PROPOSED PATIENT INFORMATION LEAFLET FOR PHENITAB

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

PHENITAB 18, 27, 36 and 54 mg Extended release tablets

Methylphenidate hydrochloride

PHENITAB 18 contains sugar (lactose monohydrate, 40 mg)

PHENITAB 27 contains sugar (lactose monohydrate, 40 mg)

PHENITAB 36 contains sugar (lactose monohydrate, 40 mg)

PHENITAB 54 mg contains sugar (lactose monohydrate, 40 mg)

Read all of this leaflet carefully before you start taking PHENITAB

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PHENITAB 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 PHENITAB is and what it is used for

2. What you need to know before you take PHENITAB

3. How to take PHENITAB

4. Possible side effects

5. How to store PHENITAB

6. Contents of the pack and other information

1. What PHENITAB is and what it is used for

The active ingredient in PHENITAB is methylphenidate.

PHENITAB is used to treat ‘attention deficit hyperactivity disorder’ (ADHD).

- it is used in children and young people between the ages of 6 and 17 and adults between the ages of 18 and 65 who meet specific criteria.

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

Your doctor will advise you about this.

2. What you need to know before you take PHENITAB

Do not take PHENITAB

- If you are allergic to methylphenidate or any of the other ingredients in PHENITAB (see section 6).
- If you have significant anxiety, tension, and agitation because PHENITAB may make these symptoms worse.
- If you have glaucoma, an eye disease.
- If you have tics or Tourette's syndrome, or there is a family history of Tourette's syndrome.
- If you are being treated or have recently been treated with monoamine oxidase (MAO) inhibitor medicines (see **Other medicines and PHENITAB**)
- If you have a tumour of your adrenal gland (phaeochromocytoma)
- If you have hyperthyroidism (an overactive thyroid) or other thyroid problems,
- 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 such as feeling like killing yourself, severe depression, where you feel very sad, worthless and hopeless or mania, where you feel unusually excitable, over-active, and uninhibited
- If you have been diagnosed with Bipolar disorder and the symptoms are not

properly controlled

- 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 are pregnant or breastfeeding (see **Pregnancy and lactation**)

Warnings and Precautions

Tell your doctor or healthcare provider before taking PHENITAB if you:

- Have heart problems which is not in the **Do not take** section above.
- Have high blood pressure
- Have had a problem with the blood vessels in your brain - such as inflammation of the blood vessels (vasculitis)
- Have mental health problems or been diagnosed with psychosis such as:
  - a ‘psychopathic’ or ‘borderline personality’ problem
  - abnormal thoughts or visions
  - aggressive behaviour
  - signs of a severe mood problem like thought of killing yourself,
  - severe depression, where you feel very sad, worthless and hopeless or mania, where you feel unusually excitable, over-active, and un-inhibited.
- Have someone in your family with motion tics, verbal tics (hard-to-control, repeated twitching of any parts of the body or repeat sounds and words), or Tourette’s syndrome
- Have anxiety, agitation or tension
- Have bipolar disorder
- Have reduced weight gain and/or height. Your doctor may carefully watch your height and weight

- Have had seizures (convulsions, epilepsy) or abnormal brain scans (EEGs - electroencephalograms)
- Have a history of drug dependence or alcoholism
- Have kidney or liver problems
- Have a problem with swallowing or swallowing whole tablets or have a narrowing or blockage of the gastrointestinal tract (oesophagus, stomach, or small or large intestine).
- Have blurred vision.

If any of the above apply to you, tell your doctor or healthcare provider before starting treatment. This is because PHENITAB can make these problems worse. Your doctor will want to monitor how the medicine affects you.

Take special care with PHENITAB

During treatment, boys and adolescents may unexpectedly experience extended 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

PHENITAB should not be used in patients under six years old.
If your child is not growing or gaining height or weight as expected, PHENITAB treatment may need to be interrupted. Children and adolescents on long-term treatment (longer than 12 months) will have their weight and growth monitored by the doctor.

Other medicines and PHENITAB

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

Do not take PHENITAB if you:

- have taken an MAOI in the last 14 days (see **Do not take PHENITAB**). Taking an MAOI with PHENITAB may cause a sudden increase in your blood pressure.
- are taking serotonergic medicine. Taking PHENITAB with these type of medicines 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.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines to prevent blood clots (anticoagulants such a warfarin)
- medicines to prevent seizures (phenobarbital, phenytoin, primidone)
- medicines used to treat depression (tricyclics and selective serotonin reuptake inhibitors)
- medicine used to treat high blood pressure (clonidine)
- vasopressor medicines used to increase blood pressure.
- medicine that reduces the acidity of urine (urinary alkalisers).

Having an operation

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

The active ingredient in PHENITAB, methylphenidate, may show up as a drug if drug testing is performed.

PHENITAB with food, drink and alcohol

PHENITAB may be taken with or without food.

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

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 healthcare provider for advice before taking this medicine.

PHENITAB should not be used in pregnancy and breastfeeding as safety has not been established (see **Do not take PHENITAB**).

Driving and using machines

PHENITAB can cause dizziness, drowsiness and visual disturbances such as blurred vision. Do not drive, operate machinery, or do activities that may be hazardous until you know how this medicine affects you.

It is not always possible to predict to what extent PHENITAB 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 PHENITAB affects them.

PHENITAB contains sugar (lactose monohydrate) and salt (sodium)

PHENITAB contains lactose anhydrous. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

PHENITAB contains less than 23 mg sodium per tablet, that is to say essentially ‘sodium-free’.

3. How to take PHENITAB

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

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

PHENITAB should not be used in children under the age of 6 years.

Take PHENITAB once each day in the morning.

PHENITAB may be taken before or after eating.

Swallow PHENITAB 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.

The maximum daily dosage of PHENITAB is 54 mg in children aged 6 to 12 years, 72 mg in adolescents aged 13 to 18 years and 108 mg in adults.

The usual dose is:

Patients new to PHENITAB:

The recommended starting dose of PHENITAB for patients who are not currently taking PHENITAB is 18 mg once daily for children, and adolescents, and 18 or 36 mg once daily for adults.

Patients currently taking another medicine containing Methylphenidate hydrochloride, twice or three times daily:

If you are changing from your current ADHD medicine (that you take two or three times a day) to PHENITAB, your doctor will prescribe a starting dose suitable to you and gradually increase the dose if required.

Long-term treatment:

If you are undergoing long-term treatment (longer than 12 months), your doctor will discontinue your treatment from time to time to monitor your progress.

Your doctor will tell you how long your treatment with PHENITAB will last. Do not stop treatment early because the ADHD symptoms may come back or unwanted effects such as depression may appear.

If you have the impression that the effect of PHENITAB is too strong or too weak, talk to your doctor or pharmacist.

If you take more PHENITAB than you should

Signs of overdose may include vomiting (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 heartbeat (slow, fast, or uneven), high blood pressure, dilated pupils and dry nose and mouth.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take a dose of PHENITAB

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 PHENITAB

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 PHENITAB.

4. POSSIBLE SIDE EFFECTS

PHENITAB can cause side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, 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 PHENITAB. 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:

- A decrease or change 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
- Mood changes or mood swings or changes in personality, uncontrolled speech and body movements (Tourette's), psychotic disorders, thinking about or feeling like killing yourself, suicide attempt, unwanted thoughts that keep coming back, seeing, feeling, or hearing things that are not real, these are signs of psychosis, feeling unusually excited, over-active and un-inhibited (mania)
- Stroke which lasts more than 24 hours and settles within a week, 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 methylphenidate or other drugs that may be taken in combination with methylphenidate.

- Inflammation or blocked arteries in the brain, bleeding 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)
- Fits (seizures, convulsions epilepsy), muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system
- Heart disorders (e.g. changes in the way your heart beats, chest pain or discomfort, fast or slow irregular heartbeat, heart attack),
- Chest pain spreading to the arms, neck, jaw, back or stomach, feeling sweaty, and breathless, feeling sick or vomiting (which may be symptoms of a heart attack / myocardial infarction)
- Difficulty breathing
- Abnormal liver function including sudden liver failure and coma, injury to liver cells
- Skin peeling or purplish red patches, severe inflammation of the skin,
- Sound of blood flowing through the heart (cardiac murmur)

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
- Anorexia, decreased appetite, reduced weight and height gain in children when used for long periods
- Inability to sleep (insomnia), trouble falling asleep, feeling nervous, feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and

abnormal behaviour, decreased sex drive, excessive teeth grinding (bruxism), feeling panic

- Headache, dizziness, feeling weak, movements which you cannot control, being unusually active, tingling feeling, prickling, or numbness of the skin, tension headache
- Trouble focussing
- Spinning sensation (vertigo)
- High blood pressure
- Cough, sore throat
- Upper abdominal pain, diarrhoea, nausea (feeling sick), abdominal discomfort, vomiting (being sick), dry mouth, indigestion
- Itching, rash or raised red itchy rashes (hives)
- Muscle tightness, muscle spasms,
- Inability to develop or maintain an erection
- High temperature (fever), feeling unusually sleepy or drowsy, feeling tired, feeling jumpy, feeling thirsty
- Changes in blood pressure and heart rate (usually an increase), weight decreased, increased alanine aminotransferase (liver enzyme) level in your blood.
- Growth retardation with prolonged use in children.

Less frequent side effects:

- Anger, feeling restless or sad (tearful), increased alertness, trouble sleeping, trouble with sex drive, confused, transient depressed moods, feeling indifferent or lacking emotion, repetitive behaviour (doing things over and over again), being obsessed with one thing (over-focussing)
- Sedation, shaking, lack of energy and enthusiasm
- Blurred vision, dry eyes, difficulty focussing

- Hot flushes, inflammation or blockage of blood vessels, called arteries, in and around the scalp, coldness of your hands and feet
- Constipation
- Increase in liver enzymes when your blood is tested
- Redness of the skin, red raised skin rash, increased sweating,
- Muscle cramps
- Blood in your urine, increased need to pass urine
- Swelling of the breasts in men.

Side effects of unknown frequency:

- Migraine, stuttering
- Extended erections, sometimes painful or an increased number of erections.
- Disorientation, talking too much
- Trouble seeing or double vision, pupil dilation
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon')
- Unusual hair loss or thinning
- Joint pain, muscle pain, muscle twitching, spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- Decreased response to therapy, chest pain, chest discomfort, decreased effect of the medicine, very high fever
- Changes in liver enzyme levels in your blood.

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 "**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 PHENITAB.

5. How to store PHENITAB

Store at or below 25 °C

Keep the bottle tightly closed to protect from moisture.

Use within 30 days of opening the container.

Store all medicines out of reach of children.

Do not use after the expiry date printed on the container.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What PHENITAB contains

The active substance is methylphenidate hydrochloride.

Each PHENITAB 18 extended release tablet contains 18 mg methylphenidate hydrochloride.

Each PHENITAB 27 extended release tablet contains 27 mg methylphenidate hydrochloride.

Each PHENITAB 36 extended release tablet contains 36 mg methylphenidate hydrochloride.

Each PHENITAB 54 extended release tablet contains 54 mg methylphenidate hydrochloride.

The ingredients of PHENITAB tablet core is colloidal anhydrous silica, hypromellose, iron oxide black, macrogol, magnesium stearate, sodium chloride and succinic acid.

The ingredients of PHENITAB tablet coating is cellulose acetate, macrogol and Opadry clear (consisting of hypromellose and macrogol).

The colour coating consist of the following:
PHENITAB 18: Opadry II Yellow (consisting of lactose monohydrate, hypromellose, titanium dioxide, triacetin, yellow iron oxide and red iron oxide).
PHENITAB 27: Opadry II Grey (consisting of lactose monohydrate, hypromellose, titanium dioxide, triacetin, black iron oxide and red iron oxide).
PHENITAB 36: Opadry II White (consisting of lactose monohydrate, hypromellose, titanium dioxide, triacetin).
PHENITAB 54: Opadry II Pink (consisting of lactose monohydrate, hypromellose, titanium dioxide, triacetin and red iron oxide).

What PHENITAB looks like and contents of the pack

PHENITAB 18: round, biconvex, yellow and homogeneous aspect film-coated tablets of approximately 8,5 mm of diameter with a hole in one side of the tablet.

PHENITAB 27: round, biconvex, grey and homogeneous aspect film-coated tablets of approximately 8,5 mm of diameter with a hole in one side of the tablet.

PHENITAB 36: round, biconvex, white and homogeneous aspect film-coated tablets of approximately 10 mm of diameter with a hole in one side of the tablet.

PHENITAB 54: round, biconvex, pink and homogeneous aspect film-coated tablets of approximately 10 mm of diameter with a hole in one side of the tablet.

White high density polyethylene (HDPE) bottle with white HDPE child resistant cap, and containing two white polyethylene capsules with desiccant.

PROPOSED PATIENT INFORMATION LEAFLET FOR PHENITAB

Pack size: 30 tablets.

Holder of the certificate of registration

Activo Health (Pty) Ltd.

Block B, Arena Office Park

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0157

South Africa

This leaflet was revised in

Will be allocated by SAHPRA upon registration.

Registration number

PHENITAB 18: 56/1.2/0587

PHENITAB 27: 56/1.2/0588

PHENITAB 36: 56/1.2/0589

PHENITAB 54: 56/1.2/0590