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(For additional information see "Phentermine: Drug information")

Brand Names: US Adipex-P; Lomaira; Suprenza [DSC]

## What is this drug used for?

· It is used to treat obesity.

## What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to phentermine or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor
  about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough;
  swelling of face, lips, tongue, or throat; or any other signs.
- If you have ever had any of these health problems: Heart disease like heart failure or a heartbeat that is not normal, drug abuse, high blood pressure, or stroke.
- If you have any of these health problems: Glaucoma; nervous, anxious, or tense state; or overactive thyroid.
- If you have taken certain drugs used for low mood (depression) like isocarboxazid, phenelzine, or tranylcypromine or drugs used for Parkinson's disease like selegiline or rasagiline in the last 14 days. Taking this drug within 14 days of those drugs can cause very bad high blood pressure.
- If you are taking any of these drugs: Fluoxetine, fluvoxamine, paroxetine, or sertraline.
- · If you are taking or will be taking another drug like this one.
- If you are pregnant or may be pregnant. Do not take this drug if you are pregnant.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

# What are some things I need to know or do while I take this drug?

#### All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug
  affects you.
- People who take drugs for weight loss like this drug may have a higher chance of having raised pressure
  in the lungs. This is rare but is often deadly. Talk with your doctor.
- If you have been taking this drug for a long time or at high doses, it may not work as well and you may
  need higher doses to get the same effect. This is known as tolerance. Call your doctor if this drug stops
  working well. Do not take more than ordered.
- If you have been taking this drug for many weeks, talk with your doctor before stopping. You may want to slowly stop this drug.
- This drug may be habit-forming; avoid long-term use. Tell your doctor if you have a history of drug or alcohol abuse.
- This drug may cause unsafe heart-related side effects. Tell your doctor if you have any heart disease.
- · Check blood pressure and heart rate as the doctor has told you. Talk with the doctor.
- If you have high blood sugar (diabetes), talk with your doctor.
- Follow the diet and workout plan that your doctor told you about.
- Talk with your doctor before you drink alcohol.
- Do not give to a child younger than 17 years of age.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant
  or you get pregnant while taking this drug, call your doctor right away.

### **Oral-disintegrating tablet:**

If you are allergic to tartrazine, talk with your doctor. Some products have tartrazine.

# What are some side effects that I need to call my doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or
  without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual
  hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Change in how you act.
- · Chest pain or pressure or a fast heartbeat.
- · A heartbeat that does not feel normal.
- · Mood changes.
- · Shakiness.
- · Shortness of breath.
- · Swelling on legs or feet.
- Very bad dizziness or passing out.
- · Very bad headache.

# What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Dizziness.
- Feeling nervous and excitable.
- · Headache.
- · Hard stools (constipation).
- · Loose stools (diarrhea).
- · Dry mouth.
- Not able to sleep.
- Bad taste in your mouth.
- · Lowered interest in sex.
- · Change in sex ability.
- · Restlessness.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

## How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

#### All dose forms:

· Take this drug early in the day to prevent sleep problems.

### Tablets and capsules:

Take before or after breakfast as your doctor has told you.

### **Oral-disintegrating tablet:**

- · Take with or without food.
- · Be sure your hands are dry before you touch this drug.
- Place on your tongue and let it melt. Water is not needed. Do not swallow it whole. Do not chew, break, or crush it.

### What do I do if I miss a dose?

- · Take a missed dose as soon as you think about it.
- · If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- · Do not take 2 doses at the same time or extra doses.

# How do I store and/or throw out this drug?

- Store at room temperature.
- · Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

# **General drug facts**

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- · Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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(For additional information see "Phentermine: Patient drug information")

For abbreviations and symbols that may be used in Lexicomp (show table)

Brand Names: US Adipex-P; Lomaira; Suprenza [DSC]

Pharmacologic Category Anorexiant; Central Nervous System Stimulant; Sympathomimetic

**Dosing: Adult** Note: Dosing is presented in terms of the salt, phentermine hydrochloride (not as phentermine base).

Obesity (short-term adjunct): Oral:

Capsule, tablet (excluding Lomaira): 15 to 37.5 mg daily given in 1 to 2 divided doses. Individualize to achieve adequate response with lowest effective dose.

Tablet (Lomaira only): 8 mg 3 times daily. Individualize to achieve adequate response with lowest effective dose.

Orally disintegrating tablet (ODT): One tablet (15 to 37.5 mg daily) every morning. Individualize to achieve adequate response with lowest effective dose.

Dosing: Pediatric Obesity (short-term adjunct): Adolescents >16 years: Refer to adult dosing.

**Dosing: Geriatric** Refer to adult dosing.

**Dosing: Renal Impairment** There are no dosage adjustments provided in the manufacturer's labeling (has not been studied). Phentermine is excreted in the urine and systemic exposure may be increased in renal impairment; use with caution.

**Dosing: Hepatic Impairment** There are no dosage adjustments provided in the manufacturer's labeling (has not been studied).

**Dosage Forms: US** Excipient information presented when available (limited, particularly for generics); consult specific product labeling. [DSC] = Discontinued product

Capsule, Oral, as hydrochloride:

Adipex-P: 37.5 mg

Generic: 15 mg, 30 mg, 37.5 mg

Tablet, Oral, as hydrochloride:

Adipex-P: 37.5 mg [scored; contains brilliant blue fcf (fd&c blue #1)]

Lomaira: 8 mg [scored; contains brilliant blue fcf (fd&c blue #1), corn starch]

Generic: 37.5 mg

Tablet Dispersible, Oral, as hydrochloride:

Suprenza: 15 mg [DSC] [contains fd&c blue #1 aluminum lake, fd&c yellow #5 aluminum lake]

Suprenza: 30 mg [DSC] [contains fd&c yellow #5 aluminum lake]

Suprenza: 37.5 mg [DSC] [contains fd&c blue #1 aluminum lake]

Generic Equivalent Available: US May be product dependent

Controlled Substance C-IV

**Administration** Avoid late evening administration.

Capsules, tablets (excluding Lomaira): Administer before breakfast or 1 to 2 hours after breakfast. Tablets may be divided in half and dose may be given in 2 divided doses.

Tablet (Lomaira only): Administer 30 minutes before meals. Tablets are scored and may be divided in half.

Orally disintegrating tablets (Suprenza): With dry hands, place tablet on the tongue and allow to dissolve, then swallow with or without water. May administer with or without food.

**Use** Obesity (short-term adjunct): Short-term (few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity with an initial body mass index (BMI) ≥30 kg/m<sup>2</sup> or ≥27 kg/m<sup>2</sup> in the presence of other risk factors (eg, diabetes, hyperlipidemia, controlled hypertension).

# **Medication Safety Issues**

#### Sound-alike/look-alike issues:

Phentermine may be confused with phentolamine, phenytoin

## Adverse Reactions Significant Frequency not defined.

Cardiovascular: Hypertension, ischemia, palpitations, tachycardia

Central nervous system: Dizziness, dysphoria, euphoria, headache, insomnia, overstimulation, psychosis,

restlessness

Dermatologic: Urticaria

Endocrine & metabolic: Change in libido

Gastrointestinal: Constipation, diarrhea, gastrointestinal distress, unpleasant taste, xerostomia

Genitourinary: Impotence

Neuromuscular & skeletal: Tremor

<1% (Limited to important or life-threatening): Acquired valvular heart disease (regurgitant), primary pulmonary hypertension

**Contraindications** Hypersensitivity or idiosyncrasy to phentermine, other sympathomimetic amines or any component of the formulation; history of cardiovascular disease (eg, arrhythmias, congestive heart failure, coronary artery disease, stroke, uncontrolled hypertension); hyperthyroidism, glaucoma, agitated states, history of drug abuse; use during or within 14 days following MAO inhibitor therapy; pregnancy, breast-feeding

## Warnings/Precautions

### Concerns related to adverse effects:

- CNS effects: May cause CNS depression, which may impair physical or mental abilities; patients must be cautioned about performing tasks that require mental alertness (eg, operating machinery or driving).
- Heart failure: In a scientific statement from the American Heart Association, phentermine has been determined to be an agent that may cause direct myocardial toxicity (magnitude: major) (AHA [Page 2016]).
- Primary pulmonary hypertension (PPH): A rare, frequently fatal disease of the lungs, PPH has been reported to occur in patients receiving a combination of phentermine and fenfluramine or dexfenfluramine. The possibility of an association between PPH and the use of phentermine alone cannot be ruled out; rare cases of PPH have been reported in patients taking phentermine alone. Discontinue in patients experiencing new-onset dyspnea, chest pain, syncope, or lower extremity edema.
- Valvular heart disease: Serious regurgitant cardiac valvular disease (primarily affecting the mitral, aortic, and/or tricuspid valves) has been reported to occur in patients receiving a combination of phentermine and fenfluramine or dexfenfluramine. The possibility of an association between valvular heart disease and the use of phentermine alone cannot be ruled out; rare cases of valvular heart disease have been reported in patients taking phentermine alone.

#### Disease-related concerns:

- Cardiovascular disease: Avoid stimulants in patients with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that could increase the risk of sudden death that these conditions alone carry.
- Diabetes: Use with caution in patients with diabetes mellitus; antidiabetic agent requirements (eg, insulin or oral hypoglycemic agents) may be decreased with anorexigens and concomitant dietary restrictions.
- Hypertension: Use with caution in patients with mild hypertension and other cardiovascular conditions that might be exacerbated by increases in blood pressure or heart rate.
- Renal impairment: Use caution in patients with renal impairment (use has not been studied); however, an increase in exposure is expected in renal impairment.
- Seizure disorders: Avoid or use with caution in patients with history of seizures (Apovian 2015).
- Tourette syndrome: Use with caution in patients with Tourette syndrome; stimulants may unmask tics.

### Concurrent drug therapy issues:

• Drug-drug interactions: Potentially significant interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information.

### Special populations:

• Elderly: Use caution in this age group due to the risk for causing dependence, hypertension, angina, and myocardial infarction.

### Dosage form specific issues:

• Tartrazine (FDC yellow #5): Some products may contain tartrazine which may cause allergic reactions in patients with sensitivity (caution in patients with asthma or aspirin hypersensitivity).

### Other warnings/precautions:

- Abuse potential: Phentermine is pharmacologically related to the amphetamines, which have a high abuse potential; prolonged use may lead to dependency. Prescriptions should be written for the smallest quantity consistent with good patient care to minimize possibility of overdose.
- Appropriate use: Phentermine is not approved for long-term use. Clinicians should carefully examine the potentially benefits against potential risks associated with use of medications in this class. Consult weight loss guidelines for current pharmacotherapy recommendations. Therapy should be used in conjunction with a comprehensive weight management program.
- Tolerance: Tolerance to the anorectic effect usually develops within a few weeks; discontinue use when tolerance develops, do not exceed recommended dosage in an attempt to overcome tolerance.

**Metabolism/Transport Effects** Substrate of CYP3A4 (minor); **Note:** Assignment of Major/Minor substrate status based on clinically relevant drug interaction potential

# **Drug Interactions**

(For additional information: Launch Lexi-Interact™ Drug Interactions Program)

Acebrophylline: May enhance the stimulatory effect of CNS Stimulants. Risk X: Avoid combination

Alcohol (Ethyl): May enhance the adverse/toxic effect of Phentermine. Risk C: Monitor therapy

Alkalinizing Agents: May decrease the excretion of Amphetamines. Risk D: Consider therapy modification

Ammonium Chloride: May decrease the serum concentration of Amphetamines. This effect is likely due to an enhanced excretion of amphetamines in the urine. *Risk C: Monitor therapy* 

Analgesics (Opioid): Amphetamines may enhance the analgesic effect of Analgesics (Opioid). *Risk C: Monitor therapy* 

Antacids: May decrease the excretion of Amphetamines. Risk C: Monitor therapy

Antihistamines: Amphetamines may diminish the sedative effect of Antihistamines. Risk C: Monitor therapy

Antihypertensive Agents: Amphetamines may diminish the antihypertensive effect of Antihypertensive Agents. *Risk C: Monitor therapy* 

Antipsychotic Agents: May diminish the stimulatory effect of Amphetamines. Risk C: Monitor therapy

Ascorbic Acid: May decrease the serum concentration of Amphetamines. Risk C: Monitor therapy

AtoMOXetine: May enhance the hypertensive effect of Sympathomimetics. AtoMOXetine may enhance the tachycardic effect of Sympathomimetics. Risk C: Monitor therapy

Cannabinoid-Containing Products: May enhance the tachycardic effect of Sympathomimetics. **Exceptions:** Cannabidiol. *Risk C: Monitor therapy* 

Carbonic Anhydrase Inhibitors: May decrease the excretion of Amphetamines. **Exceptions:** Brinzolamide; Dorzolamide. *Risk C: Monitor therapy* 

Cocaine: May enhance the hypertensive effect of Sympathomimetics. Management: Consider alternatives to use of this combination when possible. Monitor closely for substantially increased blood pressure or heart rate and for any evidence of myocardial ischemia with concurrent use. *Risk D: Consider therapy modification* 

Doxofylline: Sympathomimetics may enhance the adverse/toxic effect of Doxofylline. Risk C: Monitor therapy

Ethosuximide: Amphetamines may diminish the therapeutic effect of Ethosuximide. Amphetamines may decrease the serum concentration of Ethosuximide. *Risk C: Monitor therapy* 

Gastrointestinal Acidifying Agents: May decrease the serum concentration of Amphetamines. *Risk C: Monitor therapy* 

lobenguane I 123: Sympathomimetics may diminish the therapeutic effect of lobenguane I 123. Risk X: Avoid combination

Ioflupane I 123: Amphetamines may diminish the diagnostic effect of Ioflupane I 123. Risk C: Monitor therapy

Linezolid: May enhance the hypertensive effect of Sympathomimetics. Management: Reduce initial doses of sympathomimetic agents, and closely monitor for enhanced pressor response, in patients receiving linezolid. Specific dose adjustment recommendations are not presently available. *Risk D: Consider therapy modification* 

Lithium: May diminish the stimulatory effect of Amphetamines. Risk C: Monitor therapy

MAO Inhibitors: May enhance the hypertensive effect of Amphetamines. While linezolid and tedizolid may interact via this mechanism, management recommendations differ from other monoamine oxidase inhibitors. Refer to monographs specific to those agents for details. **Exceptions:** Linezolid; Tedizolid. *Risk X: Avoid combination* 

Methenamine: May decrease the serum concentration of Amphetamines. This effect is likely due to an enhanced excretion of amphetamines in the urine. *Risk C: Monitor therapy* 

Multivitamins/Fluoride (with ADE): May decrease the serum concentration of Amphetamines. More specifically, the ascorbic acid (vitamin C) in many multivitamins may decrease amphetamine concentrations. *Risk C: Monitor therapy* 

Multivitamins/Minerals (with ADEK, Folate, Iron): May decrease the serum concentration of Amphetamines. *Risk C: Monitor therapy* 

Multivitamins/Minerals (with AE, No Iron): May decrease the serum concentration of Amphetamines. Specifically, vitamin C may impair absorption of amphetamines. *Risk C: Monitor therapy* 

PHENobarbital: Amphetamines may decrease the serum concentration of PHENobarbital. Risk C: Monitor therapy

Phenytoin: Amphetamines may decrease the serum concentration of Phenytoin. Risk C: Monitor therapy

Sympathomimetics: May enhance the adverse/toxic effect of other Sympathomimetics. *Risk C: Monitor therapy* 

Tedizolid: May enhance the hypertensive effect of Sympathomimetics. Tedizolid may enhance the tachycardic effect of Sympathomimetics. *Risk C: Monitor therapy* 

Tricyclic Antidepressants: May enhance the stimulatory effect of Amphetamines. Tricyclic Antidepressants may also potentiate the cardiovascular effects of Amphetamines. *Risk C: Monitor therapy* 

Urinary Acidifying Agents: May decrease the serum concentration of Amphetamines. *Risk C: Monitor therapy* 

### Pregnancy Risk Factor X (show table)

**Pregnancy Implications** Use is contraindicated during pregnancy (lack of potential benefit and possible fetal harm). The risks of using appetite suppressing drugs in pregnant women are not known (NHLBI 1998) and limited information is available about the use of phentermine in pregnancy (Jones 2002; McElhatton 2006). Weight loss therapy is generally not recommended for pregnant women. Obese and overweight women should be encouraged to participate in weight reduction programs prior to attempting pregnancy; weight gain during pregnancy should be determined by their prepregnancy BMI and current guidelines (ACOG 2013; ADA 2009).

**Breast-Feeding Considerations** Use is contraindicated in breast-feeding women. It is not known if phentermine is excreted in breast milk; however, other amphetamines have been detected in breast milk. Weight loss therapy is generally not recommended for lactating women (NHLBI 1998). Weight loss programs which include physical activity and nutrition components should be discussed at the 6-week postpartum visit (ADA 2009).

# **Dietary Considerations**

Capsules, tablets (excluding Lomaira): Should be taken before breakfast or 1 to 2 hours after breakfast; avoid taking in the late evening. Most effective when combined with a low-calorie diet and behavior modification counseling.

Tablet (Lomaira only): Should be taken 30 minutes before meals.

### Monitoring Parameters Weight, waist circumference; blood pressure

## Reference Range

Adult classification of weight by BMI (kg/m²):

Underweight: <18.5

Normal: 18.5-24.9

Overweight: 25-29.9

Obese, class I: 30-34.9

Obese, class II: 35-39.9

Extreme obesity (class III): ≥40

Waist circumference: In adults with a BMI of 25-34.9 kg/m<sup>2</sup>, high-risk waist circumference is defined as:

Men >102 cm (>40 in)

Women >88 cm (>35 in)

**Mechanism of Action** Phentermine is a sympathomimetic amine with pharmacologic properties similar to the amphetamines. The mechanism of action in reducing appetite appears to be secondary to CNS effects, including stimulation of the hypothalamus to release norepinephrine.

## Pharmacodynamics and Pharmacokinetics

Absorption: Well absorbed. Rate and extent of exposure of orally disintegrating tablets (ODT) are equivalent to capsules and tablets administered under fasting conditions. Administration of the ODT after a high-fat/high-calorie breakfast decreased C<sub>max</sub> by ~5% and AUC by ~12%.

Distribution: V<sub>d</sub>: 348 L

Protein binding: 17.5%

Metabolism: Hepatic via p-hydroxylation (aromatic ring) and N-oxidation (alipthatic side chain); primarily metabolized by CYP3A4 (but does not show extensive metabolism).

Half-life elimination: ~20 hours

Time to peak: 3-4.4 hours

Excretion: Primarily urine (62%-85% as unchanged drug)

# **Pricing: US**

Capsules (Adipex-P Oral)

37.5 mg (100): \$254.15

Capsules (Phentermine HCl Oral)

15 mg (100): \$125.37

30 mg (100): \$103.75

37.5 mg (100): \$157.00

**Tablets** (Adipex-P Oral)

37.5 mg (40): \$0.00

Tablets (Lomaira Oral)

8 mg (90): \$52.20

**Tablets** (Phentermine HCl Oral)

37.5 mg (100): \$152.25

**Disclaimer:** The pricing data provide a representative AWP and/or AAWP price from a single manufacturer of the brand and/or generic product, respectively. The pricing data should be used for benchmarking purposes only, and as such should not be used to set or adjudicate any prices for reimbursement or purchasing functions. Pricing data is updated monthly.

International Brand Names Adipex (CH, KR); Adipex Retard (AT, CZ, MY); Duromine (AU, BB, BF, BJ, BM, BS, BZ, CI, CR, CY, DO, ET, GB, GH, GM, GN, GT, GY, HN, IE, JM, KE, LB, LR, MA, ML, MR, MU, MW, NE, NG, NI, NL, NZ, PA, PR, SC, SD, SL, SN, SR, SV, TN, TT, TZ, UG, ZA, ZM, ZW); Furimin (KR); Ionamin (BE, IE, LU); Ionamine (CH); Jonamin (AU); Metermine (AU); Mirapront (IT); Mirubal (VE); Normaform (CH); Panbesy (BE, HK, LU, SG, TH); Panbesy DCR (KR); Pender (KR); Phenkin (KR); Redusa (HK); Redusa Forte (HK); Sinpet (MX); Supremin (PH); Terfamex (CR, DO, EC, GT, HN, NI, PA, SV); Vitupen (KR); Weltmine (KR)

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