PATIENT INFORMATION LEAFLET

MINEX RANGE

SCHEDULING STATUS:

S5

MINEX 15 mg capsule

MINEX 30 mg capsule

Phentermine

Sugar-free

Read all of this leaflet carefully before you start taking MINEX

- 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.
- MINEX 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 MINEX is and what it is used for
2. What you need to know before you use MINEX
3. How to use MINEX
4. Possible side effects
5. How to store MINEX
6. Contents of the pack and other information

1. What MINEX is and what it is used for

MINEX contains phentermine hydrochloride, as phentermine.

MINEX 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 MINEX

Do not take MINEX:

- 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 MINEX (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 MINEX)

- if you are pregnant or breastfeeding.

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

Warnings and precautions

Take special care with MINEX:

- if you are taking any other medicines for weight loss. Taking MINEX 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 MINEX.
- 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 MINEX immediately and consult your healthcare provider if you experience any of these symptoms while taking MINEX.

Other medicines and MINEX

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 MINEX may cause a serious (possibly fatal) interaction (see Do not take MINEX). Avoid taking MAO inhibitors (e.g. isocarboxazid, linezolid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment with MINEX. Most MAO inhibitors should also not be taken for two weeks before treatment with this MINEX. 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 MINEX 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, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before using Minex.

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

Driving and using machines:

MINEX 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 MINEX may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MINEX affects you.

3. How to take MINEX

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

Always use MINEX 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 MINEX capsule, swallowed whole first thing in the morning. An evening dose should be avoided, since MINEX may prevent you sleeping. The recommended dose should not be exceeded.

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

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

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

If you have the impression that the effect of MINEX 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 MINEX than you should:

In the event of overdosage, 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 MINEX:

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

4. Possible side effects

MINEX can have side effects.

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

If any of the following happens, stop using MINEX 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 MINEX. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MINEX. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store MINEX

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 MINEX contains

The active substance is phentermine.

Each MINEX 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 (E172), titanium dioxide (E171).

30 mg capsule shell:

Brilliant blue FCF (E133), erythrosine (E127), gelatin, iron oxide black (E172), titanium dioxide (E171).

MINEX is sugar free.

What MINEX looks like and contents of the pack

MINEX are hard gelatin capsules.

MINEX 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.

MINEX 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.

MINEX 15 and 30 mg are packed into a clear PVC/Aclar or PVC/PVdC film and lacquer coated aluminium foil blister strips containing 30 capsules in a carton.

Holder of Certificate of Registration and Manufacturer

Pharma Dynamics (Pty) Ltd

1st Floor, Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

Tel: + 27 21 707 7000

www.pharmadynamics.co.za

Registration numbers

MINEX 15 mg: A53/11.3/0713

MINEX 30 mg: A53/11.3/0714