Package leaflet: Information for the patient

Dexamfetamine sulfate 5 mg tablets
Dexamfetamine sulfate 10 mg tablets
Dexamfetamine sulfate 20 mg tablets

Dexamfetamine sulfate

Read all of this leaflet carefully before your child and/or adolescent starts 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 specialist or pharmacist.
- This medicine has been prescribed for your child and/or adolescent only. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- If your child and/or adolescent gets any side effects, talk to your specialist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Dexamfetamine sulfate tablets are and what they are used for

What Dexamfetamine sulfate tablets are
Dexamfetamine sulfate tablets contain the active substance dexamfetamine sulfate.

Dexamfetamine sulfate is a psychostimulant.
It improves activity in parts of the brain. This medicine can help to improve attention span, concentration, and reduce impulsive behaviour.

What Dexamfetamine sulfate tablets are used for
Dexamfetamine sulfate tablets are 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 and adolescents 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.

Treatment with Dexamfetamine sulfate tablets must only be initiated by, and used under the supervision of a specialist in childhood or adolescent behavioural disorders.

You must talk to a specialist if your child and/or adolescent does not feel better or if they feel worse after a month. The specialist may decide that a different treatment is needed.

2. What you need to know before you take Dexamfetamine sulfate tablets

Do not use Dexamfetamine sulfate tablets if your child and/or adolescent:
- is allergic (hypersensitive) to dexamfetamine sulfate or other amfetamine compounds or any of the other ingredients of Dexamfetamine sulfate tablets (listed in section 6)
- has a thyroid problem
- has increased pressure in the eyes (glaucoma)
- has a tumour of the adrenal gland (phaeochromocytoma)
- has an eating problem, does not feel hungry or does not want to eat (e.g. anorexia nervosa)
- has very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- has advanced arteriosclerosis
- has ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease, or was born with a heart problem
- has 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)
- has mental health problems such as:
  - a psychopathic or borderline personality disorder
  - abnormal thoughts or visions or schizophrenia
  - signs of a severe mood disorder like:
    - o suicidal feelings
    - o severe depression
    - o mania
    - o mood swings (from being maniac 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) – see the 'Other medicines and Dexamfetamine sulfate tablets' section below
- has ever abused alcohol, prescription medicines, or street drugs
- has Tourette's syndrome or other motor or verbal tics
- has hard-to-control, repeated twitching of any parts of the body or repeats sounds and words
- has porphyria.

Do not use this medicine if any of the above applies to your child and/or adolescent. If you are not sure, talk to your specialist or pharmacist before you use Dexamfetamine sulfate tablets. This is because this medicine can make these problems worse.

Warnings and precautions
Talk to your specialist or pharmacist before taking Dexamfetamine sulfate tablets if your child and/or adolescent:
- has a disease of the blood or liver, or kidney problems
- has an unstable personality
- has had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- is female and has started having periods (see the 'Pregnancy and breast-feeding' section below)
- has high blood pressure
- has a heart problem which is not in the 'Do not use' section above
- has a mental health problem which is not in the 'Do not use' section above. This may include mood swings in general, unusual aggression, hallucinations, delusions, paranoia, agitation and anxiety, feelings of guilt or depression.

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

Checks that your specialist will make before Dexamfetamine sulfate tablets are given
These checks are to decide if this is the correct medicine for your child and/or adolescent. Your specialist will talk to you about:
- any other medicines your child and/or adolescent is 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 your child and/or adolescent is feeling, such as feeling high or low, having strange thoughts or if your child and/or adolescent 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 specialist will discuss whether your child and/or adolescent is at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check your child and/or adolescent'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 specialist decide if Dexamfetamine sulfate tablets are the correct medicine for your child and/or adolescent. Your specialist may decide that other medical tests are needed before they start taking this medicine.

Effect on weight/growing
Dexamfetamine sulfate tablets may cause reduced weight in some children and adolescents.
- There may be lack of weight gain.
- Your specialist will carefully watch the height and weight of your child and/or adolescent, as well as how well your child and/or adolescent is eating.
- If your child and/or adolescent is not growing as expected, then your specialist may stop treatment with Dexamfetamine sulfate tablets for a short time.

Having an operation
Tell your specialist if your child and/or adolescent is going to have an operation. Dexamfetamine sulfate tablets 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 testing
This medicine may give a positive result when testing for drug use.

Drug/laboratory test interactions
This medicine may interfere with your laboratory test results.

Children and adolescents
Dexamfetamine sulfate tablets are not for use as a treat-ment 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.

Other medicines and Dexamfetamine sulfate tablets
Tell your specialist or pharmacist if your child and/or adolescent is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

<u>Monoamine oxidase inhibitors</u>
Do not use this medicine if your child and/or adolescent is taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or has taken an MAOI in the last 14 days. Taking an MAOI with dexamfetamine sulfate may cause a sudden increase in blood pressure

If your child and/or adolescent is taking other medicines, this medicine may affect how well they work or may cause side effects. If your child and/or adolescent is taking any of the following medicines, check with your specialist or pharmacist before using Dexamfetamine sulfate tablets:
- other medicines for depression, e.g. tricyclic antidepres-sants 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, antihista-mines, lithium, noradrenaline, morphine, and meperidine.

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

Dexamfetamine sulfate tablets 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 dexamfetamine sulfate during the first three months of pregnancy do not indicate increased risk of congenital malformation in the child and/or adolescent, 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 amfetamine during pregnancy may experience withdrawal symptoms (changes in behaviour including excessive crying, unstable or irritable mood, hyperexcitability and pronounced exhaustion).

If your daughter is pregnant or breast-feeding, she may be pregnant or is planning to have a baby, ask your specialist or pharmacist for advice before using this medicine.
- Your specialist will discuss contraception.
- If your daughter is pregnant she may have to stop taking this medicine.
- It is possible that this medicine is passed into human breast milk. Therefore, your specialist will decide whether your daughter should stop breast-feeding or stop taking this medicine.

Driving and using machines
Your child and/or adolescent 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.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your specialist or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Dexamfetamine sulfate tablets contain isomalt (E953)
If you have been told by your specialist that your child and/or adolescent cannot tolerate some sugars, talk to your specialist before using this medicinal product.

3. How to take Dexamfetamine sulfate tablets

How much to take
Always use this medicine exactly as your specialist has told you. You should check with your specialist or pharmacist if you are not sure.

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

- Your specialist will usually start treatment with a low dose of one 5 mg tablet. This will be increased gradually by one 5 mg tablet at weekly intervals, as required.

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

- Your specialist will decide the need of giving Dexamfetamine sulfate once or twice daily based on the course of symptoms at different times of the day.

How to take
The medicinal product is intended for oral use.
The tablets should be taken with a drink of water, preferably with or immediately after meals. Dexamfetamine sulfate tablets 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.

The tablets have a score line and can be divided, if needed. The score line is only there to help you break the tablet if there is difficulty swallowing it whole and not to divide into equal doses. To split it, place the tablet on a solid surface with the cross-scored, smooth side downwards and then push carefully with your index finger at the centre of its top side. The tablet then breaks into four parts.

If your child and/or adolescent does not feel better, tell your specialist. They may decide a different treatment is needed.

Long-term treatment
Your specialist will decide how long the treatment is given. If your child and/or adolescent takes this medicine for more than a year, your specialist should stop treatment for a short time, e.g. during a school holiday. This will show if the medicine is still needed.

Not using Dexamfetamine sulfate tablets properly
If Dexamfetamine sulfate tablets are not used properly, it may cause abnormal behaviour. It may also mean that your child and/or adolescent can become dependent on the medicine. Tell your specialist if your child and/or adolescent has ever abused or been dependent on alcohol, prescription medicines or street drugs.

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

If your child and/or adolescent takes more Dexamfetamine sulfate tablets than they should
Talk to a specialist or call an ambulance straight away. Tell them how much has been taken. Show the package or this leaflet to the specialist. Overdosage of these tablets can be very serious.
Signs of overdose may include: excitement, hallucinations, convulsions leading to coma, irregular and rapid heartbeat, and reduced breathing.

If your child and/or adolescent forgets to take Dexamfetamine sulfate tablets
Do not use a double dose to make up for a forgotten dose. If your child and/or adolescent forgets a dose, wait until it is time for the next dose.

If your child and/or adolescent stops taking Dexamfetamine sulfate tablets
If your child and/or adolescent suddenly stops taking this medicine, this can lead to extreme tiredness, depression, mood disorders, agitation, sleep disturbances, increased appetite, or involuntary movements. Your specialist may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your specialist before stopping Dexamfetamine sulfate tablets.

If you have any further questions on the use of this medicine, ask your specialist or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, but not everybody gets them. Your specialist will talk to you about these side effects.

Stop taking Dexamfetamine sulfate tablets and immediately contact a specialist or go to the emergency centre if you experience the following symptoms:
- hallucinations, psychosis/psychotic reactions, suicidal behaviour (very rare: may affect up to 1 in 10,000 people)
- serious allergic reactions causing swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties (angioedema/ anaphylaxis) (Not known: frequency cannot be estimated from the available data)
- abnormal muscle breakdown with symptoms such as inexplicable muscle pains, muscle cramps or muscle weakness (rhabdomolysis) (Not known: frequency cannot be estimated from the available data)

Other side effects

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 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 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
- may affect rate of growth in height with 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)
- 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, sudden death
- inflammation of parts of the large intestine when the blow flow is reduced (ischaemic colitis), diarrhoea
- chest pain, increased body temperature, allergic reactions
- disturbance of the acid-base balance of the body (acidosis)
- 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 specialist or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: 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 sulfate tablets

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 the box after “EXP”. The expiry date refers to the last day of that month.

Dexamfetamine sulfate 5 mg tablets:
Store below 25°C. Store in the original package in order to protect from moisture.

Dexamfetamine sulfate 10 mg and 20 mg tablets:
This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

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 to protect the environment.

6. Contents of the pack and other information

What Dexamfetamine sulfate tablets contain
The active substance is 5 mg, 10 mg or 20 mg dexamfetamine sulfate.

The other ingredients are:
- Dexamfetamine sulfate 5 mg tablets: Isomalt (E953), magnesium stearate (E572), crospovidone (E1202).
- Dexamfetamine sulfate 10 mg and 20 mg tablets: Isomalt (E953), magnesium stearate (E572).

What Dexamfetamine sulfate tablets look like and contents of the pack
Dexamfetamine sulfate 5 mg tablets: White to off-white, clover-shaped tablets of 8 mm diameter with a deep quadrisect score-line on the upper side of the tablet and a shallow quadrisect score-line on the lower side of the tablet. Each quarter section of the tablet lower side has an imprinted S.
The score lines are to facilitate breaking into equal doses and for ease of swallowing.

Dexamfetamine sulfate 10 mg tablets: White to off-white, clover-shaped tablets of 8 mm diameter with a deep quadrisect score-line on the upper side of the tablet and a shallow quadrisect score-line on the lower side of the tablet. Each quarter section of the tablet lower side has an imprinted M.
The score lines are to facilitate breaking into equal doses and for ease of swallowing.

Dexamfetamine sulfate 20 mg tablets: White to off-white, clover-shaped tablets of 8 mm diameter with a deep quadrisect score-line on the upper side of the tablet and a shallow quadrisect score-line on the lower side of the tablet. Each quarter section of the tablet lower side has an imprinted L.
The score lines are to facilitate breaking into equal doses and for ease of swallowing.

Pack size
28 or 30 tablets in blisters made of PVC/PVDC/Alu.

Not all pack sizes may be marketed.

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