

driving or operating machinery); effects of alcohol and other CNS depressants enhanced.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Oral solution

CAUTIONARY AND ADVISORY LABELS 13, 19

ELECTROLYTES: May contain Sodium

► Sodium oxybate (Non-proprietary)

Sodium oxybate 500 mg per 1 ml Sodium oxybate 500mg/ml oral solution sugar-free | 180 ml [PoM] £324.00-£360.00 DT = £360.00 [CD2]

► Xyrem (UCB Pharma Ltd)

Sodium oxybate 500 mg per 1 ml Xyrem 500mg/ml oral solution sugar-free | 180 ml [PoM] £360.00 DT = £360.00 [CD2]

CNS STIMULANTS

Pitolisant

11-Apr-2017

- **DRUG ACTION** Pitolisant is a histamine H₃-receptor antagonist which enhances the activity of brain histaminergic neurons.

● INDICATIONS AND DOSE

Narcolepsy with or without cataplexy (initiated by a specialist)

► BY MOUTH

- **Adult:** Initially 9 mg once daily for 1 week, then increased if necessary to 18 mg once daily for 1 week, then increased if necessary to 36 mg once daily, dose to be taken in the morning with breakfast, dose can be decreased (down to 4.5 mg per day) or increased (up to 36 mg per day) according to response and tolerance

- **CAUTIONS** Acid-related gastric disorders · epilepsy · history of psychiatric disorders · severe anorexia · severe obesity
- **INTERACTIONS** → Appendix 1: pitolisant
- **SIDE-EFFECTS**
 - **Common or very common** Anxiety · asthenia · depression · dizziness · gastrointestinal discomfort · headaches · mood altered · nausea · sleep disorders · tremor · vertigo · vomiting
 - **Uncommon** Appetite abnormal · arrhythmias · arthralgia · blepharospasm · chest pain · concentration impaired · constipation · diarrhoea · drowsiness · dry mouth · epilepsy · feeling abnormal · fluid retention · gastrointestinal disorders · hallucinations · hot flush · hypertension · hypotension · malaise · metrorrhagia · movement disorders · muscle complaints · muscle weakness · oedema · on and off phenomenon · oral paraesthesia · pain · paraesthesia · QT interval prolongation · sexual dysfunction · skin reactions · sweat changes · tinnitus · urinary frequency increased · visual acuity decreased · weight decreased (review treatment if significant) · weight increased (review treatment if significant) · yawning
 - **Rare or very rare** Behaviour abnormal · cognitive impairment · confusion · loss of consciousness · memory loss · obsessive thoughts · photosensitivity reaction · sense of oppression · swallowing difficulty
- **CONCEPTION AND CONTRACEPTION** Manufacturer advises effective contraception in women of childbearing potential for at least 21 days after treatment discontinuation—pitolisant may reduce the effectiveness of hormonal contraceptives.
- **PREGNANCY** Manufacturer advises avoid unless potential benefit outweighs risk—toxicity in *animal* studies.
- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in moderate impairment; avoid in severe impairment.

Dose adjustments Manufacturer advises consider dose increase two weeks after initiation in moderate impairment; maximum daily dose of 18 mg.

● RENAL IMPAIRMENT

Dose adjustments Manufacturer advises use with caution; maximum daily dose should not exceed 18 mg.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Tablet

► Wakix (Lincoln Medical Ltd) ▼

Pitolisant (as Pitolisant hydrochloride) 4.5 mg Wakix 4.5mg tablets | 30 tablet [PoM] £310.00 DT = £310.00

Pitolisant (as Pitolisant hydrochloride) 18 mg Wakix 18mg tablets | 30 tablet [PoM] £310.00 DT = £310.00

CNS STIMULANTS > CENTRALLY ACTING SYMPATHOMIMETICS

Modafinil

10-Mar-2020

● INDICATIONS AND DOSE

Excessive sleepiness associated with narcolepsy with or without cataplexy

► BY MOUTH

- **Adult:** Initially 200 mg daily in 2 divided doses, dose to be taken in the morning and at noon, alternatively initially 200 mg once daily, dose to be taken in the morning, adjusted according to response to 200–400 mg daily in 2 divided doses, alternatively adjusted according to response to 200–400 mg once daily
- **Elderly:** Initially 100 mg daily

IMPORTANT SAFETY INFORMATION

MHRA/CHM ADVICE: MODAFINIL: POTENTIAL RISK OF CONGENITAL MALFORMATIONS DURING PREGNANCY (FEBRUARY 2020)

Post-marketing reports show that the use of modafinil in pregnancy is suspected to cause congenital malformations such as congenital heart defects, hypospadias, and orofacial clefts. Healthcare professionals are advised that modafinil is contra-indicated in pregnancy; alternative treatment options should be used, including behaviour modifying measures, sleep hygiene, and scheduled daytime naps. Females of childbearing potential should be advised on the use of contraception (see *Conception and Contraception*) and informed of the risk of congenital malformations.

- **CONTRA-INDICATIONS** Arrhythmia · history of clinically significant signs of CNS stimulant-induced mitral valve prolapse (including ischaemic ECG changes, chest pain and arrhythmias) · history of cor pulmonale · history of left ventricular hypertrophy · moderate to severe uncontrolled hypertension
- **CAUTIONS** History of alcohol abuse · history of depression · history of drug abuse · history of mania · history of psychosis · possibility of dependence
- **INTERACTIONS** → Appendix 1: modafinil
- **SIDE-EFFECTS**
 - **Common or very common** Anxiety · appetite abnormal · arrhythmias · asthenia · chest pain · confusion · constipation · depression · diarrhoea · dizziness · drowsiness · dry mouth · gastrointestinal discomfort · headaches · mood altered · nausea · palpitations · sensation abnormal · sleep disorders · thinking abnormal · vasodilation · vision disorders
 - **Uncommon** Allergic rhinitis · arthralgia · asthma · behaviour abnormal · central nervous system stimulation ·