

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S6

ACERTA 18, ACERTA 27, ACERTA 36 and ACERTA 54

Prolonged Release Tablets

Methylphenidate hydrochloride

ACERTA 18 contains 183,8 mg lactose (as monohydrate).

ACERTA 27 contains 184,5 mg lactose (as monohydrate).

ACERTA 36 contains 178,1 mg lactose (as monohydrate).

ACERTA 54 contains 165,3 mg lactose (as monohydrate).

Read all of this leaflet carefully before you start taking ACERTA:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- ACERTA 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 ACERTA IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACERTA
3. HOW TO TAKE ACERTA
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE ACERTA
6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT ACERTA IS AND WHAT IT IS USED FOR:

ACERTA improves the activity of certain parts of the brain which are underactive. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour. Although there is no cure for ADHD, it can be managed using treatment programmes.

ACERTA is used to treat attention deficit hyperactivity disorder (ADHD).

- it is used in children and young people between the ages of 6 and 17.
- it is used only after trying treatments which do not involve medicines. Such as counselling and behavioral therapy.
- it is used in adults aged 18 to 65 years who meet specific criteria for attention deficit hyperactivity disorder.

ACERTA is not for use as a treatment for ADHD in children under 6 years of age or for the initiation of treatment in adults. When treatment was started at a younger age, it might be appropriate to continue taking ACERTA when you become an adult.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACERTA:

Do not take ACERTA:

- if you are hypersensitive to methylphenidate or any of the other ingredients of ACERTA (listed in **section 6**)
- if you have increased pressure in your eye (glaucoma)
- if you have a tumour of your adrenal gland (phaeochromocytoma)
- if you are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) - see **Other medicines and ACERTA**
- if you have a thyroid problem
- if you have an eating problem when you do not feel hungry or want to eat - such as anorexia nervosa
- if you have mental health problems such as:
 - a psychopathic or borderline personality problem
 - abnormal thoughts or visions or an illness called schizophrenia
 - signs of a severe mood problem like:
 - feeling like killing yourself

- severe depression, where you feel very sad, worthless, and hopeless
- mania, where you feel unusually excitable, over-active, and uninhibited
- if you have marked anxiety, tension, and agitation. ACERTA may aggravate these symptoms
- if you have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- if 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
- if you 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 the blood vessels (vasculitis)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions:

Tell your doctor before taking ACERTA if:

- you are a girl and have started your periods (see the **Pregnancy, breastfeeding, and fertility** section below)
- you have high blood pressure
- you have a heart problem which is not in the **Do not take** section above
- you have hard to control, repeated twitching of any parts of the body or you repeat sounds and words
- you notice the patient is not gaining weight or height as they are expected to
- you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- you have ever abused or been dependent on alcohol, prescription medicines or street drugs
- you have liver or kidney problems
- you have a narrowing or blockage of your gut or food pipe
- you have a problem with swallowing or swallowing whole tablets
- you have a mental health problem which is not in the **Do not take** section above
- you have other mental health problems which include:
 - mood swings (from being manic to being depressed - called bipolar disorder)
 - feeling aggressive or hostile
 - 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 apply to you before starting treatment. This is because ACERTA can make these problems worse. Your doctor will want to monitor how the medicine affects you.

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.

Children and adolescents:

ACERTA is not for use in children younger than 6 years.

Other medicines and ACERTA:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take ACERTA 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 a MAOI with ACERTA may cause a sudden increase in your blood pressure.

Tell your doctor or pharmacist if you are taking any of the following medicines for depression or anxiety:

- tricyclic antidepressant
- selective serotonin reuptake inhibitor (SSRI)
- serotonin and norepinephrine reuptake inhibitor (SNRI).

Taking ACERTA with these types of medicine could cause a life-threatening increase of serotonin in the brain (serotonin syndrome), which may lead to feeling confused or restless, sweating, shivering,

muscle jerks or fast heartbeat. If you develop these side effects, see a doctor straight away.

ACERTA may affect how well other medicines work or may cause side effects. If you are taking any of the following medicines, check with your doctor or pharmacist before taking ACERTA:

- medicines for severe mental health problems
- medicines for epilepsy
- medicines that thin the blood to prevent blood clots
- 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 for Parkinson's disease (such as levodopa).

Having an operation:

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

Drug testing:

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

ACERTA with food and alcohol:

ACERTA can be taken with or without food.

Alcohol should be avoided when taking ACERTA.

Pregnancy, breastfeeding, and fertility:

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 ACERTA.

You should not take ACERTA if you are pregnant or breastfeeding your baby.

Driving and using machines:

You may feel dizzy, have problems focusing or have blurred vision when taking ACERTA. If these

happen it may be dangerous to do things such as drive, use machines, ride a bike or horse, or climb trees.

It is not always possible to predict to what extent ACERTA may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which ACERTA affects you.

ACERTA contains lactose (as monohydrate):

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ACERTA.

3. HOW TO TAKE ACERTA:

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

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

Adults:

- Your doctor will usually start treatment with a low dose and increase it gradually as required.
- The maximum daily dose is 54 mg for children aged 6 to 12 years and maximum of 72 mg for adolescents aged between 13 to 18 years and 108 mg in adults.
- You should take ACERTA once each day in the morning with a glass of water.

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 medicine has been released and sometimes the tablet shell may appear in your stools. This is normal.

Your doctor will tell you how long your treatment with ACERTA will last. If you have the impression that the effect of ACERTA is too strong or too weak, tell your doctor or pharmacist.

Some tests your doctor will do when you are on treatment:

- before you start - to make sure that ACERTA 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 ACERTA.

ACERTA does not need to be taken forever. If you take ACERTA 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 take more ACERTA than you should:

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

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 beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

If you forget to take ACERTA:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ACERTA:

If you suddenly stop taking ACERTA, 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 ACERTA.

4. POSSIBLE SIDE EFFECTS:

ACERTA can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACERTA, please consult your doctor, pharmacist, or other healthcare provider for advice.

If any of the following happens, stop taking ACERTA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- irregular, fast, or uneven heartbeat (palpitations).

Less frequent side effects:

- if you experience an increase in infections, and start to bleed and bruise more easily, these may be due to a decrease in number of blood cells (red cells, white cells, and platelets). Your doctor may need to perform blood tests
- seeing, feeling, or hearing things that are not real, these are signs of psychosis
- mood changes or mood swings or changes in personality
- thinking about or feeling like killing yourself
- uncontrolled speech and body movements (Tourette's)
- suicidal attempt
- fits (seizures, convulsions epilepsy)
- a sudden increase in body temperature, very high blood pressure and severe convulsions

(Neuroleptic Malignant Syndrome). It is not certain that this side effect is caused by ACERTA or other medicines that may be taken in combination with ACERTA

- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- heart attack
- 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
- severe headaches, forgetfulness or confusion, disorientation, numbness, weakness, difficulty with comprehension (these can be signs of inflammation or blocked arteries in the brain)
- inflammation or blocked arteries in the brain
- skin peeling or purplish red patches.

Unknown frequency:

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

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- cough, sore throat or nose and throat irritation; upper respiratory tract infection; sinus infection
- loss of appetite or decreased appetite
- reduced weight and height gain
- not being able to sleep
- feeling nervous
- feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour
- decreased sex drive
- tense, clenching or grinding your teeth, feeling of panic
- headache, dizziness, involuntary movement
- sleepiness, tension headache
- tingling feeling, prickling, or numbness of the skin

- inability of the eyes to automatically change focus from seeing at a distance to seeing at near
- spinning dizziness
- high blood pressure
- difficulty or pain with swallowing
- upset stomach or indigestion, stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick, dry mouth
- increased alanine aminotransferase (liver enzyme) level in your blood (seen in a blood test)
- hair loss, hives
- joint pain
- muscle tightness, muscle cramps
- inability to develop or maintain an erection
- high temperature (fever)
- lack of weight gain or height growth
- feeling tired
- changes in blood pressure or heart rate
- decreased weight.

Less frequent side effects:

- skin peeling
- anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping
- state of abnormally elevated arousal, affect, and energy
- shaking, lack of energy
- abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- blurred vision
- dry eyes
- trouble seeing or double vision
- feeling hot
- fingers and toes feeling numb, tingling, and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon)

- shortness of breath
- constipation
- increased liver test results (seen in a blood test)
- abnormal liver function including liver failure and coma.
- excessive sweating, redness of the skin, red raised skin rash
- muscle pain, muscle twitching
- blood in the urine
- increased need to pass urine
- swelling of the breasts in men
- heart murmur
- decreased platelet count and white blood cell count (seen in a blood test).

Side effects with unknown frequency:

- believing things that are not true
- addiction or abuse
- diseases and disorders that affect the blood vessels and blood supply to the brain, including inflammation of the blood vessels, stroke, brain bleeding, brain damage
- a major fit (grand mal convulsions)
- migraine
- dilated pupils
- slow, fast, or extra heart beats.

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, pharmacist or nurse. 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 ACERTA.

5. HOW TO STORE ACERTA:

Store all medicine out of reach of children.

Store at or below 30 °C.

Store in the original packaging until required for use.

Keep the container tightly closed.

Do not use the tablets after the expiry date shown on the container.

Return the expired medicine to your pharmacist for safe disposal.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What ACERTA contains:

The active ingredient is methylphenidate hydrochloride.

Tablet content:

The other ingredients are fumaric acid, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid-methyl methacrylate copolymer, silica colloidal anhydrous, triethyl citrate, talc.

Tablet coating:

- 18 mg prolonged release tablets:
Iron oxide red (E172), iron oxide yellow (E172), polyvinyl alcohol - part hydrolysed, macrogol (3350), talc, titanium dioxide (E171).
- 27 mg prolonged release tablets:
Indigo carmine aluminium lake (E132), iron oxide black (E172), iron oxide yellow (E172), polyvinyl alcohol - part hydrolysed, macrogol (3350), talc, titanium dioxide (E171).
- 36 mg prolonged release tablets:
Macrogol (3350), polyvinyl alcohol - part hydrolysed, talc, titanium dioxide (E171).
- 54 mg prolonged release tablets:
Iron oxide red (E172), macrogol (3350), polyvinyl alcohol - part hydrolysed, talc, titanium dioxide (E171).

Printing ink:

Iron oxide black (E172), isopropyl alcohol, shellac glaze.

What ACERTA looks like and contents of the pack:

ACERTA 18: Capsule shaped, biconvex, yellow tablet, with '2392' printed on one side in black ink.

ACERTA 27: Capsule shaped, biconvex, grey tablet, with '2393' printed on one side in black ink.

ACERTA 36: Capsule shaped, biconvex, white tablet with '2394' printed on one side in black ink.

ACERTA 54: Capsule shaped, biconvex, red-brown tablet with '2395' printed on one side in black ink.

The tablets are packaged in white, round HDPE containers closed with child resistant polypropylene closure with gel desiccant integrated in the cap.

Pack sizes:

18 mg tablets: 28, 30 or 90 prolonged release tablets

27 mg tablets: 28, 30 or 100 prolonged release tablets

36 mg tablets: 28, 30 or 100 prolonged release tablets

54 mg tablets: 28, 30 or 100 prolonged release tablets

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

2090

Tel: +27 11 055 0200

This leaflet was last revised in:

28 October 2024

REGISTRATION NUMBER:

ACERTA 18: 51/1.2/0285

ACERTA 27: 51/1.2/0286

ACERTA 36: 51/1.2/0287

ACERTA 54: 51/1.2/0288