

**PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **Silarosa 10 mg/mL oral solution** lisdexamfetamine dimesylate

**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.

#### **The leaflet is in sections:**

- Sections 1 to 6 are for parents and carers (sometimes called 'your guardians').
- The last section is a special section for a child or young person to read.

However, all sections are written as though the child or young person taking the medicine is reading them.

#### **What is in this leaflet**

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

#### **1. What [Product Name] is and what it is used for**

##### **What [Product Name] is**

[Product Name] 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. This medicine is a long acting medicine which works gradually over a 13-hour time period.

##### **What [Product Name] is used for**

[Product Name] is a treatment for 'attention deficit hyperactivity disorder' (ADHD). It is used:

- in children and young people between the ages of 6 and 18 who have previously taken a methylphenidate treatment that inadequately treated their ADHD. You may continue to take this medicine into adulthood if your doctor thinks you are benefiting from treatment.

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

This medicine 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 [Product Name] works**

[Product Name] 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 program, which usually includes the following:

- psychological therapy
- educational 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. Children and young people with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places.

ADHD does not affect the intelligence of a child or young person.

## **2. What you need to know before you take [Product Name]**

### **Do NOT take [Product Name] if:**

- you are allergic to lisdexamfetamine or any of the other ingredients of this medicine (listed in section 6)
- you are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 14 days (see below section, "**Other medicines and [Product Name]**")
- you have a thyroid problem
- you feel unusually excited, over-active, or un-inhibited
- 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
- you have high or very high blood pressure or narrowing of the blood vessels
- you have increased pressure in your eye (glaucoma)

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take this medicine. This is because [Product Name] can make these problems worse.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking [Product Name] treatment if you have:

- ever abused prescription medicines or street drugs or alcohol
- had kidney problems
- had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- started your periods – girls only (see the 'Pregnancy, breast-feeding' section)
- 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 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

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

### **Heart rhythm problems**

This medicine 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 [Product Name]:**

These checks are to decide if [Product Name] 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) 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 [Product Name] is the correct medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine.

### **Children below 6 years of age**

This medicine should not be used in children under 6 years of age. Safety and efficacy in this age group has not been established.

### **Other medicines and [Product Name]**

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

**Do NOT take [Product Name] 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 [Product Name] 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.

This medicine 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 [Product Name]:

- 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 this medicine.

### **Drug testing**

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

### **Pregnancy**

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 this medicine into other substances, which can cross the placenta and enter breast milk. Available data from the use of lisdexamfetamine dimesylate during the first three months of pregnancy do not indicate increased risk of birth defect 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 (trembling, irritability, tight muscle tone).

### **Breast-feeding**

Do not use this medicine during pregnancy unless explicitly advised by your doctor, or breast feed while taking [Product Name].

### **Driving and using machines**

You may feel dizzy, have problems focusing or have blurred vision when taking this medicine. If these happen it will be dangerous to do things such as drive, use machines, ride a bike or horse or climb trees.

### **[Product Name] contains sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and propylene glycol.**

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

This medicine contains 100 mg propylene glycol per ml of oral solution..

This medicine contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

## **3. How to take [Product Name]**

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

### **Dose**

- Your doctor will tell you how much to take each day.
- The recommended dose at the start of treatment is 30 mg (3 ml), but your doctor may decide to start you on 20 mg (2 ml). Later on your doctor may increase your dose. The maximum daily dose is 70 mg (7 ml).
- If you have any kidney related problems your doctor may reduce the dose.

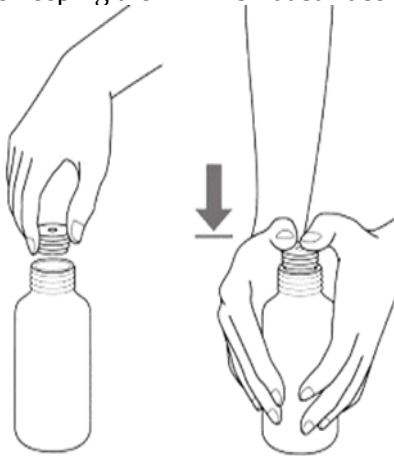
### **How to take [Product Name]**

- Take this medicine in the morning before breakfast. It can be taken with or without food.
- This medicine is for oral use only.

### **Directions for opening the bottle and using the syringe**

1. **Open the bottle:** Press downward on the cap and turn it counter-clockwise.
2. **First time use only:** a Press-In Bottle Adapter (PIBA) and an oral syringe are provided. The adapter gets inserted into the neck of the bottle to make it easier to withdraw the solution using the oral syringe. If the PIBA is not already in place, remove the PIBA and oral syringe from the plastic overwrap. With the bottle on a flat surface, insert the PIBA firmly into the bottle neck

while keeping the PIBA's flat surface facing up and pressing on it (see Fig. 1).



**Fig. 1**

3. Push the syringe plunger to the bottommost position of the syringe (toward its tip) to remove excess air. Attach the syringe to the PIBA with a slight twisting motion and ensure it is secure. Hold the syringe in place and turn the bottle upside down and gently pull down the plunger to requested dose (see Fig. 2).



**Fig. 2**

4. Fill the syringe with the liquid by pulling the syringe plunger down to just beyond the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor. Remove air bubbles from the syringe by pushing the plunger up to the appropriate graduation mark.
5. Turn the bottle the right way up. Remove the oral dosing syringe from the bottle by holding onto the bottle and twisting out gently (see Fig. 3)



**Fig. 3**

6. Empty the oral syringe into a glass of water, cola drink or fruit juice or directly in the patient's mouth by sliding the upper ring down and drink it immediately; **do not mix the solution with tea for dilution** as this may result in modification of the characteristics and effectiveness of the product. Any mixing outside the recommendations is the responsibility of the health care professional or the user.
7. After use, the bottle cap must be replaced leaving the adaptor in place.
8. Rinse the oral syringe and wash it with cold or warm water after each use and dry it completely before the next use.

The oral syringe has a maximum volume of 8 ml.

#### **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.

#### **Not taking properly [Product Name]**

If this medicine is not taken properly, it may cause abnormal behaviour. You may also start to feel like you need the medicine for reasons other than helping with your ADHD. Tell your doctor if you have ever had a problem with alcohol, prescription medicines or street drugs

#### **If you take more [Product Name] 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 heartbeat (slow, fast or uneven), high or low blood pressure, circulatory collapse, fits and coma may be seen.

#### **If you forget to take [Product Name]**

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 [Product Name]**

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 [Product Name]**

Your doctor will do some tests

- before you start - to make sure that this medicine 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 height and 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 this medicine.

#### **Long-term treatment**

This medicine does not need to be taken forever. If you take [Product Name] 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 people)**

- uneven heartbeat (palpitations)
- chest pain (may be a sign of heart problems)

##### **Uncommon (may affect up to 1 in 100 people)**

- seeing, feeling, or hearing things that are not real (hallucinations)
- feeling unusually excited, over-active, or un-inhibited (mania)
- allergic reaction (hypersensitivity)
- breathlessness or swelling of the legs (signs of heart muscle disease)

##### **Not known: frequency cannot be estimated from the available data**

- 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, delusions (psychotic episodes)
- 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 skin (angioedema) or serious skin rash seen as severe blisters of the skin and mucous membranes (Stevens- Johnson syndrome)

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 people)**

- decreased appetite
- weight loss
- being unable to sleep
- dry mouth
- stomach pains
- headache



**Common (may affect up to 1 in 10 people)**

- feeling agitated, jittery, anxious, depressed, aggressive, irritable or have mood swings
- feeling unusually sleepy, tired or restlessness
- unable to get or keep an erection or changes in sex drive
- feeling dizzy
- uncontrolled twitching, jerking, shaking, trembling or being unusually active
- fast or uneven heartbeat (tachycardia)
- difficulty breathing
- feeling or being sick or diarrhoea
- constipation
- high temperature (fever) or excessive sweating
- rash
- grinding of the teeth

**Uncommon (may affect up to 1 in 100 people)**

- 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
- itching, rash or raised red itchy rashes (urticaria)
- blurred vision
- excessive widening of the pupils of the eyes
- poor blood circulation which makes the toes and fingers go numb and pale (Raynaud's phenomenon)
- high blood pressure
- metallic taste or changes in taste (dysgeusia)
- fainting
- nosebleed

**Effects on weight**

[Product Name] may cause reduced weight in some children and adolescents.

- There may be lack of weight gain.
- Your doctor will carefully watch your height and weight, as well as how well you are eating.
- If you are not growing as expected, then your doctor may stop treatment with this medicine for a short time.

**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 [Product Name]**

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 bottle and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

**After first opening of the bottle: do not store more than 60 days.**

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 [Product Name] contains**

- The active substance is lisdexamfetamine dimesylate. Each ml of oral solution contains 10 mg lisdexamfetamine dimesylate, equivalent to 2.95 mg of dexamfetamine.
- The other ingredients are: sodium methyl parahydroxybenzoate (E 219), sodium propyl parahydroxybenzoate (E 217), sodium dihydrogen phosphate dihydrate, disodium hydrogen phosphate dihydrate, propylene glycol (E 1520), saccharin sodium, hydrochloric acid, conc. (for pH adjustment), sodium hydroxide (for pH adjustment) and purified water.

### **What [Product Name] looks like and contents of the pack**

Oral solution

The solution is clear and colourless to slightly yellow.

Amber glass bottle sealed with a child-proof and tamper evident plastic cap, containing 100 mL oral solution.

Amber PET bottle sealed with a child-proof and tamper evident plastic cap, containing 100 mL oral solution.

A dosing syringe and a plastic plug that is able to fit on the bottle as well as allow the dosing syringe to fit (Press-In Bottle Adapter) are also provided. The dosing syringe has a volume of 8 ml and the graduations are in steps of 0.1 mL up to the maximum daily dose of 7 ml.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

[To be completed nationally]

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

**This medicinal product is authorised in the Member States of the EEA under the following names:**

[To be completed nationally]

**This leaflet was last revised in 2024-11-27**

## **Information for children and young people**

This information is to help you learn the main things about your medicine called [Product Name].

If you don't enjoy reading, someone like your mum, dad or carer (sometimes called 'your guardian') can read it to you and answer any questions.

It may help if you read small bits at a time.

### **Why has the doctor given me this medicine?**

This medicine can help your 'ADHD'.

ADHD can make you:

- run about too much
- be unable 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.

### **While you are taking this medicine**

- As well as giving you this medicine, your doctor will arrange for you to learn ways to cope with your ADHD such as talking to people who can give you tips or teach you different ways to do things.
- The medicine should help your ADHD.
- You will need to go to your doctor several times for checkups. This is to make sure the medicine is working and that you are growing and developing OK.
- If you take the medicine for more than one year, your doctor may stop your medicine to see if you still need it. This will probably happen in a school holiday.
- Girls must ask their doctor for advice before taking this medicine if they think they may be pregnant, or are planning to have a baby.

### **Some people cannot have this medicine**

You cannot have this medicine if you:

- have a problem with your heart
- feel unusually excited or over-active

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

You need to talk to your doctor if you:

- have fits
- are pregnant or breastfeeding
- are taking other medicines – your doctor needs to know about all the medicines you are taking
- have bad kidney problems.

### **How do I take my medicine**

- Your doctor, your mum, dad or carer will tell you how much oral solution to take each day.
- An adult will also help you or show you how to open the bottle and use the syringe
- The recommended dose at the start of treatment is 3 mL, but your doctor may decide to start you on 2 mL. Later on your doctor may increase your dose. The maximum daily dose is 7 mL.
- Take one dose each morning. You can take it with or without food.
- Do not stop taking the medicine without talking to your doctor first.
- If you forget to take your medicine, tell an adult. You must NOT take 2 doses to make up for the dose you forgot.

**Possible side effects**

Side effects are the unwanted things that can happen when you take a medicine. If any of the following happen, tell an adult straight away. They can then talk to your doctor. The main things that could affect you are if you:

- feel your heart beating faster than usual or uneven heartbeat
- see, feel, or hear things that are not real
- feel unusually excited or over-active
- have a severe allergic reaction. This may be seen as feeling dizzy, difficulty breathing, and itching
- have fits
- notice yellowing of the eyes and/or skin
- have swelling of the skin or bad skin rash like blisters of the skin or other areas

**If you feel unwell in any way while you are taking your medicine please tell an adult straight away.**

**Other things to remember**

- Make sure you keep your medicine in a safe place, so that no one else takes it.
- The medicine is just for you - do NOT let anyone else have it. It may help you, but it could hurt someone else.
- If you forget to take your medicine don't take 2 doses the next time. Just take 1 dose at the next normal time.
- It is important not to take too much medicine or you will get ill.
- If you take too much medicine, tell your mum, dad or carer right away.
- Don't stop taking your medicine until your doctor says it's OK to stop.

This medicine contains sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and propylene glycol, ingredients that may cause allergic reactions (possibly delayed).

**Who should I ask if there is anything I don't understand?**

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