doesn't) understand?**

Your doctor, nurse or pharmacist will be able to help you.