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APPROVED PATIENT INFORMATION LEAFLET

AMFETAMINES HAVE A HIGH POTENTIAL FOR ABUSE.

ADMINISTRATION OF AMFETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO MEDICINE DEPENDENCE. MISUSE OF AMFETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS

SCHEDULING STATUS:

S6

VYSERA 30 mg Capsule
VYSERA 50 mg Capsule
VYSERA 70 mg Capsule

(lisdexamfetamine dimesilate)

No sugar

Read all of this leaflet carefully before you start taking VYSERA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- VYSERA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What VYSERA is and what it is used for

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VYSERA is a central nervous system stimulant used to treat:

- Attention Deficit Hyperactivity Disorder (ADHD) if treatment with methylphenidate and atomoxetine has failed. VYSERA increases attention and decreases impulsiveness and hyperactivity in patients with ADHD.

It is not to be taken by children with ADHD under 13 years of age as the available formulations do not allow for the flexibility to achieve the optimal dose requirements for children 6 to 12 years of age. Safety of VYSERA in children below 6 years has not been established. VYSERA should be used as part of a comprehensive treatment program which usually includes psychological, educational and social therapy.

The main ingredient in VYSERA is lisdexamfetamine dimesilate which itself is not active (such medicines are sometimes called a pro-drug). After VYSERA is taken, it is converted in the blood to dexamfetamine which is the active medicine.

Ask your doctor if you have any questions about why VYSERA has been prescribed for you/your child.
VYSERA can be abused or lead to dependence. VYSERA is a controlled substance and should be handled responsibly. It is illegal for anyone prescribed VYSERA to sell or give it to other people.

Keep VYSERA in a safe place to prevent misuse and abuse. Also, return any unused capsules to your pharmacy to safeguard against them being taken by anyone else (see Disposal section).

2. What you need to know before you take VYSERA

VYSERA capsules are not suitable for everyone
Do not take VYSERA if you/your child

- are allergic (hypersensitive) to amfetamines or any of the other ingredients of VYSERA listed in “What VYSERA contains in section 6. of this leaflet
- have a disease of the arteries due to cholesterol deposits e.g. atherosclerosis

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- have heart disease such as angina pectoris or myocardial infarction (heart attack) or other heart diseases or disorders including heart rate and rhythm disturbances
- have moderate to severe high blood pressure
- have hyperthyroidism (hyperactive thyroid)
- have an eye condition called glaucoma
- have a tumour of the adrenal gland tissue (phaeochromocytoma)
- have tics (muscle twitching usually in the face and shoulders)
- have Tourette's syndrome
- have severe depression, suicidal ideation or behaviour, thoughts or acts of self-harm or mental illness
- have periods of severe anxiety, tension or agitation
- suffer with drug dependence or abuse alcohol
- are taking or have taken an antidepressant called a monoamine oxidase inhibitor or MAOI within the past 14 days.
- Are pregnant or breastfeeding your baby (see Pregnancy, Breastfeeding and Fertility)

Do not use VYSERA beyond the expiry date (month and year) printed on the bottle.

If you/your child take VYSERA after the expiry date has passed, it may have no effect, or worse, there may be an entirely unexpected effect.

Do not give it to children unless your doctor has prescribed it. VYSERA is not recommended for use in children with ADHD under 13 years of age as the available formulations do not allow for optimisation of the dose requirements for children 6 to 12 years of age. VYSERA must not be used in children under 6 years of age.

If you are not sure whether you/your child should start using VYSERA, contact your doctor.

Warnings and Precautions

Tell your doctor or pharmacist if you or your child:

- are allergic to any other medicines, or any foods, dyes or preservatives

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- are pregnant or planning to become pregnant (See : Do not take VYSERA)
- are breastfeeding or wish to breastfeed (See : Do not take VYSERA)
- have any other medical conditions or heart problems, including ischemic heart disease (such as angina pectoris or myocardial infarction), suspicion or presence of any cardiac or heart -related abnormalities, irregular heartbeats or rate, family history of sudden/cardiac death
- suffer from blood pressure and/or taking medications to treat blood pressure
- disorders of the blood vessels of the brain e.g. stroke
- suffer from depression, bipolar illness, or schizophrenia or other mental illness
- have liver or kidney disease. Your doctor may lower the dose if you have kidney disease.
- have epilepsy or other seizures or have had an abnormal brain wave test (EEG)
- have circulation problems in fingers and toes
- feeling agitated, anxious or tense

If you have not told your doctor or pharmacist about any of the above, tell them before you/your child take any VYSERA.

Other Medicines and VYSERA

Tell your doctor or pharmacist about all the medicines you/your child are taking or have recently taken, including prescription and non-prescription medicines, vitamins and herbal supplements. VYSERA can affect the way other medicines work, and other medicines may affect how VYSERA works. Using VYSERA with other medicines can cause serious side effects.

It is especially important to tell your doctor or pharmacist if you or your child is taking medicines to treat any of the following conditions:

- depression including MAOIs
- anxiety, mania or bipolar disorder
- high blood pressure
- schizophrenia or schizophrenia-like illness
- strong pain

In addition, the following medicines may also interact with VYSERA

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- Urinary acidifying medicines e.g. ascorbic acid (Vitamin C), ammonium chloride, sodium acid phosphate
- Urinary alkalinising medicines e.g. sodium bicarbonate, acetazolamide, some thiazides

Tell your doctor or pharmacist if you/your child are taking or have recently taken other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not start any new medicine while taking VYSERA without talking to your doctor first.

VYSERA with alcohol

If you/your child drink alcohol, it could make some of the unwanted side effects of VYSERA worse. Your doctor may suggest that you/your child avoid alcohol completely while you are taking VYSERA.

Pregnancy, breastfeeding and fertility

You should not be treated with VYSERA if you are pregnant or planning to become pregnant as treatment with VYSERA may harm your unborn child

Tell your doctor immediately if you/your child become pregnant while on VYSERA.

Breastfeeding

You should not breastfeed your baby if you are on treatment with VYSERA. VYSERA may cause serious harm to your baby.

If you are pregnant or breastfeeding , think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking VYSERA

Driving and using machines

VYSERA may affect your ability to drive and use machines. You should not drive or use machines until you know how VYSERA affects you

VYSERA may cause dizziness, drowsiness and blurry or double vision.

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VYSERA 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 VYSERA

Do not share medicines prescribed for you with any other person

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

Your doctor may do regular checks of the blood, heart, and blood pressure while taking VYSERA.
Children should have their height and weight checked often while taking VYSERA.

The usual starting dose for children, adolescents and adults is 30 mg once a day. Your doctor may increase the dose until it is right for you or your child.

- Take VYSERA exactly as prescribed. VYSERA comes in 3 different strengths of capsule.
- Take VYSERA once a day in the morning.
- VYSERA can be taken with or without food.
- If you have trouble swallowing capsules, you may open your VYSERA capsule and pour all of the powder into a soft food such as yogurt, water or orange juice.
- Use all of the VYSERA powder from the capsule so you get all of the medicine.
- Using a spoon, break apart any powder that is stuck together. Stir the VYSERA powder and yogurt, water or orange juice until they are completely mixed together.
- Consume all of the yogurt, water or orange juice right away after it has been mixed. Do not store the yogurt, water or orange juice after it has been mixed with VYSERA.
- Do not worry if there is a film or residue left in the glass or container afterwards - this is not the active ingredient.

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- From time to time, your doctor may stop VYSERA treatment for a while to check your/your child's ADHD.

Your doctor will tell you how long your treatment with VYSERA will last. Do not stop your treatment early unless your doctor tells you to

If you take more VYSERA than you should

Immediately telephone your doctor or the nearest poison centre or hospital for advice, or go to Casualty department at the nearest hospital, if you think that you/your child or anyone else may have used too much VYSERA. Do this even if there are no signs of discomfort or poisoning.

If too much VYSERA is taken, the following symptoms may be experienced: confusion, restlessness, tremor, irregular heartbeat, nausea, vomiting, diarrhoea, stomach aches, seizures and coma.

If you forget to take VYSERA

If you/your child forget to take your dose in the morning then take them as usual the next morning. Do not take a double dose to make up for a forgotten capsule.

Avoid taking VYSERA in the afternoon or evening as it can cause an inability to sleep.

If you stop taking VYSERA

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

If you stop taking VYSERA your ADHD symptoms may come back.

4. Possible side effects

VYSERA can have side effects.

Should your/your child’s general health worsen or you experience any untoward effects while taking VYSERA please contact your doctor for advice

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Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happens tell your doctor immediately or go to casualty department at your nearest hospital if you/your child develop:

- allergic reaction which may result in a rash or a sharp drop in blood pressure, difficulty breathing, and hives/itching (anaphylactic reaction)
- chest pain or tightness in the chest
- shortness of breath
- irregular heart beat
- seizures (fits)
- vision problems
- mood changes such as depression or irritability
- new or worsening aggressive behaviour
- excitement, overactivity and uninhibited behaviour
- confusion, delusion or hallucinations (seeing or feeling things that are not really there)
- abnormal thinking (psychosis).
- 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

These are all serious side effects. If you/your child have them, you may have had a serious reaction to VYSERA. You/your child may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you/your child notice any of the following and they worry you:

Very common (may affect more than 1 in 10 adults)

- decreased appetite
- being unable to sleep
- dry mouth

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- 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 heartbeat (tachycardia)
- difficulty breathing
- feeling sick or diarrhoea
- constipation
- weight loss
- excessive sweating
- stomach pains
- 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

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)
- Suppression/slowing of growth (length)
- Dependence on or abuse of VYSERA

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Effects on weight

VYSERA 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 VYSERA for a short time.

Other side effects not listed above may also occur in some people. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VYSERA

5. How to store VYSERA

Store all medicines out of reach of children.
Store at or below 25 ºC.

Do not store VYSERA or any other medicines in the bathroom or near a sink. Do not leave medicines in the car or on windowsills. Heat and dampness can destroy medicines.
Do not use VYSERA after the expiry date stated on the label of the bottle

Return any unused or out of date medicine to your pharmacist. Do not dispose of any unused medicine in drains or sewerage system (e.g. toilets)

6. Contents of the pack and other information

What VYSERA contains

The active substance is lisdexamfetamine dimesilate

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The other ingredients are
Croscarmellose sodium
Magnesium stearate
Microcrystalline cellulose

The capsule shells contain gelatin, titanium dioxide (E171) (all strengths), erythrosine (E127) (30 mg and 70 mg), brilliant blue FCF (E133) (50 mg and 70 mg), and TekPrint SW-9008 (all strengths).

- **What VYSERA looks like and contents of the pack**

VYSERA capsules are packed in high density polyethylene (HDPE) bottles with polypropylene child resistant (PP CR) cap. VYSERA is supplied in bottles of 30 capsules, inside a cardboard box.

VYSERA 30 mg capsule: white opaque body and pink opaque cap, printed 'S489' and '30 mg' in black ink.

VYSERA 50 mg capsule: white opaque body and blue opaque cap, printed 'S489' and '50 mg' in black ink

VYSERA 70 mg capsule: blue opaque body and pink opaque cap, printed 'S489' and '70 mg' in black ink.

Holder of Certificate of Registration.
Takeda (Pty) Ltd
Building A, Monte Circle
64 Montecasino Boulevard
Fourways 2191,
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This leaflet was last revised in
09 September 2025

Docusign Envelope ID: AF270D8C-CCBE-87A8-8216-55CFAE7D4775

Registration Numbers

VYSERA 30 mg: 60/1.6/0799

VYSERA 50 mg: 60/1.6/0800

VYSERA 70 mg: 60/1.6/0801