SCHEDULING STATUS

Schedule 6

CONCERTA® 18 mg (extended-release tablets)

CONCERTA® 27 mg (extended-release tablets)

CONCERTA® 36 mg (extended-release tablets)

CONCERTA® 54 mg (extended-release tablets)

Methylphenidate hydrochloride

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking CONCERTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CONCERTA 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 CONCERTA is and what it is used for
2. What you need to know before you use CONCERTA
3. How to use CONCERTA
4. Possible side effects
5. How to store CONCERTA
6. Contents of the pack and other information

1. What CONCERTA is and what it is used for

CONCERTA is used for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6-17 and adults aged 18-65.

2. What you need to know before you use CONCERTA

Do not take CONCERTA:

- If you are hypersensitive (allergic) to methylphenidate or any of the other ingredients in CONCERTA (see What CONCERTA Contains).
- If you have glaucoma, an eye disease.
- If you are being treated or have recently been treated with monoamine oxidase (MAO) inhibitor medicines.
- If you have hereditary problems of galactose intolerance (Lapp lactase deficiency of glucose-galactose malabsorption)
- If you have hyperthyroidism (an overactive thyroid), severe angina (chest pain) or heart rhythm problems.

Warnings and precautions

Take special care with CONCERTA if you

Talk to your doctor *before* or while taking CONCERTA if you:

- Have a heart defect.
- Have tics (movements or sounds that you cannot control) or Tourette's syndrome, or if someone in your family has tics or Tourette's syndrome.

- Have eye problems, such as:
    - Increased pressure in the eye
    - A condition called “glaucoma”
    - Far-sightedness (difficulty seeing near objects)
- Have serious mental health problems, such as:
    - Believing things that are not true (delusions)
    - Seeing, feeling, hearing, or smelling things that are not there (hallucinations)
    - Being very over-active or over-excited
- Become aggressive, anxious or agitated or feel more aggressive, anxious or agitated than usual.
- Problems with blood vessels in the brain (such as inflamed blood vessels, stroke caused by a burst blood vessel or blocked blood supply to the brain).
- develop a persistent and painful erection of the penis.
- Develop severe headaches, weakness, or paralysis of any body part, or develop problems with coordination, vision, speaking, finding words or with your memory.
- have a history of drug dependence or alcoholism.
- have a narrowing or blockage of the gut, foodpipe (or oesophagus), stomach, or intestines).
- Are not growing as expected for your age. Your doctor may carefully watch your height and weight.
- Have high blood pressure.

- Have kidney or liver problems.
- have glaucoma, an eye disease.

If you develop any of the above conditions or symptoms while taking CONCERTA, tell your doctor immediately.

Sport

The active ingredient in CONCERTA may show up as a drug if drug testing is performed.

Other medicines and CONCERTA

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

- You should not use CONCERTA if you are treated or have been treated with (currently or within the previous 2 weeks) MAO inhibitors (see Do Not Take CONCERTA).
- CONCERTA should be used cautiously with vasopressor agents, a type of medicine that is used to increase your blood pressure.
- Tell your doctor if you take clonidine, a medicine used to treat high blood pressure
- Make sure your doctor knows if you take a type of medicine for depression or anxiety called a 'serotonin reuptake inhibitor' (SSRI) or a serotonin and norepinephrine reuptake inhibitor' (SNRI).

CONCERTA with food, drink and alcohol

CONCERTA may be taken with or without food.

Pregnancy and breastfeeding

You should not take CONCERTA if you are pregnant or breastfeeding 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 health care provider for advice before taking CONCERTA.

Driving and using machines

CONCERTA may cause dizziness and could affect your ability to drive. You are therefore advised to use caution when driving, operating machinery, or doing activities that may be hazardous.

It is not always possible to predict to what extent CONCERTA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CONCERTA affects them.

CONCERTA contains lactose

CONCERTA contains lactose (a type of sugar) which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take CONCERTA.

3. How to take CONCERTA

Do not share medicines prescribed for you with any other person

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

Your doctor will tell you how long your treatment with CONCERTA will last. Do not stop treatment early because your symptoms may reappear. If you have the

impression that the effect of CONCERTA is too strong or too weak, tell your doctor or pharmacist.

Take CONCERTA once each day in the morning. CONCERTA may be taken before or after eating.

Swallow CONCERTA tablets whole with water or other liquids. Do not chew, crush or break the tablets.

Take the dose prescribed by your doctor. The doctor may adjust the amount of medicine you take until it is right for you.

If you take more CONCERTA than you should

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

If you forget to take CONCERTA

Do not take a double dose to make up for forgotten individual doses. Consult a health care professional if you have questions.

If you stop taking CONCERTA

Do not stop taking CONCERTA early without your doctor's advice because symptoms may reappear.

4. Possible 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 CONCERTA, please consult your doctor, pharmacist or other healthcare professional for advice.

Some side-effects could be serious. If you or your child has any of the side effects below, see a doctor straight away:

Frequent side effects:

- Uneven heartbeat (palpitations)
- Mood changes or mood swings or changes in personality

Less frequent side effects:

- 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
- Feeling unusually excited, over-active and un-inhibited (mania)
- Heart attack
- Sudden death
- Suicidal attempt
- Fits (seizures, convulsion, epilepsy)
- Skin peeling or purplish red patches
- Inflammation or blocked arteries in the brain
- Muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system due to a temporary lack of blood supply to the brain
- 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
- 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 CONCERTA or other medicines that may be taken in combination with CONCERTA

- Unwanted thoughts that keep coming back
- Unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- Paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with blood vessels in your brain)

If you or your child has 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:

Frequent:

- Headache
- Feeling nervous
- Not being able to sleep
- Joint pain
- Blurred vision
- Tension headache
- Dry mouth, thirst
- Trouble falling asleep
- High temperature (fever)
- Problems with sex drive
- Unusual hair loss or thinning
- Muscle tightness, muscle cramps
- 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
- Clenching or grinding your teeth, 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

Less frequent

- Dry eye
- Constipation
- Chest discomfort
- Blood in the urine
- Listlessness
- Shaking or trembling
- Increased need to pass urine
- Muscle pain, muscle twitching
- Persistent and painful erection of the penis
- Shortness of breath or chest pain
- Feeling hot
- Increased in liver test results (seen in a blood test)

- Anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping
- Feeling disorientated or confused
- Trouble seeing or double vision
- Swelling of the breasts in men
- Excessive sweating, redness of the skin, red raised skin rash
- Muscle cramps
- Small red marks on the skin
- Abnormal liver function including liver failure and coma
- Changes in test results – including liver and blood tests
- Abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- Fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud phenomenon)
- Liver damage
- Sudden liver failure
- Migraine
- Dilated pupils
- Very high fever
- 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
- Nosebleeds

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get 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 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 CONCERTA.

5. How to store CONCERTA

Store at or below 25 °C.

Do not use the tablets after the expiry date printed on the label.

The desiccant in the pack (one or two pouches), used to keep the tablets dry, should not be eaten.

Return all unused medicine to your pharmacist.

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

Store all medicines out of reach of children.

6. Contents of the pack and other information

CONCERTA is available in a square, white, opaque high-density polyethylene (HDPE) bottle with a white polypropylene child resistant closure, with induction sealed tamper-evident membrane.

Each HDPE bottle contains one or two desiccants and will hold 30 tablets. The HDPE bottle is packed into an outer carton until required for use.

What CONCERTA contains

The active ingredient in CONCERTA is methylphenidate hydrochloride.

Each CONCERTA 18 mg tablet contains 6.49 mg lactose monohydrate

Each CONCERTA 27 mg tablet contains 4.94 mg lactose monohydrate

Each CONCERTA 36 mg tablet contains 14.44 mg lactose monohydrate

Each CONCERTA 54 mg tablet contains 7,6 mg lactose monohydrate

Other ingredients:

- Other inactive ingredients include butylated hydroxytoluene, carnauba wax, cellulose acetate, hypromellose, lactose, poloxamer, polyethylene glycol, polyethylene oxides, povidone, propylene glycol, sodium chloride, stearic acid, succinic acid, synthetic iron oxides, titanium dioxide, and triacetin.

What CONCERTA looks like and contents of the pack

CONCERTA is available in the following strengths:

- 18 mg: Capsule-shaped yellow tablet with “alza 18” printed on one side in black ink
- 27 mg: Capsule-shaped gray tablet with “alza 27” printed on one side in black ink
- 36 mg: Capsule-shaped white tablet with “alza 36” printed on one side in black ink
- 54 mg: Capsule-shaped brownish-red tablet with “alza 54” printed on one side in black ink

Each HDPE bottle contains one or two dessicants, and will hold 30 tablets. The HDPE bottle is packed into an outer carton until required for use.

Holder of Certificate of Registration

JANSSEN PHARMACEUTICA (PTY) LTD

(Reg.No. 1980/011122/07)

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27 mg:10/1.2/0500
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54 mg: 06/1.2/0030
NS 4

Botswana Reg. No.:18/27/36/54mg:
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S6

Zimbabwe Reg. No.:18/27/37/54 mg
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