

PART III: CONSUMER INFORMATION

Pr **MERIDIA**[®] sibutramine hydrochloride monohydrate

This leaflet is PART III of a three-part "Product Monograph" published when MERIDIA[®] was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about MERIDIA[®]. Contact your doctor or pharmacist if you have any questions about the drug.

The manufacturer of MERIDIA[®] offers a free weight management program, myDECISION[™]. To learn more about this program please visit the web site at www.mydecision.ca.

ABOUT THIS MEDICATION

What the medication is used for:

MERIDIA[®] (sibutramine hydrochloride monohydrate) is a once-daily prescription medication for weight loss and weight maintenance. It is to be used as part of a comprehensive weight management program supervised by your doctor, that includes a reduced calorie diet and appropriate physical activity. You will lose more weight if you increase your physical activity, in addition to eating sensibly. MERIDIA[®] can only be prescribed by a medical doctor.

MERIDIA[®] is for patients whose excess weight, in the opinion of their doctor, presents a health risk. MERIDIA[®] may be right for you if you are considerably overweight [a Body Mass Index (BMI) of 30 kg/m² or greater]. MERIDIA[®] may also be right for you if you are overweight (a BMI of 27 kg/m² or greater) in the presence of other risk factors (e.g., high blood pressure, diabetes, high cholesterol, large waist measurement). BMI is not a direct measurement of fat and therefore, these guidelines do not apply to athletes and pregnant women.

Your doctor may be equally concerned about where you are carrying your excess weight. Visceral fat, fat stored in your abdomen, is a significant health risk. The best indicator of visceral fat is abdominal circumference. This is measured at a point midway between your waist and below your ribcage. To be a health concern, a woman's abdominal circumference would exceed 88 cm or 35 inches or for men greater than 102 cm or 40 inches.

How to determine your Body Mass Index (BMI):

BMI according to a variety of weights and heights is presented in the Table at the end of this leaflet. The BMI is calculated by dividing your weight in kilograms by your height in meters squared. To use this chart:

Find the weight closest to your weight in the left-hand column.

Then move across the top row to find the height closest to your

height.

The number where these two meet is your BMI. (For example, a person who weighs 180 lbs and is 5'5", would have a BMI of 30, as would a person 6'0" and 220 lbs, or a person 5'1" and 160 lbs).

What it does:

MERIDIA[®] works by making you feel full sooner. MERIDIA[®] is not an amphetamine-type drug. Hunger will continue to tell you when to eat, but MERIDIA[®] will help you to be satisfied to eat less food.

MERIDIA[®] is prescribed to help you to be more successful losing and maintaining your weight loss, but you still need to do your part. MERIDIA[®] should be used as part of a comprehensive weight loss program supervised by your doctor, that includes a reduced calorie diet and appropriate physical activity.

Why should MERIDIA[®] be used as part of a weight management program?

Your excess weight is a result of a surplus of energy. The energy that you consume as food has been greater than the energy that you expend such as through physical activity. To lose weight and to maintain a weight loss you need to reverse this imbalance. As you increase your physical activity and decrease the amount of food you eat, you increase the energy deficit and the amount of fat you can lose. MERIDIA[®] makes it easier for you to be successful. You must do your part.

How long does it take for MERIDIA[®] to begin to work?

Every person will respond differently to MERIDIA[®] when used as part of a comprehensive weight-loss program. If you do your part, MERIDIA[®] will help. You may be able to lose 4 or more pounds (1.8 kg or more) in the first month you take MERIDIA[®]. If you find that you do not lose at least 4 pounds (1.8 kg) during the first month, your doctor may re-evaluate your situation. This may include a review of your entire weight management program, including your menu choices and level of physical activity. Your doctor may advise you to make other food choices or increase your physical activity. Alternatively your doctor may decide that it is appropriate to change your dose of MERIDIA[®] if your blood pressure and heart rate did not increase significantly.

Most people who lose weight on MERIDIA[®] lose it in the first 6 months of treatment. Your doctor may consider discontinuation of MERIDIA[®] if you have not achieved a clinically significant weight loss (at least 5% of initial body weight) within a period of three to six months.

What weight loss results have been observed with MERIDIA[®]?

Patients treated with MERIDIA[®] while on a reduced calorie diet, showed a significant weight loss during the first 6 months of treatment, and significant weight loss was maintained for one year. In one 12-month study, the average weight loss in patients

taking MERIDIA[®], 10 mg daily, was about 10 lbs. and in those taking 15 mg daily was about 14 lbs. The average weight loss in persons on only a reduced calorie diet was 3.5 lbs.

In order to achieve long-term maintenance of weight loss, you must change your lifestyle while taking MERIDIA[®] so that you are able to maintain your weight upon cessation of drug treatment. When MERIDIA[®] therapy is stopped, most patients will regain weight unless they have changed their eating habits, as well as increased their level of physical activity.

When it should not be used:

MERIDIA[®] must not be taken by people who:

- Are, in the opinion of their doctor, not medically at risk because of their excess weight.
- Have a diagnosis of coronary artery disease and/or who have angina pectoris (heart-related chest pain).
- Have arrhythmias (irregular heart beats).
- Have had a prior heart attack.
- Have a diagnosis of congestive heart failure.
- Have had a stroke or symptoms of a stroke [transient ischemic attacks (TIAs)].
- Have uncontrolled or poorly controlled high blood pressure because MERIDIA[®] substantially increases blood pressure in some patients.
- Have a diagnosis of depression or any other psychiatric illness.
- Are taking prescription medications for depression or any other psychiatric illnesses
- Are taking prescription medicines called monoamine oxidase inhibitors (MAOIs) for depression, Parkinson’s Disease, or any other disorder [for example: Eldepryl[®] (no longer available in Canada), Parnate[®], Nardil[®], Manerix
- Are taking other medications that regulate the neurotransmitter serotonin in the brain (for example: Prozac[®], Zoloft[®], Effexor[®], Luvox[®], or Paxil[®]), including herbal remedies (such as St John’s Wort).
- Are taking other weight loss medications that act on the brain (for example: phentermine). This includes prescription and over-the-counter medications and herbal products.
- Are suffering from anorexia nervosa or bulimia nervosa.
- Have had prior allergic reactions to MERIDIA[®] or sibutramine.
- Have severe liver disease
- Have any kidney disease.
- Are pregnant or planning to become pregnant.
- Are breast-feeding their infants.
- Have had seizures (epilepsy or convulsions).
- Have an eye disorder called narrow angle glaucoma.
- Are under 18 years of age.
- Are over 65 years of age.

If you have any concerns or questions about whether or not you should take MERIDIA[®], talk to your doctor.

IMPORTANT: It is very important that you make sure that your primary care doctor and all your other health care providers know

what medications you take and what medical conditions and allergies you have.

What the medicinal ingredient is:

sibutramine hydrochloride monohydrate

What the non-medicinal ingredients are:

MERIDIA[®] contains the following non-medicinal ingredients: colloidal silicon dioxide, D&C Yellow No. 10 (15 mg capsules only), FD&C Blue No. 2 (10 mg capsules only), gelatin, lactose monohydrate, magnesium stearate, microcrystalline cellulose, printing ink, silicon dioxide, sodium lauryl sulphate, and titanium dioxide.

What dosage forms it comes in:

10 and 15 mg Capsules

WARNINGS AND PRECAUTIONS

BEFORE you use MERIDIA[®] talk to your doctor or pharmacist if:

It is important that you tell your doctor all about your medical history, whether you are taking or have taken weight loss drugs in the past, current medical problems, current symptoms, what other medications you take or have taken (prescription and over-the-counter medicines and herbal products) and any prior allergies to medicines.

It is important to make sure your doctor knows if you have heart disease of any kind, high blood pressure, migraine headaches, glaucoma, seizures, depression, any psychiatric illness, Parkinson’s Disease, prior strokes, prior transient ischemic attacks (TIAs), thyroid disorders, osteoporosis, gallstones, liver disease, kidney disease, history of a major eating disorder (anorexia nervosa or bulimia nervosa) or any other medical problem.

What if I am pregnant or nursing?

MERIDIA[®] should not be used by pregnant women or nursing mothers. You should notify your doctor immediately if you become pregnant or plan to become pregnant.

What about pregnancy?

Women of child bearing potential should use an effective birth control method while taking MERIDIA[®]. Check with your doctor to make sure you are on a medically safe and effective birth control method while taking MERIDIA[®].

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with MERIDIA[®] include:

You cannot take MERIDIA[®] if you are taking prescription medicines called monoamine oxidase inhibitors (MAOIs). It is especially important to make sure you tell your doctor if you are taking MAOIs that are sometimes used to treat depression or Parkinson's Disease [for example: Eldepryl[®] (no longer available in Canada), Nardil[®], Parnate[®], Manerix[®]]. This is very important because serious, sometimes even fatal, reactions can occur if MERIDIA[®] is taken at the same time MAOIs are taken.

If you are currently taking an MAOI, your doctor will want you to stop taking it for at least two (2) full weeks before starting you on MERIDIA[®].

If you are currently taking MERIDIA[®], your doctor will want you to stop taking it for at least two (2) full weeks before starting you on an MAOI.

MERIDIA[®] must not be taken if you are taking other weight loss medications that act on the brain (for example: phentermine). This includes both prescription and over-the-counter medications and herbal products.

In addition to the above, a rare, but serious medical syndrome called the "serotonin syndrome" has been reported in patients when medications like MERIDIA[®] are taken along with other drugs that may alter serotonin activity such as: drugs for depression [for example: Desyre[®], Effexor[®], Eldepryl[®] (no longer available in Canada), Serzone[®] (no longer available in Canada), Nardil[®], Parnate[®], Paxil[®], Prozac[®], Zoloft[®], Ludiomil[®] (no longer available in Canada), Asendin[™] (no longer available in Canada), Elavil[®], Etrafon[®] (no longer available in Canada), Norpramin[®], Sinequan[®], Surmontil[®], Tofranil[®], Triavil[™] (no longer available in Canada), Luvox[®], Anafranil[®], Manerix[®]], drugs for migraine headache therapy (Imitrex[®], Maxalt[®], Zomig[®], Amerge[®]) and dihydroergotamine, certain pain medications such as Demerol[®] (meperidine), Duragesic[®] (fentanyl), and Talwin[®] (pentazocine); the cough suppressant dextromethorphan found in many cough medicines; lithium; and the amino acid tryptophan. The serotonin syndrome requires immediate medical attention and may include one or more of the following symptoms: restlessness, loss of consciousness, confusion, disorientation, anxiety, agitation, weakness, tremor, incoordination, fever, shivering, sweating, vomiting and increased heart rate.

MERIDIA[®] must not be taken with medications used to treat depression or other psychiatric illnesses.

MERIDIA[®] must not be taken with St. John's Wort.

Many over-the-counter decongestants, cough, cold and allergy remedies, containing medicines such as phenylpropanolamine (no longer available in Canada), ephedrine, or pseudoephedrine, as well as certain anti-inflammatory drugs (e.g. NSAIDs) may increase blood pressure or heart rate. Before taking these medications on your own, you should check with your doctor to make sure it is all right to take these medicines if you are already taking MERIDIA[®]. Your doctor may advise you to take a certain

type of cough, cold, decongestant or allergy medicine that will not interact with MERIDIA[®].

Will MERIDIA[®] change the way I need to take nutritional supplements?

Nutritional supplements, like vitamins, minerals and amino acids (with the exception of tryptophan) can be used along with MERIDIA[®]. You should make sure your doctor knows what nutritional supplements you are taking and why you are taking them. You should not take MERIDIA[®] if you are taking tryptophan. You should not use herbal or over-the-counter weight loss products while taking MERIDIA[®].

What about drinking alcoholic beverages?

MERIDIA[®] may increase the sedative effects of alcohol. It is important that you let your doctor know how often, and what type of alcoholic beverages you drink. In addition, alcohol will increase your caloric intake without providing nutritional value, making it more difficult to lose weight.

What about drinking coffee, tea and caffeinated beverages?

MERIDIA[®] can be safely taken with moderate use of coffee, tea or caffeinated beverages. You should check with your doctor to make sure that you do not have a medical condition that can be aggravated by these beverages independent of being on MERIDIA[®]. You should check with your doctor if you consume a great deal of caffeinated beverages or use over-the-counter pills that contain caffeine.

Will MERIDIA[®] affect the effectiveness of birth control pills?

No.

PROPER USE OF THIS MEDICATION

Usual dose:

The recommended dose, as directed by your physician, should be taken once daily in the morning. MERIDIA[®] should be swallowed whole. You may take MERIDIA[®] on an empty stomach or after a meal.

How long should I take MERIDIA[®]?

You should continue to take MERIDIA[®] while you are losing weight or continuing to maintain your weight loss. Your doctor will determine how long you should take MERIDIA[®]. Follow your doctor's advice.

The safety and effectiveness of MERIDIA[®] when taken for more than one year have not been determined.

Overdose:

In the case of an overdose, immediately speak with your doctor and/or go to the nearest emergency room for immediate medical

attention. If you are unable to reach a doctor or emergency room, call your local Poison Information Center (see the front page of your local phone directory).

Missed Dose:

If you forget to take a dose of MERIDIA[®], take the next dose the next morning. Do not take an extra capsule to “make up” for the dose that you missed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

What are some of the more common side effects of MERIDIA[®]?

MERIDIA[®], like all medications, may cause side effects. In studies the most common side effects were: dry mouth, anorexia, insomnia (inability to fall asleep) and constipation. Other side effects that may occur include: increased sweating, an increase in blood pressure, and an increase in heart rate. These side effects are generally mild, and have usually not caused people to stop taking MERIDIA[®].

Does MERIDIA[®] affect blood pressure or heart rate?

MERIDIA[®] substantially increases blood pressure and heart rate in some patients. Blood pressure increases may be smaller or less likely to occur if you succeed in losing weight.

Because increases in blood pressure are not experienced as a bothersome side effect, you will have to have your blood pressure checked on a regular basis while you are taking MERIDIA[®]. Your blood pressure and pulse should be measured prior to starting MERIDIA[®], and you will be required to visit your doctor for follow-up every two weeks during the first three months of therapy and once every 1-3 months thereafter for as long as you are taking MERIDIA[®]. If you experience a significant increase in blood pressure or heart rate while taking MERIDIA[®], your doctor may decide to decrease the dose or discontinue MERIDIA[®].

If you have well controlled high blood pressure, before starting to take MERIDIA[®] you will also have to have your blood pressure checked on a regular basis by your doctor. You should not take MERIDIA[®] if you have uncontrolled or poorly controlled high blood pressure.

Does MERIDIA[®] cause damage to the heart valves?

Certain weight loss drugs have been associated with cardiac valve dysfunction (heart valve disease). Patients in two MERIDIA[®] studies were examined by doctors who used cardiac ultrasound testing to carefully look at heart valve structure and function. In one study, 104 patients received MERIDIA[®] for 6 months. None of the patients had heart valve disease at 6 months. In another study, patients who had received either MERIDIA[®] or placebo (sugar pills) for periods of two weeks to 16 months were examined. Three out of 132 patients (2.3%) who had taken MERIDIA[®] and two out of 77 patients (2.6%) who had taken

placebo were found to have heart valve disease. In extensive postmarketing experience in other countries, including the U.S.A., there has been no increase in the incidence of cardiac valve disease. However, due to the limited number of patients studied, it is not yet known whether MERIDIA[®] may cause this condition.

When should I call my doctor?

It is important that you call your doctor immediately if you experience any symptoms or feelings that make you concerned about your health or a possible drug side effect. Let your doctor advise you on your concerns. If you experience any of the symptoms in the **SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM** Table below, stop taking MERIDIA[®] and notify your doctor immediately.

What about physician follow-up visits?

You should make sure you see your doctor as directed for regular follow-up visits where your doctor can follow your body weight, and carefully monitor your blood pressure and overall health as you try to lose weight and maintain weight loss. You will be required to visit your doctor once every two weeks for the first three months of MERIDIA[®] therapy and once every 1-3 months thereafter for as long as you are taking this medication.

What about driving a car or dangerous work activities?

Any drug that affects the central nervous system has the potential to impair judgement, thinking, coordination or motor skills. MERIDIA[®] should not interfere with your ability to drive your car. However, you should be on the alert for any signs of fatigue, sedation, or lack of alertness while driving or operating dangerous machinery.

You should check with your doctor if you have any questions with regard to your work and the use of MERIDIA[®].

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment	
		Only if severe	In all cases		
Common	Increase in blood pressure;		✓		
	Increase in heart rate;		✓		
	Light-headedness;	✓			
	Abdominal pain;	✓			
	Nausea.	✓			
Uncommon	Possible signs of serotonin syndrome: Rapid heart beats (over 100 beats per minute), restlessness, blackout spells, disorientation, mental confusion, anxiety, tremors, loss of muscle coordination, muscle stiffness or rigidity, high fever, dilated pupils, shivering, sweating, vomiting;			✓	
	Chest Pain;		✓		
	Pounding or irregular heartbeats;		✓		
	Seizures;			✓	
	Bleed or bruise easily;		✓		
	Trouble breathing/shortness of breath;		✓		
	Depression.		✓		

Additional side effects reported during post-marketing surveillance:

- Mental illnesses (thoughts of suicide, suicide and loss of contact with reality)

This is not a complete list of side effects. For any unexpected effects while taking MERIDIA®, contact your doctor or

pharmacist.

What if I develop allergic reactions?

Stop taking MERIDIA® and notify your doctor immediately if you develop a skin rash, hives or other allergic reactions.

Does MERIDIA® cause primary pulmonary hypertension (PPH)?

Certain other weight loss drugs have been associated with primary pulmonary hypertension (PPH), a rare but sometimes fatal disease. MERIDIA® works in a slightly different way from those weight loss medications. In clinical studies, no cases of PPH have been reported with MERIDIA®. Because this disease is so rare, however, it is not known whether or not MERIDIA® may cause this disease.

The first symptom of PPH is usually shortness of breath. If you experience new or worsening shortness of breath, or if you experience chest pain, fainting, or swelling of your feet, ankles, or legs, stop taking MERIDIA® and notify your doctor immediately.

HOW TO STORE IT

MERIDIA® should be stored at normal room temperature (15 to 25°C). Never leave MERIDIA® in hot or moist places.

It is important to keep MERIDIA® in a safe area where children cannot see or get it.

Never take more MERIDIA® than prescribed by your doctor.

You should never share MERIDIA® with a friend.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax: 866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information on this product, please contact the number below, 1-800-361-7852, or visit the website at www.abbott.ca.

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Amerge[®], Anafranil[®], Asendin[™], Demerol[®], Desyrel[®], Duragesic[®], Effexor[®], Elavil[®], Eldepryl[®], Etrafon[®], Imitrex[®], Ludiomil[®], Luvox[®], Manerix[®], Maxalt[®], Nardil[®], Norpramin[®], Parnate[®], Paxil[®], Prozac[®], Serzone[®], Sinequan[®], Surmontil[®], Talwin[®], Tofranil[®], Triavil[™], Zoloft[®] and Zomig[®] are trademarks of their respective owners and are not trademarks of Abbott Laboratories, Limited.

		HEIGHT, ft/in (m)																
		4'10" (1.47)	4'11" (1.50)	5'0" (1.52)	5'1" (1.55)	5'2" (1.57)	5'3" (1.60)	5'4" (1.63)	5'5" (1.65)	5'6" (1.68)	5'7" (1.70)	5'8" (1.73)	5'9" (1.75)	5'10" (1.78)	5'11" (1.80)	6'0" (1.83)	6'1" (1.85)	6'2" (1.88)
WEIGHT, lb (kg)	120 (54.5)	25	24	23	23	22	21	21	20	19	19	18	18	17	17	16	16	15
	130 (59.1)	27	26	25	25	24	23	22	22	21	20	20	19	19	18	18	17	17
	140 (63.6)	29	28	27	27	26	25	24	23	23	22	21	21	20	20	19	19	18
	150 (68.2)	31	30	29	28	27	27	26	25	24	24	23	22	22	21	20	20	19
	160 (72.7)	34	32	31	30	29	28	28	27	26	25	24	24	23	22	22	21	21
	170 (77.3)	36	34	33	32	31	30	29	28	27	27	26	25	24	24	23	22	21
	180 (81.8)	38	36	35	34	33	32	31	30	29	28	27	27	26	25	24	24	23
	190 (86.4)	40	38	37	36	35	34	33	32	31	30	29	28	27	27	26	25	24
	200 (90.9)	42	40	39	38	37	36	34	33	32	31	30	30	29	28	27	26	26
	210 (95.5)	44	43	41	40	38	37	36	35	34	33	32	31	30	29	29	28	27
	220 (100.0)	46	45	43	42	40	39	38	37	36	35	34	33	32	31	30	29	28
	230 (104.5)	48	47	45	44	42	41	40	38	37	36	35	34	33	32	31	30	30
	240 (109.1)	50	49	47	45	44	43	41	40	39	38	37	36	35	34	33	32	31
	250 (113.6)	52	51	49	47	46	44	43	42	40	39	38	37	36	35	34	33	32
	260 (118.2)	54	53	51	43	48	46	45	43	42	41	40	38	37	36	35	34	33
	270 (122.7)	57	55	53	51	49	48	46	45	44	42	41	40	39	38	37	36	35
	280 (127.3)	59	57	55	53	51	50	48	47	45	44	43	41	40	39	38	37	36
290 (131.8)	61	59	57	55	53	51	50	48	47	46	44	43	42	41	39	38	37	
300 (136.4)	63	61	59	57	55	53	52	50	49	47	46	44	43	42	41	40	39	
310 (140.9)	65	63	61	59	57	55	53	52	50	49	47	46	45	43	42	41	40	
320 (145.5)	67	65	63	61	59	57	55	53	52	50	49	47	46	45	43	42	41	

- Patients with BMI values ≥ 30 may be candidates for MERIDIA[®] therapy.
- Patients with BMI values of 27 to 29 may be candidates for MERIDIA[®] therapy if they also have a concomitant risk factor (e.g., high blood pressure, diabetes, high cholesterol, large waist measurement).