Clinical Applications for the use of Pharmacotherapy in Australian General Practice

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Disclosures: Professor John B Dixon

Apollo Endosurgery	Consultant
Bariatric Advantage	Consultant
BUPA	Research Support
I-Nova	Consultant
Medtronics	Consultant
Nestle Health Science	Consultant
NHMRC	Research Support
Nova Nordisk	Advisory board and speaker fees
Novartis	Advisory board and speaker fees

Pharmacotherapy for obesity
AFP July 2017

Lee, P. C. and J. Dixon (2017). "Pharmacotherapy for obesity." Aust Fam Physician **46**(7): 472-477.

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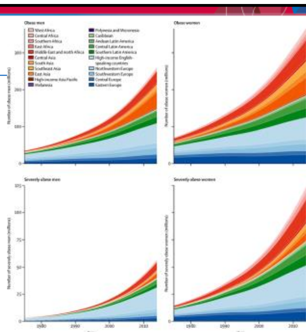
Global & Regional Obesity

High income English speaking countries

BLUE

Global & Regional Severe obesity



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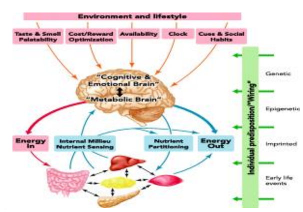
Schematic diagram showing the major factors determining neural control of appetite and regulation of energy balance



Unfortunately a rise in weight (fat) is defended just as a rise in blood pressure is defended

Huiyuan Zheng, and Hans-Rudi Berthoud Physiology 2008;23:75-83

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ANNALS OF THE NEW YORK ACADEMY OF SCIENCES
Issue: The Year in Diabetes and Obesity

Managing obesity in primary care practice: a narrative review

Raymond Carvajal,[1] Thomas A. Wadden,[1] Adam G. Tsai,[2] Katherine Peck,[1] and Caroline H. Moran[1]

Clinically meaningful weight loss results are not achieved in the primary care setting– 1-3% at 6 months to 2 years

These quite intensive combination behavioural programs struggle to achieve 5% or 5kg weight loss

Achieving 5% is currently not achievable for the majority at 12 months and less likely at 2-years

Carvajal et al. Ann NY Acad Sci 2013;1281;191-206.

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Benefits of modest weight loss 5-10%

Obesity complication	Weight loss required for therapeutic benefit (%)	Notes	References
Diabetes (prevention)	3–10	Maximum benefit at 10%	DPP Research Group, 2009 (63) Garvey et al., 2014 (64)
Hypertension	5 to >15	Blood pressure still decreasing at >15%	Wing et al., 2011 (65)
Dyslipidemia	[illegible] >15	[illegible] still decreasing at >15%	Wing et al., 2011 (65)
Hyperglycemia (elevated A1C)	3 to >15	A1C still decreasing at >15%	Wing et al., 2011 (65)
NAFLD	10	[illegible] mild fibrosis	[illegible] Patel et al., 2009 (68)
Sleep apnea	10	[illegible]	Foster et al., 2009 (69) Winslow et al., 2012 (70)
Osteoarthritis	5–10	Improves symptoms and joint stress mechanics	Christensen et al., 2007 (71) Felson et al., 1992 (72) Aaboe et al., 2011 (73)
Stress incontinence	5–10		Burgio et al., 2007 (74) Subak et al., 2009 (75)
Gastroesophageal reflex disease	5–10 in women; 10 in men		Singh et al., 2013 (76) Tutuian, 2011 (77)
Polycystic ovary syndrome	5–15 (>10 optimal)	Lowers androgens, improves ovulation, and increases insulin sensitivity	Panidis et al., 2008 (78) Norman et al., 2002 (79) Moran et al., 2013 (80)

The US FDA, EMA and our TGA use these cutpoints in assessing drug efficacy

Cefalu WT, Bray GA, Home PD, et al. *Diabetes care.* Aug 2015;38(8):1567-1582.

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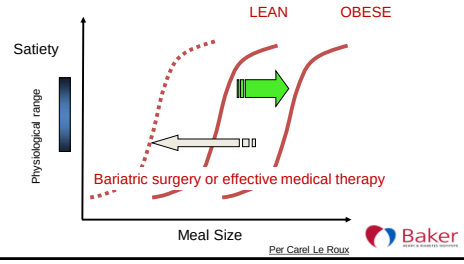
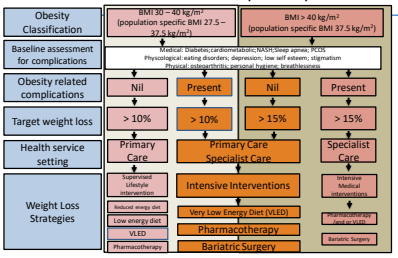
Dose response curve
"A change in regulation"



Per Carel Le Roux

The Australian Diabetes Society Obesity Treatment Algorithm[1]



Developed in conjunction with ANZOS and representatives from RACGP

1. https://diabetessociety.com.au/documents/ObesityManagementAlgorithm18.10.2016FINAL.pdf

Indications for weight management pharmacotherapy[1,2]

BMI >30 kg/m², or those with a

BMI of 27–30 kg/m² with obesity-related risks and complications.

Lower BMI thresholds (BMI >27 kg/m², or BMI >25 kg/m² with obesity-related complications) should be considered in Aboriginal and Torres Strait Islander and Asian populations.

1. National Health and Medical Research Council (2013) *Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia.* Melbourne
2. https://diabetessociety.com.au/documents/ObesityManagementAlgorithm18.10.2016FINAL.pdf

The importance of a stopping rule

There is no point

- in taking a drug that is not effective
- in continuing a drug that produces unacceptable side-effects
- In taking drug if it increases net risk of future disease

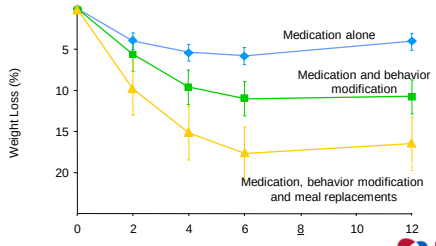
There is no point

- in stopping an effective drug if well tolerated and reduces risk

3-months on the full dose is usually a sufficient time to assess effectiveness

In chronic disease management we often combine therapy for greater efficacy so we need additional time if we increase therapy when synergy is expected

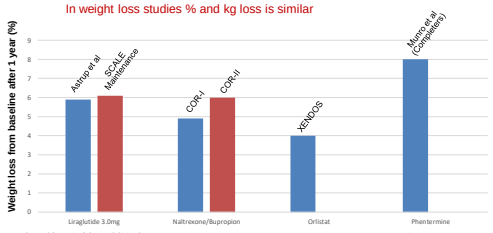
Additive Effects of Behavior and Meal Replacement Therapy With Pharmacotherapy for Obesity



Wadden et al. *Arch Intern Med* 2001;161:218.

Comparison of weight loss medications at 1-year (placebo subtracted – ITT – LOCF)

In weight loss studies % and kg loss is similar



Adapted from Cefalu et al (2015)

Cefalu WT, Bray GA, Home PD, et al. *Diabetes care.* Aug 2015;38(8):1567-1582.

I am going to focus on the use of the 4 approved drugs we have available in Australia today

Orlistat (Xenical, Alli)
Phentermine (Duromine, Metermine)
Liraglutide (Saxenda)

Naltrexone-Bupropion (Contrave)

How to use them?

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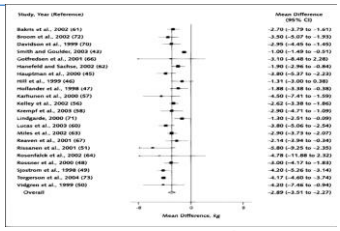
Orlistat
120mgs tds (oral)

ACTION

Inhibits intestinal lipase - reduces fat absorption by 30%

Efficacy

2.89% weight loss (2.3-3.5%)



Li, Z. et. al. Ann Intern Med 2005;142:532-546

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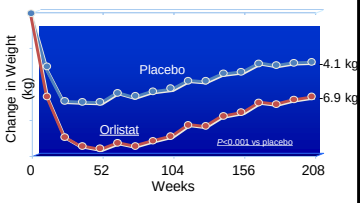
Orlistat prevention of diabetes study

XENDOS **n=3305 lifestyle plus orlistat 120x3/day or placebo x3/day**

4-year, double-blind, prospective study

BMI >/=30 kg/m2 and normal (79%) or impaired (21%) glucose tolerance (IGT)

Primary endpoints were time to onset of type 2 diabetes and change in body weight.



Torgerson JS. Et al. Diabetes Care 2004;27:155-61.

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Results at 4 years

52% completed in the treatment group compared with 34% of placebo recipients (P < 0.0001)

Diabetes incidence 9.0% with placebo and 6.2% with Orlistat a risk reduction of 37.3% (P = 0.0032)

Orlistat plus lifestyle changes resulted in a greater weight loss and reduction in the incidence of type 2 diabetes.

The latter restricted to the IGT group

Torgerson JS. Et al. Diabetes Care 2004;27:155-61.

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Side effects – related to fat malabsorption

- Steatorrhea, oily spotting, bloating and flatulence with discharge, faecal incontinence
  - Effects attenuated on a low fat diet
- Oxalate kidney stones – associated with fat malabsorption
- Fat-soluble vitamin deficiency – in the long term
  - Supplement and use caution with patients on warfarin

Drew, B. S., et al. (2007). "Obesity management: update on orlistat." Vasc Health Risk Manag **3**(6): 817-821.

- This drug is well tolerated in the long term and has beyond weight loss benefits in those with type-2 diabetes

Jacob S, Rabbia M, Meier MK, Hauptman J. Orlistat 120 mg improves glycaemic control in type 2 diabetic patients with or without concurrent weight loss. Diabetes Obes Metab 2009;11(4):361–71.

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All other medications act centrally to reduce energy intake

When asked "What is the effect of the drug ?" obese patients treated with anti-obesity drugs offer a wide variety of answers such as:

"I don't eat as much"

"I can stop eating"

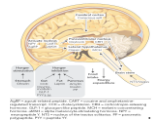
"I don't graze all day and night"

"I'm not hungry as soon as I stop eating"

"I am not food focused"

"I feel in control"

"I'm normal" (in respect to eating).



3 - Factor eating questionnaire

Improved cognitive restraint

Lower levels disinhibition

Reduced hunger

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Phentermine
15mgs , 30mgs, 40mgs (oral)
Prepared with a slow release resin – single daily dosage

Approved in the 1960s this drug has been the most commonly used weight management drug in Australia and the United states for decades

ACTION

Phentermine is a sympathomimetic amine with significant anorectic activity in animal models.

It's appetite suppressant effect is generally considered to be exerted through the hypothalamus, but it is not certain that this is the only effect related to weight loss.

EVIDENCE

Differences in weight loss at 6 months of 3.6 – 4.5 kg or %WL for phentermine-treated patients vs placebo

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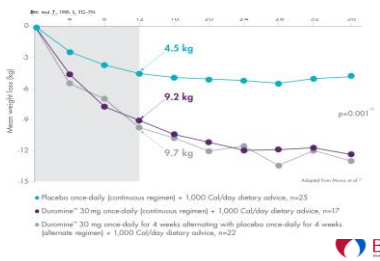
Comparison of Continuous and Intermittent Anorectic Therapy in Obesity

J. F. MUNRO,* M.B., M.R.C.P.ED. ; A. C. MacCUISH,* M.B., CH.B.
ELIZABETH M. WILSON,* S.R.N. ; L. J. P. DUNCAN,* M.B., B.SC., F.R.C.P.ED



- Placebo once-daily (continuous regimen) + 1,000 Cal/day dietary advice, n=25
- Duromine™ 30 mg once-daily (continuous regimen) + 1,000 Cal/day dietary advice, n=17
- Duromine™ 30 mg once-daily for 4 weeks alternating with placebo once-daily for 4 weeks (alternate regimen) + 1,000 Cal/day dietary advice, n=22

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Phentermine Contraindications and Precautions

Unstable hypertension, history of heart disease, hyperthyroidism, anxiety disorders, Hx of Drug & Alcohol abuse, Major psychiatric illness, pregnancy, breast feeding, MAOIs, and glaucoma

- Caution with combined use with SSRI's , ergot drugs, and clomipramine

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Phentermine

It is primarily a sympathomimetic

It's effects on dopamine and serotonin are trivial

Therefore it has little or no addictive potential

While it may be expected in some to raise blood pressure there is no clear evidence that it does

No evidence of increased CV risk

There is generally the expected fall in BP associated with weight loss

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Phentermine Treatment

Start with Duromine 15 mg/day.

Most adult patients tolerate 30 mg/day some may need 40mg

Evaluate for adverse effects.

Evaluate for effectiveness

- Weight loss
- Eating behavior – smaller meals – satiety – hunger - control

I recommend taking the dose in the morning

Titrate dose to effectiveness

- Tachyphylaxis with lower effect
- Higher doses can be used – up to 40 mg

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Side Effects

Common

- Dry mouth - usually tolerable
- Insomnia – typically fades quickly
- Increased energy
- Feeling anxious / palpitations
- Other – e.g. constipation

Warn patients of these common early issues
They usually resolve spontaneously

Less Common

- Impotence, decreased sex drive
- Irritability
- Mood elevation

If phentermine is effective and there are no adverse effects it can be continued

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Liraglutide 3mg for weight management
(TGA approved December 2015)

Liraglutide 3.0 mg	Liraglutide is a human glucagon-like peptide (GLP-1) analogue, with 97% amino acid sequence homology to endogenous human GLP-1 Like endogenous GLP-1, liraglutide binds to and activates the GLP-1 receptor (GLP-1R) GLP-1 is a physiological regulator of appetite and calorie intake

GLP-1 is hormone secreted from the distil gut in response to a meal
Slows gastric emptying = sense of fullness
Satiation
Central action to reduce hunger and provide prolonged satiety

Saxenda® Approved Product Information, December 2015

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Weight loss with liraglutide 3.0 mg

Significantly greater and clinically meaningful weight loss in a wide range of patients

Obesity and prediabetes patient population1,2	**8.0%** at week 56 compared with 2.6% in the placebo group (p<0.0001)
Type 2 diabetes population1,3	**6.0%** at week 56 compared with 2.0% in the placebo group (p<0.0001)
Obstructive sleep apnoea population1	**5.7%** at week 32 compared with 1.6% in the placebo group (p<0.0001)

Treatment arm = Liraglutide 3.0 mg plus diet and exercise; Placebo = diet and exercise alone; Data are for patients in the full analysis set, with last observation carried forward; Changes from baseline are estimated mean weight loss

1. Saxenda® Approved Product Information, December 2015. 2. Pi-Sunyer X et al. N Engl J Med 2015;373:11–22. 3. Davies ML et al. JAMA. 2015;314(7):687–699.

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Liraglutide weight-loss review

Patients who lost at least 5% of baseline weight after 16 weeks of treatment on average lost 11.2% of their baseline weight at week 56

Review progress at 16 weeks	Treatment with Saxenda® should be discontinued after 12 weeks (at week 16) on the 3.0 mg/day dose if a patient has not lost at least 5% of their initial body weight
Re-evaluate annually	The need for continuous use annually Long-term use should be informed by the limited long-term efficacy and safety data which are only documented for 1 year

Saxenda® Approved Product Information, December 2015. Pi-Sunyer X et al. N Engl J Med 2015;373:11–22.

Baker

Summary of liraglutide 3.0 mg safety profile

GI side effects are common	Most episodes of GI events were mild to moderate, transient and the majority did not lead to discontinuation of therapy
Dehydration	Potential risk of dehydration in relation to GI side effects
Gallbladder-related events	Associated with above average weight loss
Low rates of pancreatitis	Mild grade and of short duration Half the liraglutide-associated pancreatitis cases were associated with gallstones

Pi-Sunyer X et al. N Engl J Med 2015;373:11–22; Saxenda® Approved Product Information, December 2015

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Contrave PHYSICIAN PRESCRIBING CHECKLIST

Contrave is indicated, as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥ 18 years) with an initial Body Mass Index (BMI) of ≥ 30 kg/m² (obese), or ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidaemia, or controlled hypertension).

Treatment with Contrave should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight.

PATIENT DETAILS

Male ☐ Female ☐ If female, check whether there is any possibility of pregnancy as Contrave must NOT be taken during pregnancy or when breast-feeding

Age (yrs) ☐ Weight (kg) ☐ Height (m) ☐ BMI (kg/m²) ☐

Hypertension ☐ Smoking ☐ Diabetes ☐ Other CHD risk factor ☐
Hypercholesterolaemia ☐ Low HDL ☐ Hypertriglyceridaemia ☐ Current BP (mm Hg) ☐

DOES THE PATIENT HAVE:	NO	YES
Uncontrolled hypertension?		
Current seizure disorder, history of seizures or known CNS tumour?		
Current or previous diagnosis of bulimia or anorexia nervosa?		
Current dependence on chronic opioids or opiate agonists?		
Ongoing acute alcohol, benzodiazepine or opioid withdrawal treatment?		
Current treatment with bupropion or naltrexone?		
Hypersensitivity to the active ingredients or any of the excipients?		
History of bipolar disorder?		
Treatment with a MAOI within the last 14 days?		
End-stage renal failure?		
Severe hepatic impairment?		

Contraindications DO NOT PRESCRIBE

Contrave physician prescribing checklist cont…

DOES THE PATIENT HAVE:	NO	YES
Severe or moderate renal insufficiency? If diabetic or elderly patient or at risk for renal insufficiency, assess eGFR prior to initiating Contrave therapy		
Mild or moderate hepatic impairment		
Controlled hypertension		
Angina or recent history of myocardial infarction		
History of mania		
Suicidal ideation or history of attempted suicide (particularly in young people)		
Depression		
Cholecystitis		
Risk factors for seizures (e.g., history of head trauma, episodes of hypoglycaemia from diabetes treatment, concomitant medication that could lower the seizure threshold such as: antipsychotics, antidepressants, anti-malarials, tramadol, theophylline, systemic steroids, quinolones or sedating antihistamines?)		

Patients with any of these factors are at an increased risk of adverse reactions.

Treatment should only be initiated or maintained after full evaluation of the possible benefits and risks and review of Precautions section of the Product Information (PI).

MEDICINE INTERACTIONS:

The following are some of the common medicine interactions with Contrave. Refer to the Product Information (PI) for further information.

Monoamine oxidase inhibitors (MAOIs) ☐ Drugs that Lower Seizure Threshold ☐ CYP2B6 inducers ☐ CYP2B6 inhibitors ☐
Drugs Metabolised by CYP2D6 Substrates ☐ Opioid Analgesics ☐ Dopaminergic Drugs ☐ OCT2 Substrates ☐

TREAT WITH CONTRAVE Yes ☐ No ☐

Date ☐ Date of 16 week review ☐ Date of annual review ☐

Discontinue treatment if there are concerns with the safety or tolerability of ongoing treatment. The safety and efficacy of CONTRAVE for long term use (>1 year) has not been established.

CONTRAVE®[1]

CONTRAVE is available in a formulation of extended-release tablets that contain 8 mg naltrexone HCl and 90 mg bupropion HCl[1]:

Naltrexone HCl[2]

- An opioid receptor antagonist
- Indications: treatment of **alcohol dependence** and prevention of relapse to **opioid dependence**
- TGA approved since **1998**

Bupropion HCl[3]

- A dopamine and norepinephrine reuptake inhibitor
- Indications: as an adjunct to **smoking cessation in Australia**
- TGA approved since **2000.**

CONTRAVE is not approved for either of the naltrexone or bupropion indications as monotherapies

1. Contrave Approved Product Information

Indications and Usage of CONTRAVE®[1]

CONTRAVE® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for the management of weight in adult patients (≥ 18 years) with an initial body mass index (BMI) of:

- ≥30 kg/m^2 (obese), or
- ≥27 kg/m^2 to <30 kg/m^2 (overweight) in the presence of one or more weight-related comorbidities (e.g., type 2 diabetes, dyslipidemia or controlled hypertension)

1. Contrave Approved Product Information

Dosage and Administration of CONTRAVE®[1]

The maximum recommended daily dose of CONTRAVE is 2 tablets twice daily for a total dose of 32 mg naltrexone HCl and 360 mg bupropion HCl, which is reached at the start of week 4[1]

CONTRAVE® dosing should be escalated over a 4-week period		
	Morning	Evening
Week 1	1	
Week 2	1	1
Week 3	2	1
Week 4 and onwards	2	2

The need for treatment should be evaluated after 16 weeks and reevaluated annually.

Administration

- **CONTRAVE** tablets should be swallowed whole with some water. The tablets should preferably be taken with food. The tablets should not be cut, chewed, or crushed

1. Contrave Approved Product Information

Dosage and Administration of CONTRAVE®[1]

The need for continued treatment should be evaluated after 16 weeks and re-evaluated annually

<5% weight loss

Treatment with CONTRAVE should be discontinued if a patient has not lost at least 5% of baseline body weight at 16 weeks

≥5% weight loss

CONTINUE CONTRAVE if a patient has lost at least 5% of baseline body weight at 16 weeks

Clinically meaningful weight loss was defined as having achieved ≥5% weight loss at week 56.

1. Contrave Approved Product Information

Contraindications to Contrave[1]

- Uncontrolled hypertension
- Seizure disorder or a history of seizures
- Patients with known central nervous system tumour
- Patients undergoing acute alcohol or benzodiazepine withdrawal
- Patients with history of bipolar disorder
- Patients currently dependent on chronic opioids or opiate agonists (e.g., methadone), or patients with acute opiate withdrawal
- Pregnancy
- Patients with severe hepatic impairment
- Patients with end-stage renal failure

1. Contrave Approved Product Information

CONTRAVE® Precautions[1]

- **Suicide and suicidal behaviour**
- **Seizures**
  - History of head trauma
  - Excessive use of alcohol or addiction to cocaine or stimulants
  - Treatment with CONTRAVE may result in lowered blood glucose in patient with diabetes - the dose of insulin and/or diabetic medicinal products should be assessed to minimise the risk of hypoglycaemia, which could predispose patients to seizure
  - Concomitant administration of medicinal products that may lower the seizure threshold, including antipsychotics, antidepressants, antimalarials, tramadol, theophylline, systemic steroids, quinolones and sedating antihistamines
  - Consumption of alcohol during CONTRAVE® treatment should be minimised or avoided
- **Patients Receiving Opioid Analgesics**

CONTRAVE® Precautions[1]

- **Cardiovascular Disease** – There is no clinical experience establishing the safety of CONTRAVE in patients with a recent history of myocardial infarction, unstable heart disease or NYHA class III or IV congestive heart failure. Should not be used in following populations as no clinical experience establishing safety:
  - Recent History of MI
  - Unstable Heart Disease
  - NYHA Class III or IV Congestive Heart Failure
- **Hepatotoxicity**
- **Renal impairment**
- **Hepatic Impairment**
  - Not to be used in moderate - severe hepatic impairment
- **Neuropsychiatric Symptoms and Activation of Mania**
- **Drug Abuse and Dependence**

1. Contrave Approved Product Information.

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CONTRAVE PHYSICIAN PRESCRIBING CHECKLIST

Contrave (bupropion HCl/naltrexone HCl)

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Treatment with Contrave should be discontinued after 16 weeks if patients have not lost at least 5% of their initial body weight.

PATIENT DETAILS

Male ☐ Female ☐ If female, check whether there is any possibility of pregnancy as Contrave must NOT be taken during pregnancy or when breast-feeding

Age (yrs) ____ Weight (kg) ____ Height (m) ____ BMI (kg/m²) ____

Hypertension ☐ Smoking ☐ Diabetes ☐ Other CHD risk factor ____

Hypercholesterolaemia ☐ Low HDL ☐ Hypertriglyceridaemia ☐ Current BP (mm Hg) ____

DOES THE PATIENT HAVE:	NO	YES
Uncontrolled hypertension?		
Current seizure disorder, history of seizures or known CNS tumour?		
Current or previous diagnosis of bulimia or anorexia nervosa?		
Current dependence on chronic opioids or opiate agonists?		
Ongoing acute alcohol, benzodiazepine or opioid withdrawal treatment?		
Current treatment with bupropion or naltrexone?		
Hypersensitivity to the active ingredients or any of the excipients?		
History of bipolar disorder?		
Treatment with a MAOI within the last 14 days?		
End-stage renal failure?		
Severe hepatic impairment?		

Contraindications DO NOT PRESCRIBE

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Contrave physician prescribing checklist cont…

DOES THE PATIENT HAVE:	NO	YES
Severe or moderate renal insufficiency? If diabetic or elderly patient or at risk for renal insufficiency, assess eGFR prior to initiating Contrave therapy		
Mild or moderate hepatic impairment		
Controlled hypertension		
Angina or recent history of myocardial infarction		
History of mania		
Suicidal ideation or history of attempted suicide (particularly in young people)		
Depression		
Cholecystitis		
Risk factors for seizures (e.g., history of head trauma, episodes of hypoglycaemia from diabetes treatment, concomitant medication that could lower the seizure threshold such as: antipsychotics, antidepressants, anti-malarials, tramadol, theophylline, systemic steroids, quinolones or sedating antihistamines?)		

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Drugs Metabolised by CYP2D6 Substrates ☐ Opioid Analgesics ☐ Dopaminergic Drugs ☐ OCT2 Substrates ☐

TREAT WITH CONTRAVE Yes ☐ No ☐

Date ____ Date of 16 week review ____ Date of annual review ____

Discontinue treatment if there are concerns with the safety or tolerability of ongoing treatment. The safety and efficacy of CONTRAVE for long term use (>1 year) has not been established.

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Where and how do we use medications?

- If you cannot provide the behavioural program out source it
- To support weight loss and weight maintenance
- Reduce weight regain
  - Diets, VLCD, balloons, surgery, or any other ……
- The action plan always has short and long-term aims
- Combine medications to enhance effect and reduce individual doses
- Start low and go slow with the dosage
- Remember the stopping rule

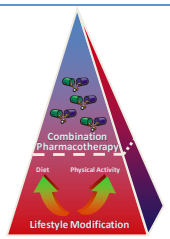
Baker

Obesity Treatment of the future

As for dysregulation of blood pressure and blood glucose we will need combination drug therapy with lifestyle interventions to successfully manage clinically severe obesity

Please be realistic with your goals:
Achieving >5% or 10% sustained weight generates major health benefits wherever your patient starts

Effective therapy and a sense of control is a lifestyle enabler
Just this time it may work!



Adapted from source: www.obesityonline.org

Baker