



# Patient Starter Book

**ADIPEX-P®** **IV**  
(phentermine HCl) 37.5 mg



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(phentermine HCl) 37.5 mg

# PRESCRIPTION PLUS LIFESTYLE PROGRAM

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*Please discuss any changes to your diet and exercise routine with your healthcare professional.*

ADIPEX-P® (phentermine hydrochloride USP) CIV is used for a short period of time (a few weeks), as part of a weight reduction treatment plan that includes exercise, behavioral changes, and a low-calorie diet, for obese people with a body mass index greater than or equal to 30 kg/m<sup>2</sup> or a body mass index greater than or equal to 27 kg/m<sup>2</sup> and other risk factors (e.g., controlled high blood pressure, diabetes, high cholesterol).

### Important Safety Information

Do not take ADIPEX-P if you:

- Have a history of heart disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled high blood pressure)
- Are taking certain medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the past 14 days
- Have thyroid problems (hyperthyroidism)
- Have glaucoma (increased pressure in the eyes)
- Have experienced agitated states or have a history of drug abuse
- Are pregnant or are nursing
- Are allergic to sympathomimetic amines such as phentermine, or any of the ingredients

**Use with Other Medicines for Weight Loss. Taking ADIPEX-P with other drugs used for weight loss is not recommended.**

**Primary Pulmonary Hypertension. A rare but often fatal disease of the lungs, has been reported in patients taking phentermine and phentermine-like products.** Tell your doctor if you have shortness of breath, chest or heart pain, or experience fainting or swelling in your lower legs. Contact your doctor immediately if you experience any decrease in the amount of exercise you are normally able to tolerate.

**Heart Valve Disease. Serious heart valve problems or disease have been reported in patients taking phentermine or other phentermine-like products for weight loss. The possibility of an association cannot be ruled out.**

**Tolerance.** There is the potential for tolerance to develop, where the same dose might not work as well as it did in the beginning. If this happens, the recommended dose should not be increased, but instead the drug should be discontinued.

**Motor Impairment.** ADIPEX-P may impair your ability to operate machinery or drive a motor vehicle.

**Risk of Abuse and Dependence.** Keep ADIPEX-P in a safe place to prevent theft, accidental overdose, misuse or abuse.

**Use With Alcohol.** Do not use ADIPEX-P with alcohol as it may result in an adverse drug reaction.

**Patients with High Blood Pressure.** ADIPEX-P may cause an increase in blood pressure. Tell your doctor if you have or have had high blood pressure.

**Patients with Diabetes.** A decrease in the dose of insulin or other oral hypoglycemic medications may be required. Talk to your physician if you are taking medications for diabetes.

**Patients with Renal Impairment.** Avoid use if you have impaired kidney function or are on dialysis.

Tell your doctor about all of your medical conditions and about all of the medications you are taking, including over-the-counter or herbal treatments.

Some side effects of ADIPEX-P include pulmonary hypertension, heart disease, palpitations, increased heart rate or blood pressure, insomnia, restlessness, dry mouth, diarrhea, constipation, and changes in sexual drive. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of ADIPEX-P. For more information, ask your healthcare provider or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**Please see accompanying full prescribing information.**

# YOUR DAILY MEAL PLAN

## 1000 Calories    1200 Calories    1500 Calories

Carbohydrates: 133 g    Carbohydrates: 154 g    Carbohydrates: 189 g  
 Protein: 56 g    Protein: 63 g    Protein: 78 g  
 Fat: 30 g    Fat: 36 g    Fat: 46 g

### Breakfast

1 Fruit (List 4)  
 1 Starch/Bread (List 1)  
 ½ Milk (List 5)  
 \* Free Foods (List 7)

### Breakfast

1 Fruit (List 4)  
 2 Starch/Bread (List 1)  
 1 Milk (List 5)  
 \* Free Foods (List 7)

### Breakfast

1 Fruit (List 4)  
 2 Starch/Bread (List 1)  
 1 Fat (List 6)  
 1 Milk (List 5)  
 \* Free Foods (List 7)

### Lunch

2 oz. Meat (List 2)  
 1 Starch/Bread (List 1)  
 1 Fruit (List 4)  
 1 Fat (List 6)  
 1 Vegetable (List 3)  
 \* Free Foods (List 7)

### Lunch

2 oz. Meat (List 2)  
 1 Starch/Bread (List 1)  
 1 Fruit (List 4)  
 1 Fat (List 6)  
 1 Vegetable (List 3)  
 \* Free Foods (List 7)

### Lunch

2 oz. Meat (List 2)  
 2 Starch/Bread (List 1)  
 1 Vegetable (List 3)  
 1 Fruit (List 4)  
 1 Fat (List 6)  
 \* Free Foods (List 7)

### Afternoon Snack

1 Fruit (List 4)

### Afternoon Snack

1 Fruit (List 4)

### Afternoon Snack

1 Fruit (List 4)

### Dinner

2 oz. Meats (List 2)  
 1 Starch/Bread (List 1)  
 1 Vegetable (List 3)  
 \* Free Foods (List 7)

### Dinner

2 oz. Meats (List 2)  
 1 Starch/Bread (List 1)  
 1 Vegetable (List 3)  
 1 Fat (List 6)  
 \* Free Foods (List 7)

### Dinner

3 oz. Meats (List 2)  
 2 Starch/Bread (List 1)  
 2 Vegetable (List 3)  
 1 Fat (List 6)  
 \* Free Foods (List 7)

### Evening Snack

1 Starch/Bread (List 1)  
 1 Milk (List 5)

### Evening Snack

1 Starch/Bread (List 1)  
 1 Milk (List 5)

### Evening Snack

1 Starch/Bread (List 1)  
 1 Milk (List 5)

## 1800 Calories    2000 Calories    2500 Calories

Carbohydrates: 234 g    Carbohydrates: 254 g    Carbohydrates: 311 g  
 Protein: 91 g    Protein: 103 g    Protein: 122 g  
 Fat: 56 g    Fat: 61 g    Fat: 79 g

### Breakfast

1 Fruit (List 4)  
 2 Starch/Bread (List 1)  
 1 Fat (List 6)  
 1 Milk (List 5)  
 \* Free Foods (List 7)

### Breakfast

1 Fruit (List 4)  
 3 Starch/Bread (List 1)  
 1 Fat (List 6)  
 1 Milk (List 5)  
 \* Free Foods (List 7)

### Breakfast

2 Fruit (List 4)  
 3 Starch/Bread (List 1)  
 2 Fat (List 6)  
 1 Milk (List 5)  
 \* Free Foods (List 7)

### Lunch

2 oz. Meat (List 2)  
 2 Starch/Bread (List 1)  
 1 Vegetable (List 3)  
 1 Fruit (List 4)  
 1 Fat (List 6)  
 \* Free Foods (List 7)

### Lunch

3 oz. Meat (List 2)  
 2 Starch/Bread (List 1)  
 2 Vegetable (List 3)  
 1 Fruit (List 4)  
 1 Fat (List 6)  
 \* Free Foods (List 7)

### Lunch

4 oz. Meat (List 2)  
 3 Starch/Bread (List 1)  
 2 Vegetable (List 3)  
 1 Fruit (List 4)  
 2 Fat (List 6)  
 \* Free Foods (List 7)

### Afternoon Snack

1 Fruit (List 4)

### Afternoon Snack

1 Fruit (List 4)  
 1 Starch/Bread (List 1)

### Afternoon Snack

1 Fruit (List 4)  
 1 Starch/Bread (List 1)

### Dinner

4 oz. Meats (List 2)  
 3 Starch/Bread (List 1)  
 2 Vegetable (List 3)  
 1 Fruit (List 4)  
 2 Fat (List 6)  
 \* Free Foods (List 7)

### Dinner

4 oz. Meats (List 2)  
 3 Starch/Bread (List 1)  
 2 Vegetable (List 3)  
 1 Fruit (List 4)  
 2 Fat (List 6)  
 \* Free Foods (List 7)

### Dinner

4 oz. Meats (List 2)  
 3 Starch/Bread (List 1)  
 2 Vegetable (List 3)  
 1 Milk (List 5)  
 2 Fat (List 6)  
 \* Free Foods (List 7)

### Evening Snack

2 Starch/Bread (List 1)  
 1 Milk (List 5)

### Evening Snack

2 Starch/Bread (List 1)  
 1 Milk (List 5)

### Evening Snack

2 Starch/Bread (List 1)  
 1 Milk (List 5)  
 1 Fruit (List 4)

# DAILY MEAL PLAN SELECTIONS

## 1. Starches & Breads

One portion of each food in this list contains about 15 g of carbohydrate, 3 g protein, a trace of fat, and 80 calories. To choose a similar portion of a starch or bread not listed, follow these general rules:

- ✓ Cereal, grain, pasta ..... ½ cup
- ✓ Bread product ..... 1 oz.

### Breads

### Portions

- ✓ Bagel (deli size) ..... ¼ (1 oz.)
- ✓ Bun (hamburger, hot dog) ..... ½ (1 oz.)
- ✓ English muffin ..... ½
- ✓ Pita (6" across) ..... ½
- ✓ Tortilla, flour or corn (6" across) ..... 1
- ✓ Whole wheat, rye, white, pumpernickel, raisin (no icing) ..... 1 slice (1 oz.)

### Cereals/Grains/Pasta

- ✓ Bran Cereal, concentrated such as  
Bran Buds®, All-Bran® ..... ⅓ cup
- ✓ Bran Cereal, flaked ..... ½ cup
- ✓ Cooked Cereal, grits, bulgur ..... ½ cup
- ✓ Macaroni, noodles, spaghetti (cooked) ..... ⅓ cup
- ✓ Puffed cereal ..... 1 ½ cups
- ✓ Ready to eat unsweetened cereal ..... ¾ cup
- ✓ Rice, white or brown ..... ⅓ cup
- ✓ Shredded wheat ..... ½ cup
- ✓ Wheat germ ..... 3 tbsp.

### Crackers/Snacks

- ✓ Graham cracker (2 ½" square) ..... 3
- ✓ Matzo ..... ¾ oz.
- ✓ Melba Toast ..... 4 slices
- ✓ Oyster crackers ..... 20
- ✓ Popcorn, popped, no fat added ..... 3 cups
- ✓ Pretzels ..... ¾ oz.
- ✓ Rice cake (4" across) ..... 2
- ✓ Rye crisp (2" x 3 ½") ..... 4
- ✓ Saltine crackers ..... 6

### Starchy Vegetables

- ✓ Beans, baked ..... ⅓ cup
- ✓ Corn ..... ½ cup or 6" cob
- ✓ Lentils, beans, or peas (dried),  
such as kidney, white, split, black-eyed ..... ½ cup
- ✓ Lima beans (frozen) ..... 2 oz.
- ✓ Peas, green (canned or frozen) ..... ½ cup
- ✓ Potato, baked ..... 1 small (3 oz.)
- ✓ Potato, mashed ..... ½ cup
- ✓ Winter squash (acorn, butternut) ..... 1 cup
- ✓ Yam or sweet potato, plain ..... ⅓ cup

### Starch Foods Prepared with Fat

(Count as 1 starch/bread exchange and 1 fat exchange)

- ✓ Biscuit (2 ½" across) ..... 1
- ✓ Chow mein noodles ..... ½ cup
- ✓ Corn bread (2" cube) ..... 1 (2 oz.)
- ✓ Cracker, round butter type ..... 6
- ✓ French fried potatoes (2-3½" long) ..... 1 cup (2 oz.)
- ✓ Muffin (small cupcake size, plain) ..... 1
- ✓ Snack chips, fat-free or baked ..... 15-20 (¾ oz.)
- ✓ Stuffing, prepared ..... ⅓ cup
- ✓ Taco shell (6" across) ..... 2



## 2. Meats & Meat Substitutes

One portion of each food in this list contains about 7 g protein. Lean meats and meat substitutes have about 55 calories per serving; other meat items have 78 to 100 calories per serving. To follow a diet low in cholesterol and saturated fat, choose the lean meats, fish, and other items that appear in bold type. Portions are weighed after cooking and with skin, bones, and fat removed.

### Beef

- ✓ Lean cuts, such as USDA Good/Choice round, sirloin, or flanked steak, tenderloin, chipped beef ..... 1 oz.
- ✓ All other cuts ..... 1 oz.

### Cheese

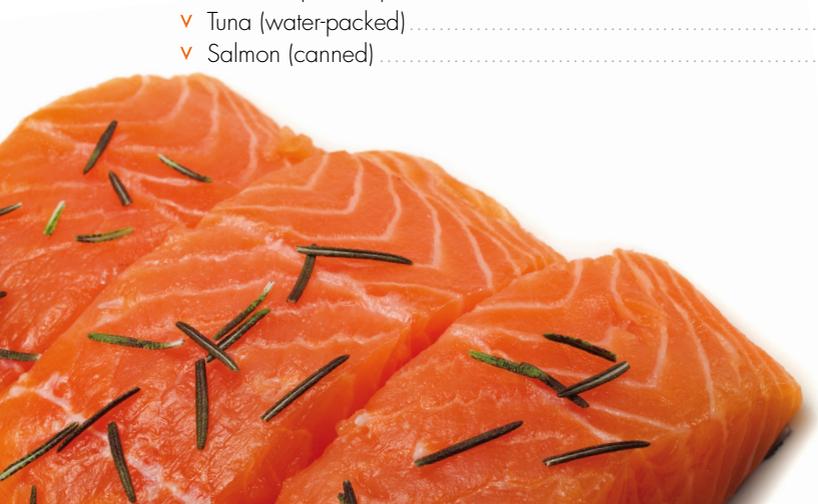
- ✓ Cottage or ricotta ..... ¼ cup
- ✓ Diet (less than 55 calories per oz.) ..... 1 oz.
- ✓ Parmesan, grated ..... 2 tbsp.
- ✓ Other cheese (except cream cheese) ..... 1 oz.

### Eggs

- ✓ Egg substitute (less than 55 calories per ¼ cup) ..... ¼ cup
- ✓ Egg white ..... 2
- ✓ Egg, whole ..... 1

### Fish & Seafood

- ✓ All fresh or frozen fish ..... 1 oz.
- ✓ Clams, crab, lobster, shrimp, scallops ..... 1 oz.
- ✓ Herring, smoked ..... 1 oz.
- ✓ Oysters ..... 6 medium
- ✓ Sardines (canned) ..... 2 medium
- ✓ Tuna (water-packed) ..... 1 oz.
- ✓ Salmon (canned) ..... 1 oz.



### Miscellaneous

- ✓ Hot dog (10 per lb.)\* ..... 1
- ✓ Lamb (all cuts) ..... 1 oz.
- ✓ Liver, heart, kidney, sweetbreads ..... 1 oz.
- ✓ Luncheon meats—95% fat free; all others ..... 1 oz.
- ✓ Peanut butter\* ..... 1 tbsp.
- ✓ Sausages, such as Polish, Italian, smoked\* ..... 1 oz.

\*Count as 1 oz. protein and 1 fat.

### Pork

- ✓ Lean cuts, such as Canadian bacon; fresh ham; canned, cured, boiled ham; tenderloin ..... 1 oz.
- ✓ Other cuts ..... 1 oz.

### Poultry

- ✓ Chicken, turkey, Cornish hen (skin removed) ..... 1 oz.

### Veal

- ✓ Lean chops and roasts ..... 1 oz.
- ✓ Cutlets ..... 1 oz.

## 3. Vegetables

One portion of each vegetable in this list contains about 5 g carbohydrate, 2 g protein, and 25 calories. If no portion size is listed, the following measurements should be used:

- ✓ Cooked vegetables or juice ..... ½ cup
- ✓ Raw vegetables ..... 1 cup

Check Free Foods (List 7) and Starches/Breads (List 1) for vegetables not listed here.

- |                               |                                   |                             |
|-------------------------------|-----------------------------------|-----------------------------|
| ✓ Asparagus                   | ✓ Cucumber                        | ✓ Spinach (cooked)          |
| ✓ Beans (green, wax, Italian) | ✓ Eggplant                        | ✓ Summer squash (crookneck) |
| ✓ Bean sprouts                | ✓ Greens (collard, mustard, etc.) | ✓ Tomato (1 large)          |
| ✓ Beets                       | ✓ Mushrooms (cooked)              | ✓ Tomato or vegetable juice |
| ✓ Broccoli                    | ✓ Okra                            | ✓ Turnip                    |
| ✓ Brussels sprouts            | ✓ Onion                           | ✓ Water chestnuts           |
| ✓ Cabbage (cooked)            | ✓ Pea pods (snow peas)            | ✓ Zucchini (cooked)         |
| ✓ Carrots                     | ✓ Peppers (green)                 |                             |
| ✓ Cauliflower                 | ✓ Radishes                        |                             |
| ✓ Celery                      | ✓ Sauerkraut                      |                             |

# 4. Fruits

One portion of each fruit in this list contains about 15 g carbohydrate and 60 calories. To choose a similar portion of a fruit not listed, follow these general rules:

- ✓ Fresh, canned, or frozen fruit, no sugar added ..... ½ cup
- ✓ Dried fruit ..... ¼ cup

## Dried Fruits

- ✓ Apple, 4 oz. .... 1 small
- ✓ Apricot ..... 3
- ✓ Date (medium) ..... 2
- ✓ Fig (small) ..... 2
- ✓ Prune (medium) ..... 3
- ✓ Raisins ..... 2 tbsp.

## Fruit Juices

- ✓ Apple juice or cider ..... ½ cup
- ✓ Cranberry juice cocktail ..... ⅓ cup
- ✓ Grape juice ..... ⅓ cup
- ✓ Prune juice ..... ⅓ cup
- ✓ Other, such as orange, pineapple, etc. .... ½ cup

## Fruit

- ✓ Apple, fresh (2" across), 4 oz. .... 1
- ✓ Applesauce, no sugar added ..... ½ cup
- ✓ Apricot, fresh (medium) ..... 4
- ✓ Banana (9" long) ..... ½
- ✓ Blackberries or blueberries, raw ..... ¾ cup
- ✓ Cantaloupe or honeydew melon ..... 1 cup
- ✓ Cherries fresh, 3 oz. .... 12
- ✓ Fig fresh (2" across) ..... 2

- ✓ Fruit cocktail, canned ..... ½ cup
- ✓ Grapefruit (medium) ..... ½
- ✓ Grapefruit segments ..... ¾ cup
- ✓ Grapes (small) ..... 15
- ✓ Kiwi (large) ..... 1
- ✓ Mandarin orange ..... ¾ cup
- ✓ Nectarine (2 ½" across) ..... 1
- ✓ Orange (2 ½" across) ..... 1
- ✓ Papaya (½" across) ..... 1 cup, cubed
- ✓ Peach (medium), 4 oz. .... 1 whole (¾ cup)
- ✓ Pear ..... ½ large/1 small
- ✓ Persimmon (native, medium) ..... 2
- ✓ Pineapple, fresh ..... ¾ cup
- ✓ Pineapple, canned ..... ½ cup
- ✓ Plum, fresh (2" across) ..... 2
- ✓ Raspberries, fresh ..... 1 cup
- ✓ Strawberries, fresh (whole) ..... 1 ¼ cups
- ✓ Tangerine (2 ½" across) ..... 2
- ✓ Watermelon ..... 1 ¼ cups



## 5. Milk & Milk Products

One portion of each milk or milk product in this list contains about 12 g carbohydrate and 8 g protein. These foods also contain 1 to 8 g fat and 90 to 150 calories per serving, depending on their butterfat content. Choose foods from the skim and low-fat milk groups as often as possible, because they contain less butterfat than do whole milk products.

### Skim and Very Low Fat Milk

✓ Skim, ½% or 1% milk	1 cup
✓ Buttermilk, low fat	1 cup
✓ Evaporated skim milk	4 fl. oz.
✓ Nonfat dry milk	⅓ cup dry
✓ Nonfat yogurt, plain	6 oz.

### Low Fat Milk

Count as 1 milk exchange and 1 fat exchange

✓ 2% milk	1 cup
✓ Low-fat yogurt, plain (with added nonfat milk solids)	6 oz.

### Whole Milk

Count as 1 milk exchange and 2 fat exchanges

✓ Whole milk	1 cup
✓ Evaporated whole milk	½ cup
✓ Whole yogurt, plain	8 oz.



## 6. Fats

One portion of each food in this list contains about 5 g fat and 45 calories. Choose unsaturated fats instead of saturated fats as often as possible.

### Monounsaturated Fats

✓ Almonds, dry roasted	6 whole
✓ Avocado (medium)	1 oz.
✓ Margarine, diet	1 tbsp.
✓ Oil (olive, peanut, canola)	1 tsp.
✓ Pecans or walnuts	2 whole

### Polyunsaturated Fats

✓ Margarine, diet	1 tbsp.
✓ Mayonnaise (regular)	2 tsp.
✓ Mayonnaise (reduced fat/diet)	1 tbsp.
✓ Oil (corn, cottonseed, soybean, safflower, sunflower)	1 tsp.
✓ Salad dressing, mayonnaise-type (reduced fat)	2 tbsp.
✓ Salad dressing, other varieties	1 tbsp.
✓ Sunflower seeds	1 tbsp.

### Saturated Fats

✓ Bacon	1 slice
✓ Butter	1 tsp.
✓ Coconut, shredded	2 tbsp.
✓ Coffee creamer, liquid	2 tbsp.
✓ Coffee creamer, powdered	4 tsp.
✓ Cream, half and half	2 tbsp.
✓ Cream (heavy, whipping)	¾ tbsp.
✓ Cream cheese	1 tbsp.

# 7. Free Foods

Each free food or drink in this list contains fewer than 20 calories per serving. You may eat as much as you want of free foods that have no portion size given; you may eat two or three servings per day of free foods that have portions listed. Be sure to spread your servings throughout the day.

## Drinks

- ✓ Bouillon or broth, no fat, low sodium
- ✓ Cocoa powder, unsweetened baking type (1 tbsp.)
- ✓ Coffee or tea
- ✓ Soft drinks, calorie-free, including carbonated drinks

## Condiments

- ✓ Coffee whitener, liquid (1 tbsp.)
- ✓ Coffee whitener, powdered (2 tsp.)
- ✓ Dill pickles, unsweetened
- ✓ Horseradish
- ✓ Hot sauce
- ✓ Ketchup (1 tbsp.)
- ✓ Mustard
- ✓ Salad dressing, low-calorie, including mayonnaise-type (1 tbsp.)
- ✓ Salsa (1/4 cup)
- ✓ Taco sauce (1 tbsp.)
- ✓ Vinegar

## Sweet Substitutes

- ✓ Gelatin, sugar-free
- ✓ Jam or jelly, sugar-free (2 tsp.)
- ✓ Whipped topping (2 tbsp.)

## Seasonings

Can be used as desired. If you are following a low sodium diet, be sure to read the labels and choose seasonings that do not contain sodium or salt.

- |                                                         |                        |
|---------------------------------------------------------|------------------------|
| ✓ Flavoring extracts<br>(vanilla, almond, butter, etc.) | ✓ Paprika              |
| ✓ Garlic or garlic powder                               | ✓ Pepper               |
| ✓ Herbs, fresh or dried                                 | ✓ Pimento              |
| ✓ Lemon or lemon juice spices                           | ✓ Soy sauce            |
| ✓ Onion powder                                          | ✓ Spices               |
|                                                         | ✓ Worcestershire sauce |

## Fruit

- ✓ Cranberries or rhubarb, no sugar (1/2 cup)

## Vegetables (raw, not to exceed 1 cup)

- ✓ Cabbage
- ✓ Celery
- ✓ Cucumber
- ✓ Green onion
- ✓ Hot peppers
- ✓ Mushrooms
- ✓ Radishes
- ✓ Salad greens (as desired)
  - Lettuce
  - Romaine
  - Spinach (raw)
- ✓ Zucchini



# CONTROLLING DIETARY FAT

## Facts

- Health authorities recommend decreasing total diet fat content to 30%: 7-10% saturated, 10% polyunsaturated, and 10-15% monounsaturated.
- Decreasing total fat intake means choosing lower-fat foods and cooking with low-fat methods.
- Substitute poly- or monounsaturated fats for saturated fats whenever possible.



NUTRITION FACTS FOR COMMONLY USED FATS  
(serving size = 1 tbsp.)

Vegetable Oils & Shortening	Polyunsaturated Fatty Acids	Monounsaturated Fatty Acids	Saturated Fatty Acids
Canola Oil	3.5g	8.4g	1g
Safflower Oil	10.1g	2g	0.8g
Sunflower Oil	3.9g	7.8g	1.2g
Corn Oil	7.4g	3.7g	1.7g
Olive Oil	1.4g	9.8g	1.8g
Sesame Oil	5.7g	5.4g	1.9g
Soybean Oil	7.8g	3.1g	2.1g
Peanut Oil	4.3g	6.2g	2.3g
Cottonseed Oil	7.1g	2.4g	3.5g
Rice Bran Oil	4.8g	5.3g	2.7g
Lard	1.4g	5.8g	5.0g
Palm Oil	1.3g	5.0g	6.7g
Butter	0.4g	3g	7g
Stick Margarine	3.4g	5.4g	2.1g
Soft Tub Margarine	3.8g	5.2g	2g
Household Vegetable Shortening	3.6g	5.3g	3.2g
Coconut Oil	0.2g	0.8g	11.8g

# EXERCISE

Talk to your doctor before beginning any exercise program.

## How Much is Right for You?

### Facts

- ✓ Exercise is a key part of weight loss—combined with a sensible diet, it helps burn more fat and less lean body tissue.
- ✓ Regular exercise keeps your metabolic rate high for up to 30 minutes after you finish—that’s why it’s especially important for weight maintenance.
- ✓ Different forms of exercise burn calories at different rates—whatever type of exercise you select, the important thing is to keep moving and exercise regularly.
- ✓ Substitute poly- or monounsaturated fats for saturated fats whenever possible.

### Warm Up and Cool Down

- ✓ Be sure to incorporate 5–10 minutes of low-level exercise before and after your exercise session, such as:
  - Walking
  - Walking in place
  - Slow jogging
- ✓ Then follow with slow smooth stretching. Hold each stretch for 10–20 seconds.
- ✓ The warm-up gets your muscles ready for exercise and helps prevent soreness and injury.
- ✓ The cool-down helps prevent soreness and helps in getting blood back to the heart so you don’t feel dizzy or light-headed.



# How Much Exercise is Enough?

1. Calculate your maximum pulse rate capacity. Do this by subtracting your age from 220.

Then, multiply that rate by 70 percent to determine a target pulse rate for a moderate activity level.

## FOR EXAMPLE, IF YOUR AGE IS 40:

$$220 - 40 = 180$$

$$180 \times 0.70 = 126$$

Target Pulse Rate  
for Moderate Exercise = 126



2. Learn how to count your actual pulse rate:

- Put two fingers high up on one side of your neck, just under the jawbone, where you can feel the carotid artery pulsing.
- Count the heartbeats you feel for 10 seconds, then multiply by 6 to get your pulse rate count per minute.

3. Continue to exercise regularly and challenge yourself to increase your fitness level along with your target pulse rate from this starting point.

**IMPORTANT: Before beginning any exercise program, consult your physician – especially if you are over 35 or have not been exercising regularly.**

Exercise required to burn off a given number of calories (based on a person weighing 150 lbs.):

- ✓ Walking–5.0 calories per minute (297 calories per hour).
- ✓ Swimming–10.0 calories per minute (603 calories per hour).
- ✓ Bike Riding–7.4 calories per minute (441 calories per hour).
- ✓ Running–11.2 calories per minute (675 calories per hour).

CALORIES EXPENDED					
Food	Calories	Minutes of Activity*			
		WALKING	SWIMMING	BIKE RIDING	RUNNING
Apple, large	110	30	9	17	13
Bacon, 2 strips	92	25	8	14	10
Banana, small	90	25	7	14	10
Beer, 1 glass	86	24	7	13	10
Cake, 2-layer, 1/8	260	72	21	39	30
Carbonated beverage, 8 oz.	97	27	8	15	11
Carrot, raw, large	30	8	2	5	3
Cereal, dry, 1 cup	100	28	8	15	11
Chicken, fried, 3 oz.	218	60	18	33	25
Cookie, oatmeal	81	22	7	12	9
Egg, fried	90	25	7	14	10
Ham (3 oz.)	125	34	10	19	14
Ice cream, 1 scoop	151	42	12	23	17
Malted milk shake (medium)	506	139	42	77	58
Milk, whole, 8 oz.	147	41	12	22	17
Milk, skim, 8 oz.	91	25	7	14	10
Orange juice, 8 oz.	112	31	9	17	13
Pancake, no butter or syrup	120	33	10	18	14
Peach, medium	38	10	3	6	4
Pie, apple, 1/8	277	76	23	42	32
Pizza, cheese, 1/8	272	75	22	41	31
Pork chop, loin	197	54	16	30	22
Club sandwich	510	141	42	77	58
Hamburger sandwich	250	69	21	38	28
Shrimp, fried	73	20	6	11	8
Spaghetti, 1 cup	224	62	19	34	25
Steak, T-bone (4 oz.)	200	55	17	30	23
Strawberry shortcake, 1 slice	218	60	18	33	25

\*Based on a 35 year old, 5.74 ft. tall female, weighing 144 lbs.





## What Exercise Can Do For You

- ✓ Exercise burns calories.
- ✓ Aerobic exercise burns fat.
- ✓ Exercise can increase muscle mass.
- ✓ Moderate exercise helps control your appetite.
- ✓ Exercise helps cope with stress and helps counter depression—common triggers of overeating.

## Exercise & Your Health

- ✓ Regular exercise:
  - Helps reduce high blood pressure
  - Helps control diabetes
  - Helps control cholesterol levels
  - Strengthens the heart and bones
  - Helps reduce high lipid levels in blood
  - Helps you to sleep better

### EXERCISE RECOMMENDATIONS FOR WEIGHT CONTROL

Frequency	Five times per week
Time	30–60 minutes of aerobic activity per session
Type	Continuous aerobic activity such as walking, stationary cycling, swimming, rowing, cross-country skiing, or jogging

# Caloric Activity Chart\*

	BODY WEIGHT (POUNDS)			
	125	150	175	200
<b>LOCOMOTION (15 MINUTES)</b>				
Walking Downstairs	29	34	40	46
Walking Upstairs	100	119	139	159
Walking-2 mph	21	26	30	34
Walking-4 mph	57	68	80	91
Cycling-5.5 mph	43	51	60	68
<b>HOUSEWORK (15 MINUTES)</b>				
Sweeping/Vacuuming	36	43	50	57
Making Beds	14	17	20	23
Washing Windows	29	34	40	46
Dusting	21	26	30	34
Preparing a Meal	21	26	30	34
Light Gardening	43	51	60	68
Mowing Grass (power)	64	77	89	102
House Painting (inside)	29	34	40	46
<b>RECREATION (15 MINUTES)</b>				
Badminton	50	60	70	80
Bowling	29	34	40	46
Canoeing-4 mph	86	102	119	137
Dancing (moderate)	50	60	70	80
Golfing (cart)	36	43	50	57
Ping-Pong	43	51	60	68
Swimming (Backstroke)	86	102	119	137
Swimming (Crawl, 50 yd/min., moderate)	100	119	139	159

\*Determining how many calories you burn is not an exact science. These numbers should be used as estimates only.



ADiPEX-P®   
(phentermine HCl) 37.5 mg

[www.adipex.com](http://www.adipex.com)

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ADI-40067 April 2017

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## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ADIPEX-P® safely and effectively. See full prescribing information for ADIPEX-P®.

**ADIPEX-P® (phentermine hydrochloride USP) for oral use CIV**

Initial U.S. Approval: 1959

### INDICATIONS AND USAGE

ADIPEX-P® is a sympathomimetic amine anorectic indicated as a short-term adjunct (a few weeks) in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index greater than or equal to 30 kg/m<sup>2</sup>, or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). (1)

The limited usefulness of agents of this class, including ADIPEX-P®, should be measured against possible risk factors inherent in their use. (1)

### DOSAGE AND ADMINISTRATION

- Dosage should be individualized to obtain an adequate response with the lowest effective dose. (2.1)
- Late evening administration should be avoided (risk of insomnia). (2.1)
- ADIPEX-P® can be taken with or without food. (2.1)
- Limit the dosage to 15 mg daily for patients with severe renal impairment (eGFR 15 to 29 mL/min/1.73 m<sup>2</sup>) (2.2)

### DOSAGE FORMS AND STRENGTHS

- Capsules containing 37.5 mg phentermine hydrochloride. (3)
- Tablets containing 37.5 mg phentermine hydrochloride. (3)

### CONTRAINDICATIONS

- History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension) (4)
- During or within 14 days following the administration of monoamine oxidase inhibitors (4)
- Hyperthyroidism (4)
- Glaucoma (4)
- Agitated states (4)
- History of drug abuse (4)
- Pregnancy (4, 8.1)
- Nursing (4, 8.3)
- Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines (4)

### WARNINGS AND PRECAUTIONS

- Coadministration with other drugs for weight loss is not recommended (safety and efficacy of combination not established). (5.1)
- Rare cases of primary pulmonary hypertension have been reported. ADIPEX-P® should be discontinued in case of new, unexplained symptoms of dyspnea, angina pectoris, syncope or lower extremity edema. (5.2)
- Rare cases of serious regurgitant cardiac valvular disease have been reported. (5.3)
- Tolerance to the anorectic effect usually develops within a few weeks. If this occurs, ADIPEX-P® should be discontinued. The recommended dose should not be exceeded. (5.4)
- ADIPEX-P® may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle. (5.5)
- Risk of abuse and dependence. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdose. (5.6)
- Concomitant alcohol use may result in an adverse drug reaction. (5.7)
- Use caution in patients with even mild hypertension (risk of increase in blood pressure). (5.8)
- A reduction in dose of insulin or oral hypoglycemic medication may be required in some patients. (5.9)

### ADVERSE REACTIONS

Adverse events have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems. (6)

To report SUSPECTED ADVERSE REACTIONS, contact TEVA USA, PHARMACOVIGILANCE at 1-866-832-8537 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

### DRUG INTERACTIONS

- Monoamine oxidase inhibitors: Risk of hypertensive crisis. (4, 7.1)
- Alcohol: Consider potential interaction (7.2)
- Insulin and oral hypoglycemics: Requirements may be altered. (7.3)
- Adrenergic neuron blocking drugs: Hypotensive effect may be decreased by ADIPEX-P®. (7.4)

### USE IN SPECIFIC POPULATIONS

- Nursing mothers: Discontinue drug or nursing taking into consideration importance of drug to mother. (4, 8.3)
- Pediatric use: Safety and effectiveness not established. (8.4)
- Geriatric use: Due to substantial renal excretion, use with caution. (8.5)
- Renal Impairment: Avoid use in patients with eGFR less than 15 mL/min/m<sup>2</sup> or end-stage renal disease requiring dialysis. (8.6)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 03/2017

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## FULL PRESCRIBING INFORMATION

### 1 INDICATIONS AND USAGE

ADIPEX-P® is indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index greater than or equal to 30 kg/m<sup>2</sup>, or greater than or equal to 27 kg/m<sup>2</sup> in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). Below is a chart of body mass index (BMI) based on various heights and weights.

BMI is calculated by taking the patient's weight, in kilograms (kg), divided by the patient's height, in meters (m), squared. Metric conversions are as follows: pounds ÷ 2.2 = kg; inches x 0.0254 = meters.

Weight (pounds)	BODY MASS INDEX (BMI), kg/m <sup>2</sup> Height (feet, inches)					
	5'0"	5'3"	5'6"	5'9"	6'0"	6'3"
140	27	25	23	21	19	18
150	29	27	24	22	20	19
160	31	28	26	24	22	20
170	33	30	28	25	23	21
180	35	32	29	27	25	23
190	37	34	31	28	26	24
200	39	36	32	30	27	25
210	41	37	34	31	29	26
220	43	39	36	33	30	28
230	45	41	37	34	31	29
240	47	43	39	36	33	30
250	49	44	40	37	34	31

The limited usefulness of agents of this class, including ADIPEX-P®, [see *Clinical Pharmacology* (12.1, 12.2)] should be measured against possible risk factors inherent in their use such as those described below.

### 2 DOSAGE AND ADMINISTRATION

#### 2.1 Exogenous Obesity

Dosage should be individualized to obtain an adequate response with the lowest effective dose.

The usual adult dose is one capsule (37.5 mg) daily as prescribed by the physician, administered before breakfast or 1 to 2 hours after breakfast for appetite control.

The usual adult dose is one tablet (37.5 mg) daily as prescribed by the physician, administered before breakfast or 1 to 2 hours after breakfast. The dosage may be adjusted to the patient's need. For some patients, half tablet (18.75 mg) daily may be adequate, while in some cases it may be desirable to give half tablets (18.75 mg) two times a day.

ADIPEX-P® is not recommended for use in pediatric patients less than or equal to 16 years of age.

Late evening medication should be avoided because of the possibility of resulting insomnia.

#### 2.2 Dosage in Patients With Renal Impairment

The recommended maximum dosage of ADIPEX-P® is 15 mg daily for patients with severe renal impairment (eGFR 15 to 29 mL/min/1.73 m<sup>2</sup>). Avoid use of ADIPEX-P® in patients with eGFR less than 15 mL/min/1.73 m<sup>2</sup> or end-stage renal disease requiring dialysis [see *Use in Specific Populations* (8.6) and *Clinical Pharmacology* (12.3)].

### 3 DOSAGE FORMS AND STRENGTHS

Capsules containing 37.5 mg phentermine hydrochloride (equivalent to 30 mg phentermine base).

Tablets containing 37.5 mg phentermine hydrochloride (equivalent to 30 mg phentermine base).

### 4 CONTRAINDICATIONS

- History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension)
- During or within 14 days following the administration of monoamine oxidase inhibitors
- Hyperthyroidism
- Glaucoma
- Agitated states
- History of drug abuse
- Pregnancy [see *Use in Specific Populations* (8.1)]
- Nursing [see *Use in Specific Populations* (8.3)]
- Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Coadministration With Other Drug Products for Weight Loss

ADIPEX-P® is indicated only as short-term (a few weeks) monotherapy for the management of exogenous obesity. The safety and efficacy of combination therapy with ADIPEX-P® and any other drug products for weight loss including prescribed drugs, over-the-counter preparations, and herbal products, or serotonergic agents such as selective serotonin reuptake inhibitors (e.g., fluoxetine, sertraline, fluvoxamine, paroxetine), have not been established. Therefore, coadministration of ADIPEX-P® and these drug products is not recommended.

### 5.2 Primary Pulmonary Hypertension

**Primary Pulmonary Hypertension (PPH) – a rare, frequently fatal disease of the lungs – has been reported to occur in patients receiving a combination of phentermine with fenfluramine or dexfenfluramine. The possibility of an association between PPH and the use of ADIPEX-P® alone cannot be ruled out; there have been rare cases of PPH in patients who reportedly have taken phentermine alone.** The initial symptom of PPH is usually dyspnea. Other initial symptoms may include angina pectoris, syncope or lower extremity edema. Patients should be advised to report immediately any deterioration in exercise tolerance. Treatment should be discontinued in patients who develop new, unexplained symptoms of dyspnea, angina pectoris, syncope or lower extremity edema, and patients should be evaluated for the possible presence of pulmonary hypertension.

### 5.3 Valvular Heart Disease

**Serious regurgitant cardiac valvular disease, primarily affecting the mitral, aortic and/or tricuspid valves, has been reported in otherwise healthy persons who had taken a combination of phentermine with fenfluramine or dexfenfluramine for weight loss. The possible role of phentermine in the etiology of these valvulopathies has not been established and their course in individuals after the drugs are stopped is not known. The possibility of an association between valvular heart disease and the use of ADIPEX-P® alone cannot be ruled out; there have been rare cases of valvular heart disease in patients who reportedly have taken phentermine alone.**

### 5.4 Development of Tolerance, Discontinuation in Case of Tolerance

When tolerance to the anorectant effect develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

### 5.5 Effect on the Ability to Engage in Potentially Hazardous Tasks

ADIPEX-P® may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly.

### 5.6 Risk of Abuse and Dependence

ADIPEX-P® is related chemically and pharmacologically to amphetamine (d- and d,l-amphetamine) and to other related stimulant drugs that have been extensively abused. The possibility of abuse of ADIPEX-P® should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. See *Drug Abuse and Dependence (9)* and *Overdosage (10)*.

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.

### 5.7 Usage With Alcohol

Concomitant use of alcohol with ADIPEX-P® may result in an adverse drug reaction.

### 5.8 Use in Patients With Hypertension

Use caution in prescribing ADIPEX-P® for patients with even mild hypertension (risk of increase in blood pressure).

### 5.9 Use in Patients on Insulin or Oral Hypoglycemic Medications for Diabetes Mellitus

A reduction in insulin or oral hypoglycemic medications in patients with diabetes mellitus may be required.

## 6 ADVERSE REACTIONS

The following adverse reactions are described, or described in greater detail, in other sections:

- Primary pulmonary hypertension [see *Warnings and Precautions (5.2)*]

- Valvular heart disease [see *Warnings and Precautions (5.3)*]

- Effect on the ability to engage in potentially hazardous tasks [see *Warnings and Precautions (5.5)*]

- Withdrawal effects following prolonged high dosage administration [see *Drug Abuse and Dependence (9.3)*]
- The following adverse reactions to phentermine have been identified:

#### Cardiovascular

Primary pulmonary hypertension and/or regurgitant cardiac valvular disease, palpitation, tachycardia, elevation of blood pressure, ischemic events.

#### Central Nervous System

Overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, psychosis.

#### Gastrointestinal

Dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances.

#### Allergic

Urticaria.

#### Endocrine

Impotence, changes in libido.

## 7 DRUG INTERACTIONS

### 7.1 Monoamine Oxidase Inhibitors

Use of ADIPEX-P® is contraindicated during or within 14 days following the administration of monoamine oxidase inhibitors because of the risk of hypertensive crisis.

### 7.2 Alcohol

Concomitant use of alcohol with ADIPEX-P® may result in an adverse drug reaction.

### 7.3 Insulin and Oral Hypoglycemic Medications

Requirements may be altered [see *Warnings and Precautions (5.9)*].

### 7.4 Adrenergic Neuron Blocking Drugs

ADIPEX-P® may decrease the hypotensive effect of adrenergic neuron blocking drugs.

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

#### Pregnancy Category X

ADIPEX-P® is contraindicated during pregnancy because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese, due to obligatory weight gain that occurs in maternal tissues during pregnancy. Phentermine has pharmacologic activity similar to amphetamine (d- and d,l-amphetamine) [see *Clinical Pharmacology (12.1)*]. Animal reproduction studies have not been conducted with phentermine. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

### 8.2 Nursing Mothers

It is not known if ADIPEX-P® is excreted in human milk; however, other amphetamines are present in human milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Because pediatric obesity is a chronic condition requiring long-term treatment, the use of this product, approved for short-term therapy, is not recommended.

### 8.5 Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

### 8.6 Renal Impairment

Based on the reported excretion of phentermine in urine, exposure increases can be expected in patients with renal impairment [see *Clinical Pharmacology (12.3)*].

Use caution when administering ADIPEX-P® to patients with renal impairment. In patients with severe renal impairment (eGFR 15 to 29 mL/min/1.73 m<sup>2</sup>), limit the dosage of ADIPEX-P® to 15 mg daily [see *Dosage and Administration (2.2)*]. ADIPEX-P® has not been studied in patients with eGFR less than 15 mL/min/1.73 m<sup>2</sup>, including end-stage renal disease requiring dialysis; avoid use in these populations.

## 9 DRUG ABUSE AND DEPENDENCE

### 9.1 Controlled Substance

Phentermine is a Schedule IV controlled substance.

### 9.2 Abuse

Phentermine is related chemically and pharmacologically to the amphetamines. Amphetamines and other stimulant drugs have been extensively abused and the possibility of abuse of phentermine should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program.

### 9.3 Dependence

Abuse of amphetamines and related drugs may be associated with intense psychological dependence and severe social dysfunction. There are reports of patients who have increased the dosage of these drugs to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity and personality changes. A severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

## 10 OVERDOSAGE

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.

### 10.1 Acute Overdosage

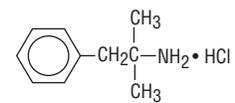
Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, and panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include tachycardia, arrhythmia, hypertension or hypotension, and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea and abdominal cramps. Overdosage of pharmacologically similar compounds has resulted in fatal poisoning usually terminates in convulsions and coma. Management of acute phentermine hydrochloride intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendations in this regard. Acidification of the urine increases phentermine excretion. Intravenous phenolamine (Regitine®, CIBA) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates overdosage.

### 10.2 Chronic Intoxication

Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia. See *Drug Abuse and Dependence (9.3)*.

## 11 DESCRIPTION

Phentermine hydrochloride USP is a sympathomimetic amine anorectic. It has the chemical name of  $\alpha,\alpha$ -Dimethylphenethylamine hydrochloride. The structural formula is as follows:



Phentermine hydrochloride is a white, odorless, hygroscopic, crystalline powder which is soluble in water and lower alcohols, slightly soluble in chloroform and insoluble in ether.

ADIPEX-P®, an anorectic agent for oral administration, is available as a capsule or tablet containing 37.5 mg of phentermine hydrochloride (equivalent to 30 mg of phentermine base).

ADIPEX-P® Capsules contain the inactive ingredients Black Iron Oxide, Corn Starch, D&C Red #33, FD&C

Blue #1, Gelatin, Lactose Monohydrate, Magnesium Stearate, Propylene Glycol, Shellac, and Titanium Dioxide. ADIPEX-P® Tablets contain the inactive ingredients Corn Starch, Lactose (Anhydrous), Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, Sucrose, and FD&C Blue #1.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

ADIPEX-P® is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, amphetamine (d- and d/l-amphetamine). Drugs of this class used in obesity are commonly known as “anorectics” or “anorexigenics.” It has not been established that the primary action of such drugs in treating obesity is one of appetite suppression since other central nervous system actions, or metabolic effects, may also be involved.

### 12.2 Pharmacodynamics

Typical actions of amphetamines include central nervous system stimulation and elevation of blood pressure. Tachyphylaxis and tolerance have been demonstrated with all drugs of this class in which these phenomena have been looked for.

### 12.3 Pharmacokinetics

Following the administration of phentermine, phentermine reaches peak concentrations ( $C_{max}$ ) after 3.0 to 4.4 hours.

#### Drug Interactions

In a single-dose study comparing the exposures after oral administration of a combination capsule of 15 mg phentermine and 92 mg topiramate to the exposures after oral administration of a 15 mg phentermine capsule or a 92 mg topiramate capsule, there is no significant topiramate exposure change in the presence of phentermine. However in the presence of topiramate, phentermine  $C_{max}$  and AUC increase 13% and 42%, respectively.

#### Specific Populations

##### Renal Impairment

Cumulative urinary excretion of phentermine under uncontrolled urinary pH conditions was 62% to 85%. Systemic exposure of phentermine may increase up to 91%, 45%, and 22% in patients with severe, moderate, and mild renal impairment, respectively [see *Dosage and Administration (2.2) and Use in Specific Populations (8.6)*].

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with phentermine to determine the potential for carcinogenesis, mutagenesis or impairment of fertility.

## 14 CLINICAL STUDIES

No clinical studies have been conducted with ADIPEX-P®. In relatively short-term clinical trials, adult obese subjects instructed in dietary management and treated with “anorectic” drugs lost more weight on the average than those treated with placebo and diet.

The magnitude of increased weight loss of drug-treated patients over placebo-treated patients is only a fraction of a pound a week. The rate of weight loss is greatest in the first weeks of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The possible origins of the increased weight loss due to the various drug effects are not established. The amount of weight loss associated with the use of an “anorectic” drug varies from trial to trial, and the increased weight loss appears to be related in part to variables other than the drugs prescribed, such as the physician-investigator, the population treated and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

The natural history of obesity is measured over several years, whereas the studies cited are restricted to a few weeks’ duration; thus, the total impact of drug-induced weight loss over that of diet alone must be considered clinically limited.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

Available in tablets and capsules containing 37.5 mg phentermine hydrochloride (equivalent to 30 mg phentermine base). Each blue and white, oblong, speckled, scored tablet is debossed with “ADIPEX-P” and “9”-“9”. The #3 capsule has an opaque white body and an opaque bright blue cap. Each capsule is imprinted with “ADIPEX-P” - “37.5” on the cap and two stripes on the body using dark blue ink.

Tablets are packaged in bottles of 30 (NDC 57844-009-56); 100 (NDC 57844-009-01); and 1000 (NDC 57844-009-10).

Capsules are packaged in bottles of 100 (NDC 57844-019-01).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

## 17 PATIENT COUNSELING INFORMATION

Patients must be informed that ADIPEX-P® is a *short-term* (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity, and that coadministration of phentermine with other drugs for weight loss is not recommended [see *Indications and Usage (1) and Warnings and Precautions (5)*].

Patients must be instructed on how much ADIPEX-P® to take, and when and how to take it [see *Dosage and Administration (2)*].

Advise pregnant women and nursing mothers not to use ADIPEX-P® [see *Use in Specific Populations (8.1, 8.3)*].

Patients must be informed about the risks of use of phentermine (including the risks discussed in Warnings and Precautions), about the symptoms of potential adverse reactions and when to contact a physician and/or take other action. The risks include, but are not limited to:

- Development of primary pulmonary hypertension [see *Warnings and Precautions (5.2)*]
  - Development of serious valvular heart disease [see *Warnings and Precautions (5.3)*]
  - Effects on the ability to engage in potentially hazardous tasks [see *Warnings and Precautions (5.5)*]
  - The risk of an increase in blood pressure [see *Warnings and Precautions (5.8) and Adverse Reactions (6)*]
  - The risk of interactions [see *Contraindications (4), Warnings and Precautions (5) and Drug Interactions (7)*]
- See also, for example, *Adverse Reactions (6) and Use in Specific Populations (8)*.

The patients must also be informed about

- the potential for developing tolerance and actions if they suspect development of tolerance [see *Warnings and Precautions (5.4)*] and
- the risk of dependence and the potential consequences of abuse [see *Warnings and Precautions (5.6), Drug Abuse and Dependence (9), and Overdosage (10)*].

Tell patients to keep ADIPEX-P® in a safe place to prevent theft, accidental overdose, misuse or abuse. Selling or giving away ADIPEX-P® may harm others and is against the law.

All trademarks are the property of their respective owners.

Manufactured In Croatia By:

**Pliva Hrvatska d.o.o.**

Zagreb, Croatia

Manufactured For:

**Teva Select Brands**, Horsham, PA 19044

Division of Teva Pharmaceuticals USA, Inc.

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