Package leaflet: Information for the user

Elvanse Adult 30 mg capsules, hard
Elvanse Adult 50 mg capsules, hard
Elvanse Adult 70 mg capsules, hard

lisdexamfetamine dimesylate

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

This medicine is used to treat ADHD:

- The full name for ADHD is 'Attention Deficit Hyperactivity Disorder'.
- The medicine helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.
- You need to have other treatments for ADHD (such as counselling and behavioural therapy) as well as this medicine.

Read Section 1 for more information.

Before you take this medicine, talk to your doctor if you:

- have heart, circulation, or mental health problems - you may not be able to take this medicine.
- are taking any other medicines - this is because Elvanse Adult can affect how other medicines work.

Read Section 2 for more information.

While taking this medicine:

- See your doctor regularly. This is because your doctor will want to check how the medicine is working.
- Do not stop taking the medicine without first talking to your doctor.
- If you take your medicine for more than a year, your doctor may stop your medicine to see if it is still needed.
- The most common side effects in adults are decreased appetite, being unable to sleep, dry mouth or headache.

Read Sections 3 and 4 for more information.

Talk to your doctor straight away if any of the following happen:

- Your mood or how you feel changes.
- You feel any problems with your heart.

Read Section 4 for more information.

The rest of this leaflet includes more detail and other important information to help you use this medicine safely and effectively.

- 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.

What is in this leaflet

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

1. What Elvanse Adult is and what it is used for

What Elvanse Adult is

Elvanse Adult contains the active substance lisdexamfetamine dimesylate which helps with your brain activity. It helps improve your attention, helps you concentrate and makes you less impulsive. Elvanse Adult is a long-acting medicine which works gradually over a 14 hour time period.

What it is used for

Elvanse Adult is a part of a comprehensive treatment programme for 'attention deficit hyperactivity disorder' (ADHD)

- for adults who have had ADHD since childhood. If you have not been treated for ADHD before, the doctor will check if you have had ADHD since childhood before prescribing Elvanse Adult.

You must talk to a doctor if you do not feel better or if you feel worse after one month of treatment.

Elvanse Adult is not recommended for all patients with ADHD and the decision to use this medicine is based on a thorough medical evaluation.

For children and adolescents aged 6 to 17 years, another product containing lisdexamfetamine dimesylate is available. Lisdexamfetamine dimesylate is not used as a treatment for ADHD in children under 6 years of age because it is not known if it is safe or of benefit in such young people.

How Elvanse Adult works

Elvanse Adult improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention, concentration and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes the following:

- psychological therapy
- educational therapy
- behavioural therapy
- occupational therapy
- social therapy

It is prescribed only by doctors who have experience in treating people with behaviour problems.

About ADHD

People with ADHD find it hard to:

- sit still
- concentrate

It is not their fault that they cannot do these things. However, ADHD can cause problems with everyday life. People with ADHD may have difficulty working, learning, with relationships and have low self-esteem.

ADHD does not affect the intelligence of a person.

2. What you need to know before you take Elvanse Adult

Do NOT take Elvanse Adult

- if you are allergic to lisdexamfetamine, other amfetamine compounds or any of the other ingredients of this medicine (listed in Section 6)
- if you are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 14 days
- if you have a thyroid problem
- if you feel unusually excited, over-active, or un-inhibited
- if you 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
- if you have high or very high blood pressure or narrowing of the blood vessels
- if you have increased pressure in your eye (glaucoma)

Do not take Elvanse Adult if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take Elvanse Adult. This is because Elvanse Adult can make these problems worse.

Warnings and precautions

Talk to your doctor or pharmacist before using Elvanse Adult treatment if you have:
- ever abused prescription medicines or street drugs
- had kidney problems
- had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- hard-to-control and repeated twitching of any parts of the body or you repeat sounds and words
- high blood pressure
- family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances
- a heart problem which is not in the 'Do not take' section above
- a history of stroke
- a mental health problem. These may include:
    - mood swings (from being manic to being depressed - called 'bipolar disorder')
    - starting to be aggressive or unfriendly (hostile), or your aggression gets worse
    - seeing, hearing or feeling things that are not there (hallucinations)
    - believing things that are not true (delusions)
    - feeling unusually suspicious (paranoia)
    - feeling agitated, anxious or tense
    - feeling depressed or guilty

Or if you are a female able to become pregnant, plan to become pregnant or are pregnant (see the 'Pregnancy and breast-feeding' section)

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

If Elvanse Adult is not used properly, it may cause abnormal behaviour and the user may start to depend on the medicine. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs. Do not give this medicine to anyone else even if the symptoms seems similar.

Elvanse Adult may cause heart rhythm disorders in some patients. If you experience palpitations or irregular heartbeat during the period of treatment, you should inform your doctor immediately. The risk of heart problems may increase with increase of the dose. Therefore, the recommended dosage should be followed.

Checks that your doctor will make before you start taking Elvanse Adult

These checks are to decide if Elvanse Adult is the correct medicine for you. Your doctor will ask you about:

- any other medicines you are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) that you or your family may have
- how you are feeling, such as feeling happy or sad, having strange thoughts, or if you have 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 check your mental health history, and check if any of your family have a history of suicide, bipolar disorder (mood swings from being manic to being depressed) or depression.

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

Effects on weight

Elvanse Adult may cause weight loss in some people.

Your doctor will watch your weight, as well as how well you are eating. If you are losing weight, your doctor may stop treatment with Elvanse Adult for a short time.

Other medicines and Elvanse Adult

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

Do NOT take Elvanse Adult if you:

- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 14 days. Taking an MAOI with Elvanse Adult may cause a sudden increase in your blood pressure. Your doctor or pharmacist will be able to tell you if are taking a medicine that is an MAOI.

Elvanse Adult and some other medicines can affect each other. If you are taking any of the following medicines, check with your doctor or pharmacist before taking Elvanse Adult:

- medicines for severe mental health problems
- medicines used to reduce or increase blood pressure
- medicines used during surgery such as painkillers
- cough and cold remedies. Some of these contain medicines that can affect blood pressure so it is important to check with your pharmacist when you buy any of these products

- medicines that can affect the acidity of your urine, such as vitamin C (ascorbic acid) or sodium bicarbonate (for example in medicines for indigestion)

If you are unsure about whether the medicines you are taking are in the list above, ask your doctor or pharmacist before taking Elvanse Adult.

Drug testing

This medicine may give a positive result when testing for drug use.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your body breaks down Elvanse Adult into other substances which can cross the placenta and enter breast milk. Available data from the use of Elvanse Adult 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 characterised by high blood pressure and protein in the urine) and preterm birth. Newborns exposed to amfetamine during pregnancy may experience withdrawal symptoms (trembling, irritability, tight muscle tone).

You should not use this medicine during pregnancy unless explicitly advised by your doctor, or breast feed while taking Elvanse Adult.

Driving and using machines

The medicine can affect your ability to drive as it may make you sleepy or dizzy, or you may have problems focusing or have blurred vision. If these happen it will be dangerous to do things such as drive or use machines.
• 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:
○ A doctor has prescribed this medicine for you and
○ You have taken it according to his or her instructions, or with the information in this leaflet and
○ It was not affecting your ability to drive safely.
Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Elvanse Adult contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take Elvanse Adult

How much to take

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

Elvanse Adult is only for you. Do not give this medicine to anyone else, even if their symptoms seem similar.

How to take Elvanse Adult

- Take Elvanse Adult in the morning before breakfast. It can be taken with or without food.
- There are two ways to take Elvanse Adult:
    - Swallow the capsule whole with a drink of water
    - Open the capsule and empty the contents into:
        - Soft food such as yogurt
        - A glass of water or orange juice

      Use a spoon to break up any bits and stir the Elvanse Adult and yogurt, water or orange juice until they are completely mixed together. Eat all the yogurt or drink all the water or orange juice immediately after mixing with Elvanse Adult. Do not store it. Do not worry if there is a film left in the glass or container afterwards – this is not the active ingredient.

Dose

- Your doctor will tell you what strength of capsule to take each day.
- The recommended dose at the start of treatment is 30 mg. However, some patients need a lower starting dose of 20 mg. Your doctor will decide which dose you should start your treatment with. Later your doctor may increase your dose if considered necessary. The maximum daily dose is 70 mg.
- If you have any kidney related problems, your doctor may reduce the dose.
- If you are elderly your doctor will study your blood pressure and cardiovascular status before starting and during treatment (see section 2 'Do not take Elvanse Adult' and 'Warnings and precautions'). Your doctor may also need to reduce the dose.
- Do not split the dose of a capsule; take the entire contents of the capsule. Do not take anything less than one capsule per day.

If you do not feel better after 1 month of treatment

If you do not feel better, tell your doctor. You may need a different treatment.

If you are not using Elvanse Adult properly

If you use Elvanse Adult improperly, you may experience abnormal behaviour or you could become dependent on the medicine. Therefore, please tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs before.

If you take more Elvanse Adult than you should

If you take too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much you have taken.

Signs of overdose may include: restlessness, shaking, increased uncontrolled movements, muscle twitching, fast breathing, being confused, an inclination to fight or quarrel, seeing, feeling or hearing things that are not real (hallucinations), panicked state, high fever or muscle breakdown. Tiredness and depression may follow. Being or feeling sick, vomiting, diarrhoea and stomach cramps may also occur. Changes in heart beat (slow, fast or uneven), high or low blood pressure, circulatory collapse, fits and coma may be seen.

If you forget to take Elvanse Adult

Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until the next day. Avoid taking it in the afternoon because of the possibility of sleep disturbances (insomnia).

If you stop taking Elvanse Adult

If you stop taking this medicine, ADHD symptoms may come back.

Do not stop taking the medicine without first talking to your doctor. You should not suddenly stop taking this medicine on your own.

Things your doctor will do when you take Elvanse Adult

Your doctor will do some tests
- before you start - to make sure that Elvanse Adult is safe for you and will be of benefit to you.
- after you start - your doctor will do tests at least every 6 months, but possibly more often. The tests will also be done if the dose is changed. These tests will include:
  - checking your appetite
  - measuring weight
  - measuring blood pressure and heart rate
  - checking whether you have any problems with your mood, state of mind or any other unusual feelings, or if these have got worse while taking Elvanse Adult.

Long-term treatment

Elvanse Adult does not need to be taken forever. If you take Elvanse Adult for more than a year, your doctor should stop treatment for a short time; this may happen during a holiday. This will show if you still need the medicine.

If you have 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 about these side effects.

Some side effects could be serious. If you get any of the side effects below, see a doctor straight away:

Common (may affect up to 1 in 10 adults)
- uneven heartbeat (palpitations)
- chest pain (may be a sign of heart problems)

Uncommon (may affect up to 1 in 100 adults)
- feeling unusually excited, over-active, or un-inhibited (mania)
- allergic reaction (hypersensitivity)

Not known: frequency cannot be estimated from the available data
- seeing, feeling or hearing things that are not real (hallucinations)
- severe allergic reaction characterised by a sharp drop in blood pressure, difficulty breathing, and hives/itching (anaphylactic reaction)
- seeing or feeling or hearing things that are not real, paranoia and delusions (psychotic episodes)
- worsening of Tourette's Disorder with signs such as hard-to-control, repeated twitching of any parts of the body or repeating sounds and words (tics)
- fits (seizures)
- abnormal heart rhythm, life-threatening irregular heart rhythm (seen on an electrocardiogram). See section 2 'Warnings and precautions'
- allergic liver injury seen as possible yellowing of the eyes and/or skin (eosinophilic hepatitis)

- swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties (angioedema) or serious skin rash, with or without blisters, of the skin and mucous membranes or skin irritation, sores or swelling in the mouth, throat, eyes, nose and around the genitals (Stevens-Johnson syndrome)
- breathlessness or swelling of the legs (signs of heart muscle disease)

If you have any of the side effects above, see a doctor straight away.

Other side effects include the following. If they get serious, please tell your doctor or pharmacist:

Very common (may affect more than 1 in 10 adults)
- decreased appetite
- being unable to sleep
- dry mouth
- headache

Common (may affect up to 1 in 10 adults)
- feeling agitated, jittery, anxious, or irritable
- feeling unusually tired or restlessness
- unable to get or keep an erection or changes in sex drive
- feeling dizzy
- uncontrolled jerking, shaking, trembling or being unusually active
- hard-to-control, repeated twitching of any parts of the body or repeating sounds and words (tics)
- having mood swings
- high blood pressure, fast or uneven heart beat (tachycardia)
- difficulty breathing
- feeling sick or diarrhoea
- constipation
- weight loss
- excessive sweating
- stomach pain
- grinding of the teeth

Uncommon (may affect up to 1 in 100 adults)
- talking excessively
- feeling depressed, anxious, low, or uneasy (dysphoria)
- feeling excessively happy or excited (euphoria)
- excessive picking of the skin
- uncontrolled twitching or jerking of the body
- feeling unusually sleepy
- itching, rash or raised red itchy rashes (urticaria)
- blurred vision
- high temperature (fever)
- being sick
- metallic taste or changes in taste (dysgeusia)
- fainting
- nosebleed

Not known: frequency cannot be estimated from the available data
- excessive widening of the pupils
- aggression
- poor blood circulation which makes the toes and fingers go numb and pale (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 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 Elvanse Adult

Do not store above 25°C.

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

Store this medicine in a safe storage space, where other people cannot access it. It can cause serious harm to people when it has not been prescribed for them.

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

Do not use this medicine if the capsules look damaged in any way.

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 Elvanse Adult contains

The active substance is lisdexamfetamine dimesylate.

Each 30 mg capsule contains 30 mg lisdexamfetamine dimesylate, equivalent to 8.9 mg of dexamfetamine.

Each 50 mg capsule contains 50 mg lisdexamfetamine dimesylate, equivalent to 14.8 mg of dexamfetamine

Each 70 mg capsule contains 70 mg lisdexamfetamine dimesylate, equivalent to 20.8 mg of dexamfetamine

The other ingredients are:

- Capsule content: microcrystalline cellulose (E460), croscarmellose sodium (E468), magnesium stearate (E572)
- Capsule shell: gelatin, titanium dioxide (E171)
  - The 30 mg capsule also contains erythrosine (E127)
  - The 50 mg capsule also contains brilliant blue FCF (E133)
  - The 70 mg capsule also contains brilliant blue FCF (E133) and erythrosine (E127)
- Printing ink: shellac (E904), potassium hydroxide (E525), black iron oxide (E172), propylene glycol (E1520) and ammonia solution, concentrated (E527)

What Elvanse Adult looks like and contents of the pack

Capsules, hard

The 30 mg capsules have a white opaque body and pink opaque cap, printed ‘S489’ and ’30mg’ in black ink.

The 50 mg capsules have a white opaque body and blue opaque cap, printed ‘S489’ and ’50mg’ in black ink.

The 70 mg capsules have a blue opaque body and pink opaque cap, printed ‘S489’ and ’70mg’ in black ink.

Pack sizes: 28 or 30 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Elvanse Erwachsene
Denmark	Aduvanz
Finland, Germany, Iceland	Elvanse Adult
Norway	Aduvanz
Spain	Elvanse Adultos
Sweden	Elvanse Vuxen
United Kingdom (Northern Ireland)	Elvanse Adult

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