PATIENT INFORMATION LEAFLET FOR

VYFOCIS

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

VYFOCIS 30 mg capsules

VYFOCIS 50 mg capsules

VYFOCIS 70 mg capsules

Lisdexamfetamine dimesilate

Sugar free.

Read all of this leaflet carefully before you start taking VYFOCIS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- VYFOCIS 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 VYFOCIS is and what it is used for
2. What you need to know before you take VYFOCIS
3. How to take VYFOCIS

4. Possible side effects
5. How to store VYFOCIS
6. Contents of the pack and other information

1. What VYFOCIS is and what it is used for

VYFOCIS contains lisdexamfetamine dimesilate that is used to treat:

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

2. What you need to know before you take VYFOCIS:

Do not take VYFOCIS if you/your child:

- are allergic (hypersensitive) to amfetamines or any of the other ingredients of VYFOCIS listed in "What VYFOCIS contains" in **section 6** of this leaflet.
- have a disease of the arteries due to cholesterol deposits e.g. atherosclerosis.
- have heart disease such as angina or myocardial infarction (heart attack).
- 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**").

Warnings and precautions

VYFOCIS can be abused or lead to dependence. VYFOCIS is a controlled substance and should be handled responsibly. It is illegal for anyone prescribed VYFOCIS to sell or give it to other people.

Tell your doctor or health care provider if you or your child has ever abused prescription medicines or street drugs.

You should not stop taking VYFOCIS without consulting your doctor.

VYFOCIS should be used as part of a comprehensive treatment program which usually includes psychological, educational and social therapy.

Tell your doctor or pharmacist if you or your child:

- have a family or medical history of irregular heart rhythm (as shown on an electrocardiogram), or if you have a disease and/or take treatment that makes you susceptible to heartbeat irregularities.
- 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 heartrate,

family history of sudden/cardiac death.

- suffer from blood pressure and/or taking medications to treat blood pressure.
- have a mental health problem - these may include:
    - mood swings (from being manic to being depressed)
    - starting to be aggressive or unfriendly (hostile), or your aggression gets worse
    - seeing, hearing or feeling things that are not there
    - believing things that are not true
    - feeling agitated, anxious or tense.
- had fits (seizures, convulsions, epilepsy).
- have hard-to control and repeated twitching of any parts of the body or you repeat sounds and words.
- have liver or kidney disease. Your doctor may lower the dose if you have kidney disease.
- have circulation problems in fingers and toes.
- have blurry vision.

Children and adolescents

VYFOCIS should not be used 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.

VYFOCIS must not be used in children under 6 years of age.

Other medicines and VYFOCIS

Always tell your health care provider if you are taking any other medicine. (This includes

all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any medicines, in particular:

- a medicine called a ‘monoamine oxidase inhibitor’ (MAOI) used for depression
- medicine that can affect the acidity of your urine, such as vitamin C or sodium bicarbonate
- medicine for severe mental health problems
- medicine used to reduce or increase blood pressure
- medicines used during surgery such as painkillers.

Pregnancy and breastfeeding

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 health care provider for advice before taking VYFOCIS.

Pregnancy

Do not take VYFOCIS if you are pregnant or planning to become pregnant as treatment with VYFOCIS may harm your unborn child.

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

Effects on infants

Newborns exposed to amfetamine during pregnancy may experience withdrawal symptoms (trembling, irritability, tight muscle tone).

Breastfeeding

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

Driving and using machines

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

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

3. How to take VYFOCIS

Do not share medicines prescribed for you with any other person.

Always take VYFOCIS 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 VYFOCIS.

Children should have their height and weight checked often while taking VYFOCIS.

- Take VYFOCIS exactly as prescribed.
- VYFOCIS can be taken with or without food.
- Take VYFOCIS once a day in the morning.
- If you have trouble swallowing capsules, you may open your VYFOCIS capsule and pour all of the powder into a soft food such as yogurt, water or orange juice.
- Use all of the VYFOCIS powder from the capsule so you get all of the medicine.
- Using a spoon, break apart any powder that is stuck together. Stir the VYFOCIS 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 VYFOCIS.
- Do not worry if there is a film or residue left in the glass or container afterwards - this is not the active ingredient.

The usual starting dose for adolescents and adults is 30 mg once a day.

If the decision is made to increase the dose beyond 30 mg/day, daily dosage may be adjusted in increments of 20 mg in intervals no more frequently than weekly.

If you take more VYFOCIS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

If you forget to take VYFOCIS

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 VYFOCIS in the afternoon or evening as it can cause an inability to sleep.

4. Possible side effects

VYFOCIS can have side effects.

Not all side effects reported for VYFOCIS are included in this leaflet. Should your

general health worsen or if you experience any untoward effects while receiving VYFOCIS, please consult your doctor, pharmacist or other health care provider for advice.

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

- allergic reaction which may result in a rash or more rarely to a sharp drop in blood pressure, difficulty breathing, and hives/itching (anaphylactic reaction)
- chest pain or tightness in the chest
- shortness of breath
- irregular heartbeat
- 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).

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

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

- decreased or loss of appetite

- trouble sleeping
- headache
- dry mouth
- weight loss
- suppression/slowing of growth (length)
- upper belly pain
- agitation, anxiety, aggression, affect liability, irritability, feeling jittery, feeling tired, feeling sleepy
- dizziness, restlessness, excessive motor activity with or without feelings of restlessness, tic, tremor
- rapid heartbeat (tachycardia), palpitations, increased blood pressure
- nausea, vomiting, diarrhoea
- involuntary clenching or grinding of the teeth
- rash, fever, shortness of breath
- excessive sweating
- excessive widening of the pupil
- decreased sex drive, erectile dysfunction
- circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon): Fingers or toes may feel numb, cool, painful; change colour or have sensitivity to temperature
- dependence on or abuse of VYFOCIS.

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail to drugsafetysa@cipla.com or by telephone to 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of VYFOCIS.

5. How to store VYFOCIS

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use VYFOCIS after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage system (e.g. toilets).

6. Contents of the pack and other information

What VYFOCIS contains

The active substance is lisdexamfetamine dimesilate.

The other ingredients are:

Croscarmellose sodium

Magnesium stearate

Microcrystalline cellulose

Capsule shell: gelatin

Capsules shell colourants

- 30 mg: titanium dioxide (E171), FD&C Red No. 3 (E127), D&C Yellow No. 10

(E104)

- 50 mg: titanium dioxide (E171), FD & C Blue No.1 (E133)
- 70 mg: titanium dioxide (E171), FD&C Red No. 3 (E127), D&C Yellow No.10 (E104), FD&C Blue No.1 (E133)

Printing ink (all strengths)

- Shellac
- Propylene glycol
- Titanium Dioxide (E171)
- Black Iron Oxide (E172)

What VYFOCIS looks like and contents of the pack

VYFOCIS capsules are packed in white HDPE bottles with a white cap and a silica gel desiccant cannister, in a carboard carton.

VYFOCIS 30 mg capsule: Orange cap and white body, “ALV” printed axially on the orange cap, “564” printed axially on the white body, all printing in grey ink and containing white to pale yellow powder.

VYFOCIS 50 mg capsule: Dark blue cap and white body, “ALV” printed axially on the dark blue cap, “566” printed axially on the white body, all printing in grey ink and containing white to pale yellow powder.

VYFOCIS 70 mg capsule: Orange cap and blue body, “ALV” printed axially on the orange cap, “568” printed axially on the blue body, all printing in grey ink and containing white to pale yellow powder.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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VYFOCIS 30: 56/1.6/1238

VYFOCIS 50: 56/1.6/1240

VYFOCIS 70: 56/1.6/1242

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR code to be generated and included after approval