### Package Leaflet: Information for the user

Affenid XL 18mg

#### methylphenidate hydrochloride

Affenid XI 18, 27, 36 or 54 mg prolonged release tablets (referred to as Affenid throughout this leaflet) contains the active substance methylphenidate hydrochloride.

#### Important things you need to know about your medicine

#### 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 as well as this

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
- You are taking any other medicines this is because Affenid 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 may stop your medicine to see if it is still needed, it you take it for more than a year
- The most common side effects are feeling nervous, not being able to sleep or having a headache.

Read Sections 3 and 4 for more information.

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

- Your mood and 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 on the safe and effective use of this

- 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 has been written in sections:

- Sections 1 to 6 are for parents and carers (sometimes called
- The last section is a special section for a child or young person About ADHD to read. However, all sections are written as though the child or voung person taking the medicine is reading them.

#### The sections are:

- 1. What Affenid is and what it is used for
- . What you need to know before you take Affenid
- B. How to take Affenid
- Possible side effects
- 5. How to store Affenid
- 6. Contents of the pack and other information

Information for children and young people

Now read the rest of this leaflet before you start taking this medicine because it contains important information for you.

### 1. What Affenid is and what it is used for

#### What it is used for

Affenid is used to treat 'attention deficit hyperactivity disorder

- It is used in children aged 6 years and over and in adults
- It is used only after trying treatments which do not involve medicines, such as counselling and behavioural therapy.

Affenid is not for use as a treatment for ADHD in children under 6 years of age.

#### How it works

Affenid improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour. The medicine is given as part of a treatment programme, which

- psychological educational and
- social therapy.

t is prescribed only by doctors who have experience in children. adolescents or adults with behaviour problems. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had ADHD since childhood Although there is no cure for ADHD, it can be managed using treatment programmes

Children and adolescents with ADHD find it hard:

- to sit still and
- to concentrate.

It is not their fault that they cannot do these things

Many children and adolescents struggle to do these things. However. ADHD can cause problems with everyday life. Children and adolescents with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or Do not take Affenid if any of the above apply to you. If you are no in other places.

This is because Affenid can make these problems worse. Adults with ADHD often find it hard to concentrate. They often feel restless, impatient and inattentive. They may have difficulty organising their private life and work.

Warnings and precautions

have a narrowing or blockage of your gut or food-pipe

medicines or street drugs

#### ADHD does not affect intelligence. have liver or kidney problems

### Do not take Affenid if you:

Not all patients with ADHD need to be treated with medicine.

- have had fits (seizures, convulsions, epilepsy) or any abnormal are allergic to methylphenidate or any of the other ingredients of brain scans (EEGs) this medicine (listed in section 6)
- have a thyroid problem

2. What you need to know before you take Affenid

- have increased pressure in your eve (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma) have an eating problem where you do not feel hungry or want to eat - such as 'anorexia nervosa' body or you repeat sounds and words
- have very high blood pressure or narrowing of the blood vessels. have high blood pressure have a heart problem which is not in the 'Do not take' section. which can cause pain in the arms and leas
- have ever had heart problems such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart section above disease or were born with a heart problem
- have had a problem with the blood vessels in your brain such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of 'bipolar disorder') the blood vessels (vasculitis)
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor)- see 'Other medicines and Affenid'
- have mental health problems such as:
- a 'psychopathic' or 'borderline personality' problem
- abnormal thoughts or visions or an illness called
- signs of a severe mood problem like:
- feeling like killing vourself
- severe depression, where you feel very sad, worthless and Ouring treatment, boys and adolescents may unexpectedly
- mania. where you feel unusually excitable, over-active, and

sure, talk to your doctor or pharmacist before you take Affenia.

Talk to your doctor before taking Affenid if you:

- have a problem with swallowing or swallowing whole tablets
- any other medical problems (such as heart problems) you or your family may have how you are feeling, such as feeling high or low, 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 have ever abused or been dependent on alcohol, prescription. and words) are a girl and have started your periods (see the 'Pregnancy. any mental health or behaviour problems you or other family
- breast-feeding and contraception' section below) members have ever had. Your doctor will discuss whether you have hard-to-control, repeated twitching of any parts of the are at risk of having mood swings (from being manic to being depressed - called 'bipolar disorder'). They will check your mental health history, and check if any of your family have a history of suicide, bipolar disorder or depression.

are taking a medicine called a 'monoamine oxidase inhibitor

syndrome), which may lead to feeling confused or restless.

these side effects, see a doctor straight away.

sweating, shivering, muscle jerks or fast heart-beat. If you develop

(MAOI) used for depression, or have taken an MAOI in the last

It is important that you provide as much information as you can. This will help your doctor decide if Affenid is the correct have a mental health problem which is not in the 'Do not take' medicine for you. Your doctor may decide that other medical tests are needed before you start taking this medicine. For adult patients that are new to Affenid, your doctor may refer you to a

Other medicines and Affenid

Do not take Affenid if you

#### Other mental health problems include:

- mood swings (from being manic to being depressed called heart specialist.
- feeling aggressive or hostile
- seeing, hearing or feeling things that are not there (hallucinations Tell your doctor if you are taking, have recently taken or might take any other medicines.
- 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 apply to you 14 days. Taking an MAOI with Affenid may cause a sudden increase in your blood pressure (see "Do not take Affenid"). before starting treatment. This is because Affenid can make these problems worse. Your doctor will want to monitor how the Tell your doctor or pharmacist if you or your child is taking any of medicine affects vou. the following medicines for depression or anxiety:

 tricvclic antidepressant experience prolonged erections. This may be painful and can occur selective serotonin reuptake inhibitor (SSRI) at any time. It is important to contact your doctor straight away if your serotonin and norepinephrine reuptake inhibitor' (SNRI). erection lasts for longer than 2 hours, particularly if this is painful. Taking Affenid with these types of medicine could cause a ife-threatening increase of 'serotonin' in the brain (serotonin

# Checks that your doctor will make before you start taking

These checks are to decide if Affenid is the correct medicine for vou. Your doctor will talk to you about:

any other medicines you are taking

- If you are taking other medicines. Affenid may affect how well whether there is any family history of sudden unexplained death they work or may cause side effects. If you are taking any of the following medicines, check with your doctor or pharmacist before
  - medicines for severe mental health problems medicines for Parkinson's disease (such as levodona)
  - medicines for epilensy
  - medicines used to reduce or increase blood pressure
  - 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.

If you are in any doubt about whether any medicines you are taking are included in the list above, ask your doctor or pharmacist before

Please tell you doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

#### Having an operation Tell your doctor if you are going to have an operation. You should

not take Affenid on the day of your 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

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

#### Affenid with alcohol

Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some

### Pregnancy, breast-feeding and contraception

or are planning to have a baby, ask your doctor for advice before taking this medicine.

defects, whilst a small increase in the risk of malformations of the heart when used during the first three months of pregnancy You should take Affenid once each day in the morning with a glass could not be ruled out. Your doctor will be able to give you more

information about this risk. Tell your doctor or pharmacist before using Affenid if you are:

- whether you should take Affenid.
- breast-feeding or planning to breast-feed. Affenid passes into breast milk. Therefore, your doctor will decide whether you

#### Driving and using machines

vision when taking Affenid. If these happen it may be dangerous to do things such as drive, use machines, ride a bike or horse or

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely

in Great Britain – go to https://www.gov.uk/drug-driving-law.

#### Affenid contains lactose

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars contact your doctor before taking this medicine.

Always take this medicine exactly as your doctor has told you.

The aim should be the lowest dose that is effective for you. Your

doctor will decide the maximum daily dose for you or your child.

### Affenid contains sodium

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

## . How to take Affenid

#### foods and medicines contain alcohol. How much to take

Check with your doctor or pharmacist if you are not sure. If you are pregnant or breast-feeding, think you may be pregnan Your doctor will usually start treatment with a low dose and increase the daily dose by 18 mg no sooner than once a week if

Available data do not suggest an increased risk of overall birth

having sex. Your doctor will discuss contraception with you.

- The tablet does not dissolve completely after all of the drug has pregnant or think you may be pregnant. Your doctor will decide been released and sometimes the tablet shell may appear in your stools. This is normal.
- should breast-feed while taking Affenid.

## or for children who are switching from another stimulant

You may feel dizzy, have problems focussing or have blurred to methylphenidate the maximum daily dose is 54 mg. Use in adults

 adult patients may require a higher daily dosage but the doctor There is further information for patients who are intending to drive will aim to give you the lowest dose that is effective For adults who have not taken Affenid before

 the recommended starting dose is 18 mg daily The maximum daily dose in adults is 72 mg.

For adults who have taken Affenid before:

regularly to see if any adjustment is required

If you do not feel better after 1 month of treatment

Your doctor may decide you need a different treatment. Not using Affenid properly

## If Affenid is not used properly, this may cause abnormal behaviour

It may also mean that you start to depend on the medicine. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

If you do not feel better after 1 month of treatment, tell your doctor

The tablet should be swallowed whole and not chewed, broken, or

the recommended starting dose of Affenid is 18 mg once daily

if you have already taken Affenid as a child or adolescent, the

same daily dosage (mg/day) can be used: your doctor will check

for children who are not currently taking methylphenidate

crushed. The tablet may be taken with or without food.

Use in children aged 6 years and over

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

#### If you take more Affenid than you should

If you take too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken. Medical treatment might be needed.

Signs of overdose may include; being sick, feeling agitated, shaking increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing,

feeling or hearing things that are not real (hallucinations), sweating flushing headache high fever changes in heart heat (slow fast or uneven), high blood pressure, dilated pupils and dry nose and mouth

#### If you forget to take Affenid

Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

#### If you stop taking Affenid

If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Affenid.

#### Things your doctor will do when you are on treatment Your doctor will do some tests

- before you start to make sure that Affenid is safe and will be
- after you start they will be done at least every 6 months, but possibly more often. They will also be done when the dose

state of mind or any other unusual feelings. Or if these have

Affenid does not need to be taken for ever. If you take Affenid for

time, this may happen during a school holiday. This will show if the

If you have any further questions on the use of this product, ask

Like all medicines, this medicine can cause side effects, although

not everybody gets them. Although some people get side effects

more than a year, your doctor should stop treatment for a short

- these tests will include:
- checking your appetite

Long-term treatment

medicine is still needed.

got worse while taking Affenid

- measuring height and weight
- measuring blood pressure and heart rate
- skin peeling or purplish red patches. checking whether you have any problems with your mood
  - inflammation or blocked arteries in the brain
  - difficulties in speech (these can be signs of problems with the plood vessels in your brain)
  - muscle spasms which you cannot control affecting your eyes. nead, neck, body and nervous system
  - decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily
- vour doctor or pharmacist. a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant 4. Possible side effects Syndrome'). It is not certain that this side effect is caused ov Affenid or other drugs that may be taken in combination

with Affenid.

most people find that Affenid helps them. Your doctor will talk to you about these side effects

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

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

 uneven heartbeat (palpitations) mood changes or mood swings or changes in personality

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

- thinking about or feeling like killing yourself
- seeing, feeling, or hearing things that are not real, these are
- uncontrolled speech and body movements (Tourette's)
- signs of allergy such as rash, itching or hives on the skin. swelling of the face, lips, tongue or other parts of the body. shortness of breath, wheezing or trouble breathing

### Rare (may affect up to 1 in 1.000 people)

feeling unusually excited, over-active and un-inhibited (mania)

#### Very rare (may affect up to 1 in 10,000 people)

- sudden death
- suicidal attempt
- fits (seizures, convulsions epilepsy)

- temporary paralysis or problems with movement and visior
  - inability to develop or maintain an erection itching, rash or raised red itchy rashes (hives)

    - feeling unusually sleepy or drowsy, feeling tired

    - increased alanine aminotransferase (liver enzyme) level in your
    - fingers and toes feeling numb, tingling and changing cough, sore throat or nose and throat irritation; upper respirator
    - high blood pressure, fast heart beat (tachycardia)
    - dizziness (vertigo), feeling weak, movements which you cannot control, being unusually active

## Not known (frequency cannot be estimated from the available

- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- prolonged erections, sometimes painful or an increased number

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

#### Other side effects include the following, if they get serious, chest discomfort please tell your doctor or pharmacist:

- Very common (may affect more than 1 in 10 people) headache
- feeling nervous
- not being able to sleep.

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

- blurred vision
- tension headache
- drv mouth, thirst
- trouble falling asleep
- high temperature (fever decreased sex drive
- unusual hair loss or thinning
- muscle tightness, muscle cramps
- loss of appetite or decreased appetite

  - muscle cramps
- excessive teeth grinding (bruxism)
- feeling of panic
- tingling feeling, prickling, or numbness of the skin
- colour (from white to blue, then red) when cold ('Raynaud's tract infection: sinus infection phenomenon').

#### feeling aggressive, agitated, anxious, depressed, irritable, tense, iittery and abnormal behaviour

- upset stomach or indigestion, stomach pain, diarrhoea, feeling migraine sick, stomach discomfort and being sick.
- excessive sweating weight decreased.

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

- blood in the urine
- listlessness shaking or trembling
- increased need to pass urine
- muscle pain, muscle twitching
- shortness of breath or chest pain
- increases in liver test results (seen in a blood test)
- anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping.

#### Rare (may affect up to 1 in 1.000 people)

- problems with sex drive
- feeling disorientated or confused trouble seeing or double vision
- swelling of the breasts in men

#### redness of the skin, red raised skin rash. Very rare (may affect up to 1 in 10.000 people)

- small red marks on the skin
- abnormal liver function including sudden liver failure and coma
- changes in test results including liver and blood tests this medicine. abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
  - Keep this medicine out of the sight and reach of children

# Not known (frequency cannot be estimated from the available

- dilated pupils
  - slow, fast or extra heart beats
  - a major fit ('grand mal convulsions')
  - believing things that are not true
  - severe stomach pain, often with feeling and being sick problems with the blood vessels of the brain (stroke, cerebral
  - arteritis or cerebral occlusion) inability to control the excretion of urine (incontinence)
  - spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
  - nosebleed

stuttering

very high fever

#### Effects on growth

When used for more than a year. Affenid may cause reduced growth in some children. This affects less than 1 in 10 children there may be lack of weight gain or height growth.

- vour 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 treatment with Affenid may be stopped for a short time.

#### Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/vellowcard 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

### 5. How to store Affenid

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Keep the bottle tightly closed in order to protect from moisture

#### The pack contains two small desiccant canisters. These are used 36 mg: Round, biconvex, white film-coated tablets of approximately 10 mm of diameter with a small hole in one side to keep the tablets dry and should not be eaten.

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 Affenid contains The active substance is methylphenidate hydrochloride

- Not all pack sizes may be marketed Affenid XL 18 mg prolonged release tablets contain 18 mg of Marketing Authorisation Holder methylphenidate hydrochloride
- Affenid XL 27 mg prolonged release tablets contain 27 mg of Zentiva Pharma UK Limited. 12 New Fetter Lane.
- l ondon FC4A 1.IP Affenid XL 36 mg prolonged release tablets contain 36 mg of methylphenidate hydrochloride. United Kinadom
- Affenid XL 54 mg prolonged release tablets contain 54 mg of Manufacturer: Laboratorios LICONSA S A

#### The other ingredients are

- Avda, Miralcampo, Nº 7, Polígono Industrial Miralcampo Tablet core: hypromellose, macrogol, succinic acid, magnesium 19200 Azugueca de Henares (Guadalaiara), Spain stearate, sodium chloride, silica colloidal anhydrous, black iron This leaflet was last revised in January 2023 oxide (E172).
- Film coating: cellullose acetate, macrogol
- Information for children and young people Clear coating: hypromellose, macrogol, phosphoric acid (for pH This info is to help you learn the main things about your medicine
- Colour coating: lactose monohydrate, hypromellose, triacetin. called Affenid XL. If you don't enjoy reading, someone like your titanium dioxide (E171), vellow iron oxide (E172) (18 mg), red iron mum. dad or carer (sometimes called 'your guardian') can read it oxide (E172) (18mg, 27mg, 54mg), black iron oxide (E172) (27mg).

## What Affenid looks like and contents of the pack

Affenid is available in four strengths: 18 mg, 27 mg, 36 mg and Fach tablet is a different colour to aid identification:

- 18 mg: Round, biconvex, vellow film-coated tablets of approximately 9 mm of diameter with a small hole in one side of
- 27 mg: Round, biconvex, grev film-coated tablets of approximately 9 mm of diameter with a small hole in one side of the tablet.

### While you are taking this medicine

- as well as taking this medicine you will also get help with ways
- this medicine should help you. But it does not cure ADHD.
- ups. This is to make sure the medicine is working and that you are growing and developing OK.
- stop your medicine to see if it is still needed. This will probably canisters are used to keep the tablets dry and should not be eaten happen in a school holiday Pack sizes are: 30 tablets, 60 tablets (2x30) or 90 tablets (3x30).
  - medicine worse.
  - contraception. Girls must tell their doctor straight away if they think they may be pregnant. We do not know how this medicine affects unborn babies.

### Some people cannot have this medicine

- You cannot have this medicine if: vou have a problem with your heart
- vou feel very unhappy, dépressed or have a mental illness.

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

- You need to talk to your doctor if:
- vou have epilepsy (fits) vou are pregnant or breastfeeding

How do I take my medicine?

vour medicine

Possible side effects

doctor first

vou are taking other medicines – your doctor needs to know about all the medicines you are taking.

do not stop taking the medicine without talking to your

trust straight away. They can then talk to your doctor.

The main things that could affect you are:

Side effects are the unwanted things that can happen when you

take a medicine. If any of the following happen, tell an adult you

#### to you and answer any questions. It may help if you read small bit swallow your medicine with water. vour doctor will tell you how many times a day you should take

- Why have I been given this medicine? This medicine can help children and young people with 'ADHD'.
- ADHD can make vou: run about too much

vourself. It is not your fault.

- not be able to pay attention
- act quickly without thinking about what will happen next It affects learning, making friends and how you think about

- to cope with your ADHD such as talking to ADHD specialists.
- having different moods than usual, not being able to get to sleep skin rashes, bruising easily, getting out of breath you will need to go to your doctor several times a year for check-the medicine can also make you feel sleepy. If you feel sleepy
- if you take the medicine for more than one year, your doctor ma
  - vour heart beating faster than usual. do not drink alcohol. Alcohol may make the side effects of this If you feel unwell in any way while you are taking your
  - medicine please tell an adult you trust straight away. if you are having sex, please talk to your doctor about Other things to remember

feeling worried or nervous

feeling dizzy, or getting head aches

- make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters the medicine is special 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 two tablets the
  - next time. Just take one tablet at the next normal time. if you do take too much medicine, tell your mum, dad or carer

being very depressed and unhappy or wanting to hurt yoursel

it is important **not to do outdoor sports** like riding a horse

or bike, swimming or climbing trees. You could hurt yourself

- it is important not to take too much medicine or you will get ill
- don't stop taking your medicine until your doctor says it's OK

### Who should I ask if there is anything I don't understand? Your mum. dad, carer, doctor, nurse or pharmacist will be able to

Other sources of information For information on large print, Braille or audio CD call emc accessibility on

1065035990

#### 54 mg: Round biconvex pink film-coated tablets of approximately 10 mm of diameter with a small hole in one side

The medicinal product is available in a plastic bottle includin

2 desiccant canisters with a child resistant cap. The desiccar