

● SIDE-EFFECTS

- ▶ **Common or very common** Anxiety · appetite increased · arthralgia · back pain · confusion · constipation · diarrhoea · dizziness · drowsiness · dry mouth · fatigue · headache (on discontinuation) · myalgia · nausea · oedema · postural hypotension · sleep disorders · tremor · vomiting · weight increased
- ▶ **Uncommon** Hallucination · mania · movement disorders · oral disorders · syncope
- ▶ **Rare or very rare** Aggression · pancreatitis
- ▶ **Frequency not known** Agranulocytosis · arrhythmias · bone marrow disorders · dysarthria · eosinophilia · granulocytopenia · hyponatraemia · jaundice (discontinue) · QT interval prolongation · rhabdomyolysis · seizure · serotonin syndrome · severe cutaneous adverse reactions (SCARs) · SIADH · skin reactions · sudden death · suicidal tendencies · thrombocytopenia · urinary retention · withdrawal syndrome
- **PREGNANCY** Use with caution—limited experience; monitor neonate for withdrawal effects.
- **BREAST FEEDING** Present in milk; use only if potential benefit outweighs risk.
- **HEPATIC IMPAIRMENT** Manufacturer advises caution (risk of increased plasma concentration, no information available in severe impairment).
- **RENAL IMPAIRMENT** Clearance reduced by 30% if eGFR less than 40 mL/minute/1.73 m²; clearance reduced by 50% if eGFR less than 10 mL/minute/1.73 m².
- **TREATMENT CESSATION** Nausea, vomiting, dizziness, agitation, anxiety, and headache are most common features of withdrawal if treatment stopped abruptly or if dose reduced markedly; dose should be reduced over several weeks.
- **DIRECTIONS FOR ADMINISTRATION** Orodispersible tablet (*Zispin SolTab*[®]) should be placed on the tongue, allowed to disperse and swallowed.
- **PATIENT AND CARER ADVICE** Counselling on administration of orodispersible tablet advised. Blood Disorders Patients should be advised to report any fever, sore throat, stomatitis or other signs of infection during treatment. Blood count should be performed and the drug stopped immediately if blood dyscrasia suspected.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: capsule, oral suspension, oral solution

Tablet

CAUTIONARY AND ADVISORY LABELS 2, 25

▶ Mirtazapine (Non-proprietary)

Mirtazapine 15 mg Mirtazapine 15mg tablets | 28 tablet [PoM]
£4.60 DT = £2.88

Mirtazapine 30 mg Mirtazapine 30mg tablets | 28 tablet [PoM]
£4.50 DT = £2.48

Mirtazapine 45 mg Mirtazapine 45mg tablets | 28 tablet [PoM]
£6.00 DT = £2.60

Oral solution

CAUTIONARY AND ADVISORY LABELS 2

▶ Mirtazapine (Non-proprietary)

Mirtazapine 15 mg per 1 ml Mirtazapine 15mg/ml oral solution sugar free sugar-free | 66 ml [PoM] £57.45 DT = £54.45

Orodispersible tablet

CAUTIONARY AND ADVISORY LABELS 2

EXCIPIENTS: May contain Aspartame

▶ Mirtazapine (Non-proprietary)

Mirtazapine 15 mg Mirtazapine 15mg orodispersible tablets | 30 tablet [PoM] £19.19 DT = £1.72

Mirtazapine 30 mg Mirtazapine 30mg orodispersible tablets | 30 tablet [PoM] £19.19 DT = £1.76

Mirtazapine 45 mg Mirtazapine 45mg orodispersible tablets | 30 tablet [PoM] £19.19 DT = £2.14

▶ Zispin SolTab (Merck Sharp & Dohme Ltd)

Mirtazapine 15 mg Zispin SolTab 15mg orodispersible tablets | 30 tablet [PoM] £15.06 DT = £1.72

Mirtazapine 30 mg Zispin SolTab 30mg orodispersible tablets | 30 tablet [PoM] £15.06 DT = £1.76

Mirtazapine 45 mg Zispin SolTab 45mg orodispersible tablets | 30 tablet [PoM] £15.06 DT = £2.14

ANTIDEPRESSANTS > TRICYCLIC ANTIDEPRESSANTS

Amitriptyline hydrochloride

16-Jul-2019

● INDICATIONS AND DOSE

Abdominal pain or discomfort (in patients who have not responded to laxatives, loperamide, or antispasmodics)

▶ BY MOUTH

- ▶ **Adult:** Initially 5–10 mg daily, to be taken at night; increased in steps of 10 mg at least every 2 weeks as required; maximum 30 mg per day

Major depressive disorder [not recommended—increased risk of fatality in overdose]

▶ BY MOUTH

- ▶ **Adult:** Initially 50 mg daily in 2 divided doses, then increased in steps of 25 mg once daily on alternate days if required, maximum 150 mg daily in 2 divided doses
- ▶ **Elderly:** Initially 10–25 mg daily, increased if necessary up to 100–150 mg daily in 2 divided doses, dose increases dependent on individual patient response and tolerability—doses above 100 mg should be used with caution

Major depressive disorder in patients with cardiovascular disease [not recommended—increased risk of fatality in overdose]

▶ BY MOUTH

- ▶ **Adult:** Initially 10–25 mg daily, increased if necessary up to 100–150 mg daily in 2 divided doses, dose increases dependent on individual patient response and tolerability—doses above 100 mg should be used with caution

Neuropathic pain | Migraine prophylaxis | Chronic tension-type headache prophylaxis


▶ BY MOUTH

- ▶ **Adult:** Initially 10–25 mg daily, dose to be taken in the evening, then increased, if tolerated, in steps of 10–25 mg every 3–7 days in 1–2 divided doses; usual dose 25–75 mg daily, dose to be taken in the evening, doses above 100 mg should be used with caution (doses above 75 mg should be used with caution in the elderly and in patients with cardiovascular disease); maximum per dose 75 mg

Emotional lability in multiple sclerosis

▶ BY MOUTH

- ▶ **Adult:** Initially 10–25 mg daily; increased, if tolerated, in steps of 10–25 mg every 1–7 days; maximum 75 mg per day

- **UNLICENSED USE** Not licensed for use in abdominal pain or discomfort in patients who have not responded to laxatives, loperamide, or antispasmodics. [EvGr] Amitriptyline hydrochloride is used for emotional lability in multiple sclerosis,  but is not licensed for this indication.

- **CONTRA-INDICATIONS** Arrhythmias · during manic phase of bipolar disorder · heart block · immediate recovery period after myocardial infarction

- **CAUTIONS** Cardiovascular disease · chronic constipation · diabetes · epilepsy · history of bipolar disorder · history of psychosis · hyperthyroidism (risk of arrhythmias) · increased intra-ocular pressure · patients with a significant risk of suicide · phaeochromocytoma (risk of arrhythmias) · prostatic hypertrophy · susceptibility to angle-closure glaucoma · urinary retention