

## Package Leaflet: Information for the user

### Affenid XL 18 mg prolonged release tablets

### Affenid XL 27 mg prolonged release tablets

### Affenid XL 36 mg prolonged release tablets

### Affenid XL 54 mg prolonged release tablets

methylphenidate hydrochloride

The name of your medicine is Affenid XL 18, 27, 36 or 54 mg prolonged release tablets (referred to as Affenid throughout this leaflet), it contains the active substance methylphenidate hydrochloride. The name 'methylphenidate' will also be used in this leaflet.

**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 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.
- You are taking any other medicines - this is because methylphenidate 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.
- Your doctor may stop your medicine to see if it is still needed, if 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 medicine.**

- 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 '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.

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 methylphenidate can affect how other medicines work.

Read Section 2 for more 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' (ADHD):

- 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 usually includes:

- psychological
- educational and
- social therapy.

It 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.

### About ADHD

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 in other places.

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.

Not all patients with ADHD need to be treated with medicine. ADHD does not affect intelligence.

## 2. What you need to know before you take Affenid

### Do not take Affenid if you:

- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- have a thyroid problem
- have increased pressure in your eye (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma)
- have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words

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

**How to take Affenid**

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Not all patients with ADHD need to be treated with medicine. ADHD does not affect intelligence.

- have a narrowing or blockage of your gut or food-pipe
- pregnant or think you may be pregnant. Your doctor will decide whether you should take methylphenidate.

**any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:**

- any other medical problems (such as heart problems) you or your family may have
- abnormal brain scans (EEGs)

**Use in children aged 6 years and over**

- the recommended starting dose of Affenid is 18 mg once daily for children who are not currently taking methylphenidate, or for children who are switching from another stimulant to methylphenidate.

**Driving and using machines**

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

**Use in adults**

- the maximum daily dose in adults is 72 mg.

**For adults who have taken Affenid before:**

- if you have already taken Affenid as a child or adolescent, the same daily dosage (mg/day) can be used; your doctor

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

There is further information for patients who are intending to drive in Great Britain - go to <https://www.gov.uk/drug-driving-law>.

**Having an operation**

Tell your doctor if you are going to have an operation. You should not take methylphenidate 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

**If you do not feel better after 1 month of treatment**

**Other medicines and Affenid**

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

**Drug testing**

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

## 3. How to take Affenid

If Affenid is not used properly, this may cause abnormal behaviour. It may also mean that you start to depend on the medicine affects you.

**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.

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 necessary.

**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.

**Signs of overdose**

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

- have liver or kidney problems

**Check that your doctor will make before you start taking Affenid**

The tablet should be swallowed whole and not chewed, broken, or crushed. The tablet may be taken with or

without food.

The tablet does not dissolve completely after all of the drug

- have a narrowing or blockage of your gut or food-pipe
- pregnant or think you may be pregnant. Your doctor will decide whether you should take methylphenidate.

**any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:**

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**Available data do not suggest an increased risk of overall birth defects, whilst a small increase in the risk of malformations of**

**the heart when used during the first three months of pregnancy**

**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 methylphenidate if you are:**

- having sex. Your doctor will discuss contraception with you

**Signs of overdose**

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

- any other medicines you are taking

changes in heart beat (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 of benefit.

- after you start - they will be done at least every 6 months, but possibly more often. They will also be done when 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 Affenid.

**Long-term treatment**  
Affenid does not need to be taken for ever. If you take Affenid for more than a year, your doctor should stop treatment for a short time, this may happen during a school holiday. This will show if the medicine is still needed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Although some people get side effects, most people find that methylphenidate 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 signs of psychosis
- 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)
- after you start - they will be done at least every 6 months, but possibly more often. They will also be done when the dose is changed.

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

- heart attack
- sudden death
- suicidal attempt
- fits (seizures, convulsions epilepsy)
- skin peeling or purplish red patches
- inflammation or blocked arteries in the brain
- temporary paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain)
- muscle spasms which you cannot control affecting your eyes, head, 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

#### Long-term treatment

Affenid does not need to be taken for ever. If you take Affenid for more than a year, your doctor should stop treatment for a short time, this may happen during a school holiday. This will show if the medicine is still needed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

• prolonged erections, sometimes painful or an increased number of erections.

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)

- headache
- feeling nervous
- not being able to sleep.

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

- joint pain
- blurred vision
- tension headache
- dry mouth, thirst
- trouble falling asleep
- high temperature (fever)
- decreased sex drive
- unusual hair loss or thinning
- muscle tightness, muscle cramps

#### 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
- obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions)).

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

- loss of appetite or decreased appetite
- inability to develop or maintain an erection
- itching, rash or raised red itchy rashes (hives)
- feeling unusually sleepy or drowsy, feeling tired
- excessive teeth grinding (bruxism)
- feeling of panic
- tingling feeling, prickling, or numbness of the skin
- increased alanine aminotransferase (liver enzyme) level in your blood
- cough, sore throat or nose and throat irritation; upper respiratory tract infection; sinus infection
- high blood pressure, fast heart beat (tachycardia)
- dizziness (vertigo), feeling weak, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour
- upset stomach or indigestion, stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick.

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

- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- weight decreased.

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

- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)

The medicinal product is available in a plastic bottle including 2 desiccant canisters with a child resistant cap. The desiccant canisters are used to keep the tablets dry and should not be eaten.

Pack sizes are: 30 tablets, 60 tablets (2x30) or 90 tablets (3x30). Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

Zentiva Pharma UK Limited,  
12 New Fetter Lane,  
London, EC4A 1JP,  
United Kingdom

#### Some people cannot have this medicine

You cannot have this medicine if:

- you have a problem with your heart
- you feel very unhappy, depressed or have a mental illness.

#### Other things to remember

- 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.

#### Effects on growth

When used for more than a year, methylphenidate 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.

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

You need to talk to your doctor if:

- you have epilepsy (fits)
- Film coating: cellulose acetate, macrogol.

**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.

#### Reporting of side effects

This info is to help you learn the main things about your medicine called Affenid XL. 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.

#### How do I take my medicine?

- swallow your medicine with water.
- your doctor will tell you how many times a day you should take your medicine

• do not stop taking the medicine without talking to your doctor first.

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

The main things that could affect you are:

- 18 mg: Round, biconvex, yellow film-coated tablets of approximately 9 mm of diameter with a small hole in one side of the tablet.
- 27 mg: Round, biconvex, grey 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 to cope with your ADHD such as talking to ADHD specialists.

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

The medicinal product is available in a plastic bottle including 2 desiccant canisters with a child resistant cap. The desiccant canisters are used to keep the tablets dry and should not be eaten.

- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)

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

- Affenid XL 18 mg prolonged release tablets contain 18 mg of methylphenidate hydrochloride.

- Affenid XL 27 mg prolonged release tablets contain 27 mg of methylphenidate hydrochloride.

- Affenid XL 36 mg prolonged release tablets contain 36 mg of methylphenidate hydrochloride.

- Affenid XL 54 mg prolonged release tablets contain 54 mg of methylphenidate hydrochloride.

##### Manufacturer:

Laboratorios LICONSA, S.A.  
Avda. Miralcampo, N° 7, Polígono Industrial Miralcampo

19200 Azuqueca de Henares (Guadalajara), Spain

##### This leaflet was last revised in October 2025

#### Information for children and young people

This info is to help you learn the main things about your medicine called Affenid XL. 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.

#### 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/yellowcard](http://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.

#### How do I take my medicine?

- swallow your medicine with water.

• your doctor will tell you how many times a day you should take your medicine

• do not stop taking the medicine without talking to your doctor first.

#### Other sources of information

#### For information on large print, Braille or audio CD call emc accessibility on 0800 198 5000

#### What Affenid looks like and contents of the pack

Affenid is available in four strengths: 18 mg, 27 mg, 36 mg and 54 mg.

Each tablet is a different colour to aid identification:

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

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

#### Why have I been given this medicine?

This medicine can help children and young people with 'ADHD'.

#### ADHD can make you:

- run about too much

- not be able to pay attention

- act quickly without thinking about what will happen next (impulsive).

- affects learning, making friends and how you think about yourself. It is not your fault.

#### Feeling worried or nervous

#### Feeling dizzy, or getting head aches

#### Dilated pupils

#### Excessive sweating

#### Increased pressure in the eye

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 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 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.

5. How to store Affenid

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

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