

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S5

MUSALOS 15 mg capsule

MUSALOS 30 mg capsule

Phentermine

Read all of this leaflet carefully before you start taking MUSALOS

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

1. What MUSALOS is and what it is used for

MUSALOS contains phentermine hydrochloride, as phentermine.

MUSALOS is used with a doctor-approved exercise, behaviour change, and reduced-calorie diet program to help you lose weight. It is used by certain overweight people, such as those who are obese or have weight-related medical problems. Losing weight and keeping it off can lessen the many health risks that come with obesity, including heart disease, diabetes, high blood pressure, and a shorter life.

It is not known how this medicine helps people to lose weight. It may work by decreasing your appetite, increasing the amount of energy used by your body, or by affecting certain parts of the brain. This medicine is an appetite suppressant and belongs to a class of medicines called sympathomimetic amines.

2. What you need to know before you take MUSALOS

Do not take MUSALOS:

- if you are hypersensitive (allergic) to phentermine, to any other sympathomimetic medicines (e.g. decongestants such as pseudoephedrine, stimulants such as amphetamine, appetite suppressants such as diethylpropion) or any of the other ingredients of MUSALOS (see section 6)
- if you have uncontrolled high blood pressure

- if you have had a stroke or minor stroke
- if you have a history of heart problems
- if you have an overactive thyroid
- if you have a history of mental/mood problems (e.g. eating disorder (anorexia) or depression)
- if you have glaucoma (damage to the optic nerve of the eye)
- if you have a history of drug or alcohol dependence or abuse
- if you have obstructive uropathy (urine unable to drain from the kidneys to the bladder)
- if you suffer from epilepsy (fits) which is poorly controlled
- if you are taking MAO inhibitors (see Other medicines with MUSALOS)
- if you are pregnant or breastfeeding.

Children under the age of 12 years should not take MUSALOS.

Warnings and precautions

Take special care with MUSALOS:

- if you are taking any other medicines for weight loss. Taking MUSALOS with other medicines for weight loss is not recommended
- if you have mild hypertension (high blood) pressure or kidney problems
- if you suffer from epilepsy

- if you suffer from diabetes. You should check your blood sugar levels regularly as directed by your doctor. Your doctor may need to adjust your diabetes medicine during treatment with MUSALOS.
- if you develop symptoms such as difficulty breathing, chest pain, fainting, swelling of your lower arms or legs, or reduced ability to exercise as you may have a serious lung disease called primary pulmonary hypertension. Discontinue taking MUSALOS immediately and consult your healthcare provider if you experience any of these symptoms while taking MUSALOS.

Other medicines and MUSALOS

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:

MAO inhibitors with MUSALOS may cause a serious (possibly fatal) interaction (see Do not take MUSALOS). Avoid taking MAO inhibitors (e.g. isocarboxazid, linezolid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment with MUSALOS. Most MAO inhibitors should also not be taken for two weeks before treatment with this MUSALOS. Ask your doctor when to start or stop taking and MAO inhibitor.

Other medicines for weight loss, including fenfluramine and dexfenfluramine.

Sympathomimetic medicines e.g. decongestants such as pseudoephedrine, stimulants such as amphetamine, appetite suppressants such as diethylpropion (see section 2).

High blood pressure medicine (e.g. clonidine, guanethidine, methyldopa).

Drinking alcohol and MUSALOS can cause a side effect.

Medicines to treat depression such as SSRIs (e.g. fluoxetine, sertraline, fluvoxamine, paroxetine) and clomipramine.

Dihydroergotamine and ergotamine to treat severe headaches.

Medicines used in the treatment of diabetes.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using MUSALOS.

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

Driving and using machines:

MUSALOS may make you dizzy or drowsy or cause blurred vision. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely.

It is not always possible to predict to what extent MUSALOS may interfere your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MUSALOS affects you.

3. How to take MUSALOS

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

Always use MUSALOS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and Children over 12 years:

The usual dose is one MUSALOS capsule, swallowed whole first thing in the morning. An evening dose should be avoided, since MUSALOS may prevent you sleeping. The recommended dose should not be exceeded.

Do not take MUSALOS with any other weight loss medicines (see Other medicines and MUSALOS).

Children under the age of 12 years should not take MUSALOS (see Do not take MUSALOS).

Your doctor will tell you how long your treatment with MUSALOS will last.

If you have the impression that the effect of MUSALOS is too strong or too weak, tell your doctor or pharmacist. Do not increase your dose to increase the effects of this medicine.

If you take more MUSALOS than you should:

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

Symptoms of overdose may include:

Irritability, rapid respiration, agitation, euphoria (intense excitement or happiness), restlessness, overactive reflexes, disorientation, tremor, aggressiveness, hallucinations (seeing or hearing things that are not there), panic attack, irregular heartbeat, convulsions (fits), fatigue, coma, high or low blood pressure, nausea, vomiting, diarrhoea and stomach cramps.

If you forget to take MUSALOS:

If you forget to take MUSALOS, take a dose as soon as you remember, then continue to take MUSALOS at the usual times. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MUSALOS can have side effects.

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

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

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

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

- changes in the way your heart beats, for example, if you notice it is beating faster
- pressure, tightness, or pain in your chest or arms that may spread to your neck, jaw or back; shortness of breath, cold sweats (signs of a heart attack or other heart problems)
- numbness or paralysis in the face, leg, or arm, most likely on just one side of the body (signs of a stroke)
- shortness of breath, initially while exercising and eventually while at rest, fatigue, dizziness or fainting spells, chest pressure or pain, swelling in your ankles, legs and eventually in your abdomen (signs of a blockage of the artery which takes blood from the heart to the lungs).

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:

- overstimulation, restlessness, nervousness, problems sleeping, tremor, dizziness, headache.

Less frequent side effects:

- euphoria (intense excitement or happiness) followed by extreme tiredness and depression, mood changes, hallucinations (seeing or hearing things that are not there).

The following side effects have been reported but the frequency for them to occur is not known:

- impaired emotions and loss of contact with external reality
- blurred vision
- dizziness and light-headedness (high blood pressure)
- nausea, vomiting, dry mouth, stomach cramps, unpleasant taste, diarrhoea, constipation
- skin rash and hives
- you pass more urine than normal or more frequently than normal
- problems with sexual performance or sex drive.

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. 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 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 MUSALOS.

5. How to store MUSALOS

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blisters in carton until required for use.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What MUSALOS contains

The active substance is phentermine.

Each MUSALOS capsule contains phentermine hydrochloride, equivalent to either 15 mg or 30 mg phentermine.

The other ingredients are:

Magnesium stearate, sodium polystyrene sulfonate.

15 mg capsule shell:

Gelatin, iron oxide black, titanium dioxide.

30 mg capsule shell:

Brilliant blue FCF, erythrosin, gelatin, iron oxide black, titanium dioxide.

MUSALOS is sugar free.

What MUSALOS looks like and contents of the pack

MUSALOS are hard gelatin capsules.

MUSALOS 15 mg: Size '3' hard gelatin capsule with white opaque cap and grey opaque body, imprinted with 'PT' on cap and '15' on body in black ink and containing brown to light brown coloured spherical beads.

MUSALOS 30 mg: Size '3' hard gelatin capsule with purple cap and grey opaque body, imprinted with 'PT' on cap and '30' on body in white ink and containing brown to light brown coloured spherical beads.

MUSALOS 15 and 30 mg are packed into a clear plastic and plain aluminium foil blister strips containing 30 capsules in a carton.

Holder of Certificate of Registration

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MUSALOS 30 mg: A53/11.3/0712