PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

CONTRAMYL XR 18 mg (prolonged release tablets)

CONTRAMYL XR 27 mg (prolonged release tablets)

CONTRAMYL XR 36 mg (prolonged release tablets)

CONTRAMYL XR 54 mg (prolonged release tablets)

Methylphenidate hydrochloride

Contains sugar:

Each CONTRAMYL XR 18 mg tablet contains: sucrose 10,013 mg

Each CONTRAMYL XR 27 mg tablet contains: sucrose 15,024 mg

Each CONTRAMYL XR 36 mg tablet contains: sucrose 20,027 mg

Each CONTRAMYL XR 54 mg tablet contains: sucrose 30,040 mg

Read all of this leaflet carefully before you start taking CONTRAMYL XR

- 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.
- CONTRAMYL XR 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 CONTRAMYL XR is and what it is used for

- CONTRAMYL XR contains the active substance methylphenidate that 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.
- CONTRAMYL XR is used to treat attention deficit hyperactivity disorder (ADHD).

2. What you need to know before you take CONTRAMYL XR

Do not take CONTRAMYL XR:

- if you are hypersensitive (allergic) to methylphenidate or any of the other ingredients of CONTRAMYL XR (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 (MAOI) - see ‘Taking other medicines with CONTRAMYL XR ’;
- if you have thyroid disorders;
- if you have an eating problem when you do not feel hungry or want to eat - such as ‘anorexia nervosa’ or other anorexic disorders, severe mood disorders, 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, overactive and uninhibited;
- diagnosis or history of severe and episodic (Type I) bipolar (affective) disorder (that is not well controlled);
- if you have or 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 disorder;
- 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 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);
- family history or diagnosis of Tourette's syndrome (uncontrolled speech and body movements);
- if you have liver or kidney function disorders;
- if you are pregnant or breastfeeding (see '*Pregnancy and Breastfeeding*');
- if you are not sure, talk to your doctor or pharmacist before taking CONTRAMYL XR.

Do not give to a child of younger than 6 years old (see *'Take special care with CONTRAMYL XR*').

Warnings and precautions

Take special care with CONTRAMYL XR:

- If children are not growing or gaining weight as expected, their treatment must be stopped (see sub-header '*Children and adolescents' below*). Suppression of growth has been reported with long-term use of medicines such as CONTRAMYL XR.
- If you are an adult - the safety and efficacy have not been established for the initiation of treatment or the routine continuation of treatment beyond 18 years of age. Your doctor will review the need for further treatment on a regular basis.
- If you are elderly - you should not receive CONTRAMYL XR as safety and efficacy has not been established in this age group.

- If you have a heart disorder or whether there is any family history of sudden unexplained death (see '*Do not take CONTRAMYL XR*').
- If you have high blood pressure and/or cerebrovascular disorders (see '*Do not take CONTRAMYL XR*').
- If you have hemiplegic cerebral palsy your doctor may treat you with CONTRAMYL XR.
- If you have other mental health problems not mentioned under '*Do not take CONTRAMYL XR'* such as:
    - mood swings (from being manic to being depressed - called 'bipolar disorder');
    - starting to be aggressive or hostile, or your aggression gets worse;
    - 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;
    - suicidal tendency.
- If you have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words.
- If you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs).
- If you have ever abused or been dependent on alcohol, prescription medicines or street 'drugs'.
- Chronic abuse of CONTRAMYL XR can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour.
- If your doctor decides to stop your treatment, he will carefully supervise you since severe depression may occur as well as chronic over-activity.
- If you suffer from severe depression or extreme tiredness.
- If you have liver, kidney or blood disorders.
- If you have a narrowing or blockage of your gut or food-pipe and/or have a problem with swallowing or swallowing whole tablets.

- **'Substance' testing/screening:** CONTRAMYL XR may give a positive result when testing for 'drug' use. This includes testing used in sport.
- Tell your doctor if you experience long and painful erections.
- If you are taking medicines for depression or anxiety called serotonergic medicines (*see section 'Other medicines and CONTRAMYL XR').*

Children and adolescents

Take special care with CONTRAMYL XR in children and adolescents as the safety and efficacy for long-term (more than 12 months) treatment with CONTRAMYL XR has not been systematically evaluated.

If the treatment is intended for children under the age of 6 years: CONTRAMYL XR should not be given to children in this age group as safety and efficacy has not been established (see '*Do not take CONTRAMYL XR*').

Other medicines and CONTRAMYL XR

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

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

- Medicines for epilepsy (e.g. phenobarbitone, phenytoin, primidone).
- Antidepressants (tricyclics and selective serotonin reuptake inhibitors). Taking methylphenidate 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 immediately.
- Antidepressant medicine called 'monoamine oxidase inhibitor' (MAOI). Taking an MAOI with CONTRAMYL XR can cause a sudden increase in your blood pressure.

- Tell your doctor if you are going to have an operation. You should not take CONTRAMYL XR 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.
- Tell your doctor if you are taking clonidine or other centrally acting alpha-2 agonists as long-term safety in combination with CONTRAMYL XR has not been evaluated.
- Tell your doctor if you are taking dopaminergic medicines, such as antipsychotics, because CONTRAMYL XR may interact with these medicines.
- Remember to tell your doctor if you start taking any other medicines while you are taking CONTRAMYL XR.
- Medicines used to reduce or increase blood pressure.
- Medicines that thin the blood to prevent blood clots (e.g. warfarin).

CONTRAMYL XR with food and drink and alcohol

Do not drink alcohol while taking CONTRAMYL XR. Alcohol may make the side effects of CONTRAMYL XR worse. Remember that some foods and medicines contain alcohol.

Pregnancy and 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 this medicine.

Pregnancy:

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

Tell your doctor or pharmacist before using CONTRAMYL XR if you are pregnant or think you may be pregnant. Your doctor will decide whether you should take CONTRAMYL XR as it may be harmful to your baby.

Breastfeeding:

It is possible that the ingredient methylphenidate, as contained in CONTRAMYL XR, is passed into human breast milk. Therefore, your doctor will decide whether you should breastfeed your baby while taking CONTRAMYL XR.

Driving and using machines

CONTRAMYL XR can cause dizziness, drowsiness and visual disturbances.
It is not always possible to predict to what extent CONTRAMYL XR 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 CONTRAMYL XR affects them.

CONTRAMYL XR contains sucrose

CONTRAMYL XR contains sucrose (a type of sugar), which may have an effect on the control of your blood sugar if you have diabetes mellitus.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CONTRAMYL XR.

3. How to take CONTRAMYL XR

Do not share medicines prescribed for you with any other person.
Always take CONTRAMYL XR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is:

- You should take CONTRAMYL XR once each day in the morning with a glass of water and must not be chewed, divided or crushed.
- Even though the tablets have a score line, it is not intended as a break line and the tablets should not be divided and taken at different intervals.
- You may take CONTRAMYL XR with or without food.
- Your doctor will usually start CONTRAMYL XR treatment with a low dose and increase it gradually as required.

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

Elderly:

The use of CONTRAMYL XR in elderly patients over 65 years has not been studied.

If you take more CONTRAMYL XR than you should

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

If you forget to take a dose of CONTRAMYL XR

- If you miss a dose, wait and take your next dose at the usual time.
- Do not take a double dose to make up for forgotten individual doses.

If you stop taking CONTRAMYL XR

- If you suddenly stop taking CONTRAMYL XR, the 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 CONTRAMYL XR.

If you have any further questions on the use of CONTRAMYL XR, ask your doctor.

4. Possible side effects

CONTRAMYL XR can have side effects.

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

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

- Anaphylactic reactions - this is an immediate hypersensitivity reaction resulting in life-threatening breathing difficulty, usually followed by collapse of the arteries and veins and shock;
- hypersensitivity reactions including pruritus and sudden swelling of the skin or mucous membranes (e.g. throat or tongue) with difficulty breathing;
- flaking off of skin (skin peeling) itching of the skin; rashes and eruptions; or purplish red patches;
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome').

These are all very serious side effects. If you have them, you may have had a serious reaction to CONTRAMYL XR. 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:

- disturbance in or loss of regular heart rhythm; fast heartbeat (tachycardia); awareness of one's own heartbeat;
- unexplained fainting, shortness of breath (these can be signs of heart problems), heart attack and sudden cardiac death, increase in heart rate, slowness of the heartbeat, as evidenced by slowness of the pulse rate, fast or extra heartbeats;
- tics (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words)*;*
- mania (feeling unusually excited, overactive and uninhibited); disorientation; confusion;
- excessive drowsiness or sleepiness*;*
- psychotic disorders (seeing, feeling, or hearing things that are not real and not there, these are signs of psychosis);

- suicidal ideation-suicide attempt (including completed suicide); transient depressed mood; abnormal thinking; lack of feeling or emotion (apathy); repetitive behaviours; over-focussing; a belief or impression that is not in accordance with a generally accepted reality (delusion); thought disturbance;
- abuse and dependence;
- fits (seizures, convulsions, epilepsy, a major fit (Grand mal convulsion));
- problems with the blood vessels in your brain (stroke);
- cerebral arteritis and/or occlusion; peripheral coldness; fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon);
- liver enzyme elevations; abnormal liver function; including hepatic coma.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- inflammation of the throat; upper respiratory tract infection; sinus infection;
- anorexia; decreased appetite and weight loss; reduced height gain during prolonged use in children;
- not being able to sleep; nervousness;
- rapid changes in emotion; aggression; agitation; feeling anxious; depression; irritability; mood swings;
- decreased interest in sex;
- grinding of the teeth; panic attack;
- dizziness;
- difficulty of moving; sensation of movement;
- unpleasant tingling feeling in arms or legs;
- tension headache;
- eye focus impairment;
- high blood pressure;

- cough, pain in mouth and throat;
- stomach pain; diarrhoea; nausea; stomach discomfort; vomiting; dry mouth; upset stomach or indigestion;
- loss of hair; itching of the skin; rash; smooth, slightly elevated area on the skin, which is redder and paler than the surrounding skin;
- pain in a joint; muscle tightness; muscle spasms or cramps;
- growth retardation during prolonged use in children;
- fatigue;
- feeling jittery; lack or loss of strength or energy; thirst;
- increased alanine aminotransferase (this will be established by blood tests).

The following side effects have been reported less frequently:

- anaemia (reduced numbers of red blood cells which can cause tiredness, headaches and shortness of breath);
- leucopenia (reduction in the number of white blood cells);
- thrombocytopenia (reduction in the number of blood platelets which are cells that help blood to clot);
- swelling of the ear(s);
- worsening of pre-existing tics (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words);
- excessive, rapid speech;
- abnormally increased responsiveness;
- sedation;
- tremor;
- blurred vision; dry eyes;
- difficulties in visual focusing; visual disorders, seeing double;
- hot flush;
- constipation;

- hyperhidrosis (excessive sweating); macular rash;
- pain in a muscle or muscles; muscle twitching; muscle cramps;
- blood in the urine; pollakiuria (frequent, abnormal urination during the day);
- swelling of the breasts in men;
- chest pain;
- 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.

The following side effects have been reported but the frequency is unknown:

- Pancytopenia (a decrease in all types of blood cells);
- migraine;
- abnormal dilation of the pupil (mydriasis);
- restriction of motion of the jaws;
- fever;
- erectile dysfunction;
- urinary frequency- inability to control the excretion of urine (incontinence);
- liver failure.

Post-marketing possible side effect:

- Nosebleed.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CONTRAMYL XR.

5. How to store CONTRAMYL XR

Store all medicines out of reach of children.

Store at or below 25 ºC.

Keep the container tightly closed.

Keep in the original container until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

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

Do not store in a bathroom.

6. Contents of the pack and other information

What CONTRAMYL XR contains:

The active substance is methylphenidate hydrochloride.

CONTRAMYL XR prolonged release tablets containing 18 mg, 27 mg, 36 mg or 54 mg of methylphenidate hydrochloride.

The other ingredients are:

- *Active pellets:*

Hypromellose; sugar spheres; talc

- *EC pellet coating:*

Ethylcellulose; hydroxypropylcellulose; talc; triethyl citrate

- *HPMC/AS pellet coating:*

Hypromellose acetate succinate

- *Final blending:*

Carmellose sodium; cellulose; microcrystalline; magnesium stearate; silica, colloidal anhydrous

- *Tablet coating (API):*

Opadry® II white (Macrogol 3350; polyvinyl alcohol; talc, titanium dioxide);

Opadry® II yellow (Iron oxide yellow; macrogol 3350; polyvinyl alcohol; talc);

Opadry® II red (Iron oxide red; macrogol 3350; polyvinyl alcohol; talc)

Tablet coating colour 18 mg: Opadry® II white; Opadry® II yellow

Tablet coating colour 27 mg: Opadry® II yellow

Tablet coating colour 36 mg: Opadry® II white

Tablet coating colour 54 mg: Opadry® II white; Opadry® II red

What CONTRAMYL XR looks like and contents of the pack:

What CONTRAMYL XR looks like:

CONTRAMYL XR 18 mg:

Yellowish to yellow, round, biconvex, film-coated tablets.

CONTRAMYL XR 27 mg:

Yellow, oblong, biconvex, film-coated tablets with break scores on both sides.

CONTRAMYL XR 36 mg:

White to off-white, oblong, biconvex, film-coated tablets with break scores on both sides.

CONTRAMYL XR 54 mg:

Reddish to red, oblong, biconvex, film-coated tablets with break scores on both sides.

Contents of the pack:

CONTRAMYL XR tablets are available in white high-density polyethylene (HDPE) bottles with round, white, child-resistant, tamper-evident screw caps with three break-points on the tamper-evident ring made of polypropylene and aperture for desiccant insert.

Packs of 30’s.

Holder of Certificate of Registration

Viatris South Africa (Pty) Ltd

4 Brewery Street

Isando, Johannesburg,

1609

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