Mental health & swallowing difficulties

Rosemont®

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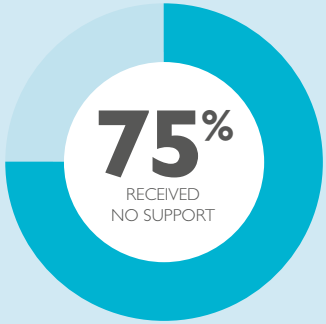
Mental health is a world-wide issue. The World Health Organisation suggests that 280 million people are affected by depression, 40 million by bipolar affective disorder and 24 million by schizophrenia[1].

In the UK, mental health problems are the largest single source of disability[2,3]. One assessment concluded that three quarters of people with mental health problems received no support at all[3], despite mental illness accounting for nearly half of all ill health in people under 65[4].

20% of older people living in the community and 40% of care home residents are affected by depression[3] and one in four UK adults experiences a diagnosable mental health problem in any given year[3]. 70 million working days are lost annually due to mental health problems[5] and the Centre for Mental Health has suggested that the cost to the economy in England alone equates to over £105 billion[6].

The consequences of poor mental health are considerable and not always obvious. Physical and mental health are closely linked and those individuals with severe and prolonged mental illness are at risk of dying on average 15 to 20 years earlier than other people[3]. Healthcare costs for those with co-existing mental health problems and long-term conditions are around 50% higher than the general population[7].

IN THE UK



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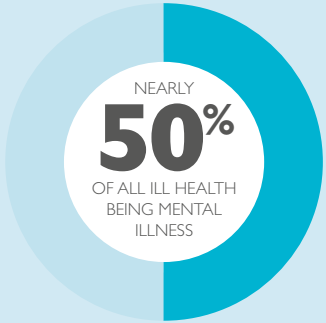
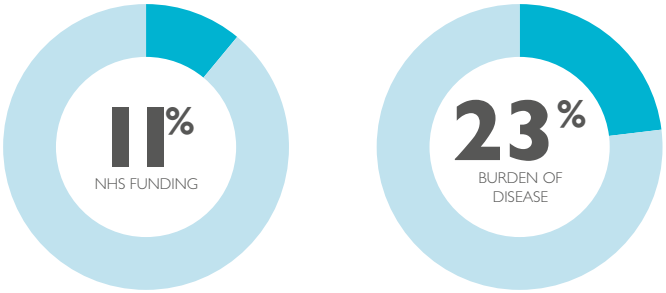


In the past, people with mental health problems have experienced stigma and discrimination, with many struggling to get the right help at the right time[3].

Historically, the NHS has treated their minds and bodies separately and services have been significantly underfunded[3]. Spending on mental health has equated to approximately 11% of the NHS budget, despite accounting for 23% of the burden of disease in the UK[8].



This is now changing. Public attitudes toward mental health are more accepting and the NHS Long Term Plan suggests a shift towards a 'whole person' approach, with a commitment to put mental healthcare on a level footing with physical health services[9]. NHS England's Five Year Forward View for Mental Health sets out plans for improving and expanding mental healthcare – including the NHS creating a new ringfenced local investment fund worth at least £2.3 billion a year by 2023/24[9].

Medication is the most common form of treatment for a mental health problem[10]. Talking therapy is suggested as a first line option for milder forms of depression with guidelines suggesting that people in the UK with moderate to severe depression should be offered a combination of an antidepressant and talking therapy such as Cognitive Behavioural Therapy (CBT)[11].

Elderly psychiatric care settings

Within elderly psychiatric care settings, matters of mental capacity and consent compound the difficulties of medication administration.

Issues such as confused patients who do not understand the need to take medication, patients with swallowing difficulties and patients who refuse to swallow medicines are regularly being encountered by care givers during medication administration.

In one study of older adults with mental illness in an institutionalised setting, a number of patients were observed spitting out their medication[12]. Literature suggests that the most common course of action to overcome these problems when administering medication is changing the prescription to a liquid formulation[13].

Refusing medication

Refusal of medication is a major problem in mental health care. The mean daily incidence rate for refusal of medication is once per day in an average acute psychiatric ward[14]. Whilst patients do have the right to refuse treatment if they are competent, in some circumstances (such as being admitted to hospital under the Mental Health Act 1983) patients might be required by law to take their medication[15]. Liquids can be an alternative for patients who need encouragement to take their medication[16].

Depression and dysphagia

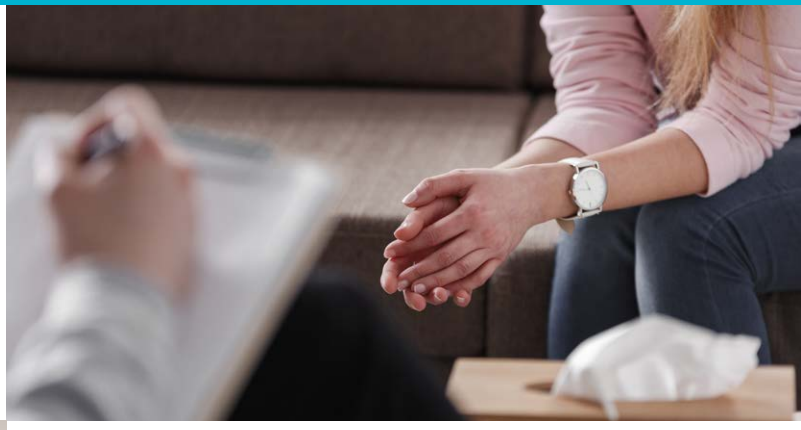
Medications have become the mainstay of psychiatric treatment[14]. The treatment of major depressive disorders specifically requires prolonged pharmacotherapy, and lack of compliance due to a swallowing difficulty can result in poor long-term outcomes and ultimately, treatment failure[17].

Compliance with medication is poor in patients with depression and is particularly prevalent in patients who do not like, or have difficulty in swallowing, tablets and capsules[17]. A study published in 2012 found that there was an association between depression severity and swallowing difficulties, with patients who had high depression scores reporting more general swallowing difficulties than those with lower scores[18]. If a patient is unable to swallow their medicines, they are unlikely to take them, and a licensed liquid medicine may therefore be a better choice[19].

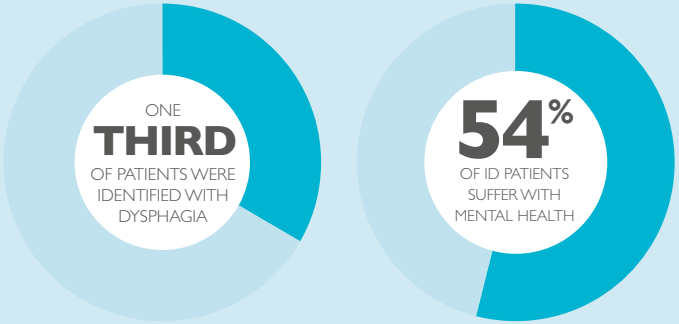
Psychotic disorders and dysphagia

The treatment of psychotic disorders carries several risk factors for dysphagia: antipsychotic drugs decrease oesophageal propulsion through impairment of muscle function and in conjunction with anticholinergic agents, cause dry mouth, contributing to difficulty swallowing[20].

All antipsychotics can cause extrapyramidal symptoms (EPS). Dysphagia or swallowing difficulties have been identified in some patients as an EPS with an incidence reported in both first, and second generation antipsychotics[21]. The incidence of dysphagia reported through adverse events however is small with a range of 0.43% to 2.08%[21].



The management of dysphagia associated with antipsychotics includes discontinuing the medication, reducing the dose or dividing the dose. Should these not be clinically suitable options, switching to another antipsychotic can be considered[21]. There are several situations where it may be appropriate to switch between antipsychotics, such as inadequate therapeutic response and intolerable adverse effects. However, there are also contraindications where the clinical risk associated with switching the molecule or lowering the dose outweighs the benefit[22]. Switching antipsychotic medication has uncertain clinical effects (positive or negative) and carries the risk of clinical worsening[22]. Liquid medications are easier to swallow, and dosage can readily be modified for individual patients[23].



Prevalence of swallowing difficulties

The prevalence of swallowing difficulties in patients within acute and community mental health settings is greater than that of the general population and may be a part of the disease or a side effect of the medication[24]. Dysphagia can be intrinsic to a mental health problem[25] and in one study, approximately a third of patients with a variety of mental health disorders were identified with dysphagia[26].

Mental health problems amongst adults with intellectual disabilities are quite common and more than double the rate of mental health problems in the general population[27]. One study found that 54% of people with intellectual disabilities have a mental health problem[28]. For these patients, dysphagia is both common[29] and a significant issue[30].

Improved management of dysphagia in such patients could reduce associated health conditions, hospital admissions and premature death[29].

Patient acceptance of prescribed medication is an important component of compliance.

Discussions with patients who experience discomfort when swallowing tablets, to identify an alternative formulation that they are willing to take, is an important step[23].

Altering solid dose forms

Crushing tablets and opening capsules can change the pharmacokinetic or bioavailability profile of a medicine which can impact efficacy and safety[31,32]. Altering modified release medication may also result in initial overdose, followed by under-dosing and may make the medicine taste unpleasant[19]. Guidance from the NHS on medications commonly used in the treatment of mental health suggests that even where crushing is acknowledged, solubility can be poor and dispersing in water may take over two minutes[33].

Liquid Medicines

Licensed liquid medicines can provide a more appropriate formulation for patients with swallowing difficulties[19]. They are easy to swallow, and the dosage can readily be modified for individual patients[23]. Many commonly used solid medications are available as licensed liquid medicines[33] and liquid formulations of antipsychotics in particular have been acknowledged to have been a success in treating patients with mental health problems[23]. Liquid medications are often associated with a higher acquisition price than solid dose forms but a study in the Journal of Medical Economics suggests that improved compliance potentially offsets those extra costs[34]. As an example, preventing one day's admission to a psychiatric hospital would fund liquid chlorpromazine instead of a solid dose form for 3 patients for a year[34].

With more than 50 years of experience, Rosemont are the experts in liquid medicines, delivering effective medication management for patients with swallowing difficulties.

Rosemont are committed to the pursuit of excellence in everything we do and from our state-of-the-art manufacturing facility, we develop, manufacture and supply 4 million bottles a year of high-quality liquid medicines. We currently have a range of over 130 products including an unrivalled 70 licensed liquid products and all our medicines, both licensed and specials, are manufactured in accordance with Good Manufacturing Practice (GMP).

We are proud, not just of our products, but of our unique involvement with patient groups and experts within the field of swallowing difficulties. We believe that work has been instrumental in helping to establish best practice for the care of these patients.

Rosemont have developed a portfolio of 8 licensed liquid medicines used to treat mental health conditions, several of which are the only licenced liquids of that molecule on the market. Consequently, we are uniquely placed to provide solutions for patients with mental health problems who suffer from swallowing difficulties.

ROSEMONT LIQUID MEDICINES

The following pages detail our liquid medicines that are used in the treatment of patients with mental health issues who have a requirement for medication in a liquid form.

For full details on our product portfolio, please visit

www.rosemontpharma.com

Please refer to the full summary of Product Characteristics (SmPC) before prescribing.

Rosemont Product Range

Antidepressant and Antipsychotic

Antidepressant
Amitriptyline Hydrochloride Oral Solution
25mg/5ml and 50mg/5ml

PRODUCT DESCRIPTION
Amitriptyline Hydrochloride Oral Solution

STRENGTH
25mg/5ml and 50mg/5ml

PACK SIZE
Both strengths available as 150ml

INDICATIONS
Amitriptyline is indicated for:

- the treatment of major depressive disorder in adults.
- the treatment of neuropathic pain in adults.
- the prophylactic treatment of chronic tension type headache (CTTH) in adults.
- the prophylactic treatment of migraine in adults.
- the treatment of nocturnal enuresis in children aged 6 years and above when organic pathology, including spina bifida and related disorders, have been excluded and no response has been achieved to all other non-drug and drug treatments, including antispasmodics and vasopressin-related products.

Antidepressant
Mirtazapine Oral Solution
15mg/ml

PRODUCT DESCRIPTION
Mirtazapine Oral Solution

STRENGTH
15mg/ml

PACK SIZE
66ml

INDICATIONS
Mirtazapine is indicated in adults for the treatment of episodes of major depression.

Antidepressant

Venlafaxine Oral Solution

37.5mg/5ml and 75mg/5ml

PRODUCT DESCRIPTION

Venlafaxine Oral Solution

STRENGTH

37.5mg/5ml and 75mg/5ml

PACK SIZE

Both strengths available as 150ml

INDICATIONS

For the treatment and prevention of recurrence of major depressive episodes.

The only licensed liquid venlafaxine product in the UK

Antipsychotic

Quetiapine Rosemont Oral Suspension

20mg/ml

PRODUCT DESCRIPTION

Quetiapine Rosemont Oral Suspension

STRENGTH

20mg/ml

PACK SIZE

150ml

INDICATIONS

Quetiapine is indicated for:

- Treatment of Schizophrenia.
- Treatment of bipolar disorder:
  - For the treatment of moderate to severe manic episodes in bipolar disorder.
  - For the treatment of major depressive episodes in bipolar disorder.
  - For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to quetiapine treatment.

Antipsychotic

Chlorpromazine Hydrochloride Oral Syrup

100mg/5ml and 25mg/5ml

PRODUCT DESCRIPTION

Chlorpromazine Hydrochloride Oral Syrup

STRENGTH

100mg/5ml and 25mg/5ml

PACK SIZE

Both strengths available as 150ml

INDICATIONS

Chlorpromazine is indicated for:

- Schizophrenia and other psychoses (especially paranoid), mania and hypomania;
- In severe anxiety, psychomotor agitation, excitement and violent or dangerously impulsive behaviour. Chlorpromazine is used as an adjunct in the short-term management of these conditions;
- Nausea and vomiting of terminal illness (where other drugs have failed or are not available);
- Childhood schizophrenia and autism;
- Intractable hiccups.

Antipsychotic

Promazine Hydrochloride Oral Syrup

25mg/5ml and 50mg/5ml

PRODUCT DESCRIPTION

Promazine Hydrochloride Oral Syrup

STRENGTH

25mg/5ml and 50mg/5ml

PACK SIZE

Both strengths available as 150ml

INDICATIONS

Promazine is indicated for:

- As an adjunct to short-term management of moderate to severe psychomotor agitation.
- Agitation and restlessness in the elderly.

Antipsychotic
Risperidone Oral Solution
1mg/ml

PRODUCT DESCRIPTION

Risperidone Oral Solution

STRENGTH

1mg/ml

PACK SIZE

100ml

INDICATIONS

Risperidone is indicated for:

- the treatment of schizophrenia.
- the treatment of moderate to severe manic episodes associated with bipolar disorders.
- the short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others.
- the short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation.

Antipsychotic
Trifluoperazine Oral Solution
5mg/5ml

PRODUCT DESCRIPTION

Trifluoperazine Oral Solution

STRENGTH

5mg/5ml

PACK SIZE

150ml

INDICATIONS

Low Dosage - Trifluoperazine is indicated as an adjunct in the short term management of anxiety states, depressive symptoms secondary to anxiety, and agitation. It is also indicated in the symptomatic treatment of nausea and vomiting.

High Dosage - Trifluoperazine is indicated for the treatment of symptoms and prevention of relapse in schizophrenia and in other psychoses, especially of the paranoid type, but not in depressive psychoses. It may also be used as an adjunct in the short term management of severe psychomotor agitation and of dangerously impulsive behaviour, for example, mental subnormality.

Abbreviated Prescribing Information: Amitriptyline Hydrochloride 25mg/5ml and 50mg/5ml Oral Solution. Consult Summary of Product Characteristics before prescribing. Presentation: Oral solutions containing either 25mg/5ml or 50mg/5ml amitriptyline hydrochloride. **Therapeutic Indications:** The treatment of major depressive disorder and neuropathic pain in adults, prophylactic treatment of chronic tension type headache (CTTH), prophylactic treatment of migraine. The treatment of nocturnal enuresis in children aged 6 years and above when organic pathology, including spina bifida and related disorders, have been excluded and no response has been achieved to all other non-drug and drug treatments, including antispasmodics and vasopressin-related products. **Posology and Method of Administration:** *Major depressive disorder:* Adults: Initially 25 mg twice daily. The dose can be increased by 25 mg every other day up to 150 mg daily divided into two doses. Patients over 65 years of age and patients with cardiovascular disease initially 10 mg – 25 mg daily, increased up to 100 mg – 150 mg divided into two doses. Doses above 100 mg should be used with caution. *Neuropathic pain, prophylactic treatment of chronic tension type headache and prophylactic treatment of migraine prophylaxis:* Adults: 25 mg - 75 mg daily in the evening. The initial dose should be 10 mg - 25 mg in the evening. Doses can be increased by 10 mg - 25 mg every 3 – 7 days. The dose can be taken once daily, or be divided into two doses. A single dose above 75 mg is not recommended. Patients over 65 years of age and patients with cardiovascular disease a starting dose of 10 mg - 25 mg in the evening. Doses above 75 mg should be used with caution. *Neuropathic pain:* symptomatic. *Prophylactic treatment of chronic tension type headache and prophylactic treatment of migraine in adults* must be continued for an appropriate length of time and reassessed regularly. *Special populations: Reduced renal function:* the product can be given in usual doses to patients with renal failure. *Reduced liver function:* careful dosing and a serum level determination is advisable. *Cytochrome P450 inhibitors of CYP2D6:* a lower dose of amitriptyline should be considered if a strong CYP2D6 inhibitor is added to amitriptyline treatment. *Known poor metabolisers of CYP2D6 or CYP2C19* consider a 50% reduction of the recommended starting dose. Method of administration: for oral use. When stopping therapy the drug should be gradually withdrawn over several weeks. **Paediatric population:** *Major depressive disorder.* Amitriptyline should not be used in children aged less than 18 years. *Nocturnal enuresis:* children aged 6 to 10 years: 10 mg – 20 mg, children aged 11 years and above: 25 mg – 50 mg daily. The dose should be increased gradually and administered 1-1½ hours before bedtime. An ECG should be performed prior to initiating therapy. Maximum treatment course should not exceed 3 months. If repeated courses are needed, a medical review should be conducted every 3 months. When stopping treatment, amitriptyline should be withdrawn gradually. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. Recent myocardial infarction. Any degree of heart block or disorders of cardiac rhythm and coronary artery insufficiency. Concomitant treatment with monoamine oxidase inhibitors (MAOIs). Severe liver disease. Children under 6 years of age. **Special warnings and Precautions for use:** Cardiac arrhythmias and severe hypotension with high dosage, QT interval prolongation, anaesthetics, use with caution in patients with convulsive disorders, urinary retention, prostatic hypertrophy, hyperthyroidism, paranoid symptomatology and advanced hepatic or cardiovascular disease, pylorus stenosis and paralytic ileus, in patients with the rare condition of shallow anterior chamber and narrow chamber angle, attacks of acute glaucoma due to dilation of the pupil may be provoked, suicide, suicidal thoughts, in manic depressives, a shift towards the manic phase may occur, amitriptyline may modify insulin and glucose responses, hyperpyrexia, withdrawal symptoms such as headache, malaise, insomnia and irritability may occur. Used with caution in patients receiving SSRIs. Concomitant administration of amitriptyline and buprenorphine/opioids may result in serotonin syndrome. Nocturnal enuresis: ECG to be performed prior to initiating therapy. Not to be combined with an anticholinergic drug. Same precautions observed when treating patients with depression should be followed when treating patients with enuresis. **Any warning from the MC, CHM CSM or MHRA: No, Black Triangle notice:** Not applicable. **Legal Category:** POM. The very common and common reactions are presented below and refer the SmPC for other adverse reactions: Very common: aggression, somnolence, tremor, dizziness, headache, drowsiness, speech disorder (dysarthria), accommodation disorder, palpitations, tachycardia, orthostatic hypotension, congested nose, dry mouth, constipation, nausea, hyperhidrosis, weight increased. Common: Confusional state, libido decreased, agitation, disturbance in attention, dysgeusia. paresthesia, ataxia, mydriasis, atrioventricular block, bundle branch block, micturition disorders, erectile dysfunction, fatigue, feeling thirst, electrocardiogram abnormal, electrocardiogram QT prolonged, electrocardiogram QRS complex prolonged, and hyponatremia. **Pack Size and NHS Price:** 150ml: 25mg/5ml - £15.70, 50mg/5ml - £17.20. **Marketing Authorisation Number:** 25 mg/5 ml: PL 00427/0115 and 50 mg/5 ml: PL 00427/0116. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. **Date of Preparation:** December 2022.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

Abbreviated Prescribing Information: Mirtazapine 15mg/ml oral solution. Consult Summary of Product Characteristics before prescribing. Presentation: Oral solution. Clear, colourless-to-straw aqueous solution containing 15 mg of mirtazapine per 1ml. **Therapeutic Indications:** Mirtazapine is indicated in adults for the treatment of episodes of major depression. **Posology and Method of Administration:** *Adults:* The effective daily dose is between 15 mg and 45 mg; the starting dose is 15 mg or 30 mg. With an insufficient response, the dose can be increased up to the maximum dose. If there is no response within a further 2-4 weeks, then treatment should be stopped. Patients with depression should be treated for a sufficient period of at least 6 months to ensure that they are free from symptoms. Mirtazapine should be discontinued gradually. *Older people:* The recommended dose is the same as that for adults. In elderly patients an increase in dosing should be done under close supervision. *Renal or hepatic impairment:* The clearance of mirtazapine may be decreased in patients with moderate to severe renal or hepatic impairment. *Method of administration:* To be taken preferably as a single night-time dose before going to bed, but it may also be given in two divided doses, the higher dose taken at night. **Paediatric population:** Mirtazapine should not be used in patients under the age of 18 years. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. Concomitant use of mirtazapine with monoamine oxidase (MAO) inhibitors. **Special Warnings and Precautions for use:** Not to be used in the treatment of children and adolescents under the age of 18 years. Caution should be exercised in patients with history of suicide-related events or are those exhibiting a significant degree of suicidal ideation prior to commencement of treatment. Bone marrow depression has been reported during treatment with Mirtazapine. Treatment should be discontinued if jaundice occurs. Careful dosing as well as regular and close monitoring is necessary in patients with: epilepsy and organic brain syndrome, hepatic impairment, renal impairment, cardiac diseases, low blood pressure, diabetes mellitus. Worsening of psychotic symptoms can occur, the depressive phase of bipolar disorder can transform into the manic phase. Mirtazapine should be discontinued in any patient entering a manic phase. Abrupt termination of treatment after long term administration may sometimes result in withdrawal symptoms. Care should be taken in patients with micturition disturbances like prostate hypertrophy and in patients with acute narrow-angle glaucoma and increased intra-ocular pressure. Akathisia/psychomotor restlessness: patients who develop these symptoms, increasing the dose may be detrimental. Caution should be exercised when prescribed in patients with known cardiovascular disease or family history of QT prolongation, and in concomitant use with other medicinal products thought to prolong the QTc interval and in patients concomitantly treated with medications known to cause hyponatraemia. Serotonin syndrome may occur when selective serotonin reuptake inhibitors (SSRIs) are used concomitantly with other serotonergic active substances. Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), bullous dermatitis and erythema multiforme, have been reported in association with mirtazapine treatment. If signs and symptoms suggestive of these reactions appear, mirtazapine should be withdrawn immediately and must not be restarted. Care should be taken when switching from tablets to oral solution. **Any warning from the MC, CHM CSM or MHRA:** No. **Black Triangle notice:** Not applicable. **Legal Category:** Prescription only medicine. The very common and commonly reported adverse reactions are: *Very common:* weight increased, increase in appetite, somnolence, sedation, headache, and dry mouth. *Common:* abnormal dreams, confusion, anxiety, insomnia, lethargy, dizziness, tremor, amnesia, orthostatic hypotension, nausea, diarrhea, vomiting, constipation, exanthema, arthralgia, myalgia, back pain, oedema peripheral, and fatigue. Refer the SmPC for details of other adverse reactions. **Pack Size and NHS Price:** 66 ml - £137.59. **Marketing Authorisation Number:** PL 00427/0241. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. **Date of Preparation:** Jan 2024.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

Abbreviated Prescribing Information: Venlafaxine 37.5mg/5ml and 75mg/5ml Oral Solution. Consult Summary of Product Characteristics before prescribing. Presentation: A clear colourless to almost colourless solution, containing 37.5mg/5ml or 75mg/5ml Venlafaxine (as Hydrochloride). **Therapeutic Indications:** Treatment of major depressive episodes. For prevention of recurrence of major depressive episodes. **Posology and Method of Administration:** *Major depressive episodes:* The initial 75 mg/day dose may be increased up to a maximum dose of 375 mg/day. Dosage increases can be made after clinical evaluation at intervals of 2 weeks or more, but not less than 4 days. Treatment should continue for at least six months following remission. *Elderly patients:* No specific dose adjustments are considered necessary. *Hepatic and renal impairment:* A 50% dose reduction should be considered. *Withdrawal symptoms seen on discontinuation of venlafaxine:* The dose should be gradually reduced over a period of

at least one to two weeks. For oral use, taken with food the same time each day. Suitable for administration via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. **Paediatric population:** Not recommended for use in children and adolescents under the age of 18 years. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients, concomitant treatment with irreversible monoamine oxidase inhibitors (MAOIs). Must not be initiated for at least 14 days after discontinuation of treatment with an irreversible MAOI, and must be discontinued for at least 7 days before starting treatment with an irreversible MAOI. **Special Warnings and Precautions for use:** Caution should be exercised when co-administered with alcohol and/or other drugs due to overdose and possible adverse interactions and death. Increased risk of suicide/suicidal thoughts or self-harm especially in early treatment and following dose changes. Should not be used in the treatment of those under the age of 18 years. Serotonin syndrome may occur, particularly with concomitant use of other serotonergic agents. Patients with raised intraocular pressure or patients at risk for acute narrow-angle glaucoma (angle-closure glaucoma) be closely monitored. Blood pressure should be monitored, especially after dose increases. Heart rate increases can occur. Should be used with caution in patients with cardiac disease and risk of arrhythmia. QTc prolongation and Torsade de Pointes, ventricular tachycardia and fatal cardiac arrhythmias have been reported. Treatment should be discontinued in any patient who develops seizures. Cases of hyponatraemia and/or the Syndrome of Inappropriate Antidiuretic Hormone (SIADH) secretion may occur. Caution should be exercised in volume-depleted or dehydrated patients. Elderly patients, and patients taking diuretics. The risk of haemorrhage and the risk of skin and mucous membrane bleeding may be increased. Risk of postpartum haemorrhage may be increased. Serum cholesterol levels should be monitored. Co-administration with weight loss agents is not recommended. Mania/hypomania or aggression may occur. Akathisia and dry mouth may develop. In patients with diabetes, venlafaxine may alter glycaemic control. May cause symptoms of sexual dysfunction. False-positive urine immunoassay screening tests for phencyclidine (PCP) and amphetamine have been reported. Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt. Venlafaxine should be gradually tapered when discontinuing treatment according to the patient's needs. **Any warning from the MC, CHM CSM or MHRA. No. Black Triangle notice:** Not applicable. **Legal Category:** POM. **A list of very common and common reactions is presented below and refer the SmPC for other reaction:** *Very common:* Dizziness, headache, nausea, dry mouth, hyperhidrosis. *Common:* Serum cholesterol increased, weight loss, decreased appetite, confusional state, depersonalisation, anorgasmia, libido decreased, nervousness, insomnia, abnormal dreams, paraesthesia, sedation, tremor, somnolence, hypertonia, accommodation disorder, mydriasis, visual impairment, including blurred vision, tinnitus, palpitations, hypertension, vasodilatation, yawning, constipation, vomiting, diarrhoea, dysuria, pollakiuria, ejaculation disorder, anorgasmia, erectile dysfunction, menstrual disorders associated with increase bleeding, asthenia, fatigue, chills, and blood cholesterol increased. **Pack Size and NHS Price:** 37.5mg/5ml x 150ml - £186.90, 75mg/5ml x 150ml - £244.65. **Marketing Authorisation Number:** 37.5mg/5ml: PL 00427/0253 and 75mg/5ml: PL 00427/0254. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. **Date of Preparation:** May 2023.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

Abbreviated Prescribing Information: Quetiapine Rosemont 20mg/ml Oral Suspension Consult Summary of Product Characteristics before prescribing. Presentation: An off-white oral suspension, each 1ml containing 20mg Quetiapine. **Therapeutic Indications:** Quetiapine oral suspension is indicated for the treatment of Schizophrenia; bipolar disorder; moderate to severe manic episodes in bipolar disorder; major depressive episodes in bipolar disorder; and for the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to quetiapine treatment. **Posology and Method of Administration:** Quetiapine Oral Suspension can be administered with or without food. For the treatment of schizophrenia, Quetiapine Oral Suspension should be administered twice a day. The total daily dose for the first four days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4) and from Day 4 onwards, the dose should be titrated to the usual effective dose of 300 to 450 mg/day. Depending on the clinical response and tolerability of the individual patient, the dose may be adjusted within the range 150 to 750 mg/day. For the treatment of manic episodes associated with bipolar disorder, Quetiapine Oral Suspension should be administered twice a day. The total daily dose for the first four days of therapy is 100 mg (Day 1), 200 mg (Day 2), 300 mg (Day 3) and 400 mg (Day 4). Further dosage adjustments up to 800 mg/day by Day 6 should be in increments of no greater than 200 mg/day. The usual effective dose is in the range of 400 to 800 mg/day. Quetiapine Oral Suspension should be administered once daily at bedtime for the treatment of major depressive episodes in bipolar disorder. The total daily dose for the first four days of therapy is 50 mg (Day 1), 100 mg (Day 2), 200 mg (Day 3) and 300 mg (Day 4). The recommended daily dose is 300 mg. For preventing recurrence of manic, mixed or depressive episodes in bipolar disorder, the dose may be adjusted depending on clinical response and tolerability of the individual patient, within the range of 300 to 800 mg/day administered twice daily. It is important that the lowest effective dose is used for maintenance therapy. Quetiapine should be used with caution in the elderly and in patients with known hepatic impairment, especially during the initial dosing period. Dose adjustment is not necessary in patients with renal impairment. **Paediatric population:** Quetiapine Oral Suspension is not recommended for use in children and adolescents below 18 years of age. **Contra-indications:** Hypersensitivity to the active substance or any of the excipients. Concomitant administration of cytochrome P450 3A4 inhibitors. **Special Warnings and Precautions for use:** Caution should be exercised with the following: Suicidal thoughts or clinical worsening, patients with major depressive episodes in bipolar disorder, decline in metabolic profile, extrapyramidal symptoms, tardive dyskinesia, somnolence, dizziness including sedation, orthostatic hypotension, sleep apnoea syndrome, seizures, neuroleptic malignant syndrome, severe neutropenia and agranulocytosis, anticholinergic effects, weight gain, hyperglycaemia, lipid changes, QT prolongation, cardiomyopathy, myocarditis, severe cutaneous adverse reactions (SCARS), withdrawal symptoms, dysphagia, constipation, intestinal obstruction, venous thromboembolism, pancreatitis, and in concomitant use with strong hepatic enzyme inducers. Concomitant administration of quetiapine and other serotonergic agents, such as MAO inhibitors, selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine re-uptake inhibitors (SNRIs) or tricyclic antidepressants may result in serotonin syndrome, a potentially life-threatening condition. If concomitant treatment with other serotonergic agents is clinically warranted, careful observation of the patient is advised, and a dose reduction or discontinuation of therapy should be considered depending on the severity of the symptoms. Quetiapine is not approved for patients with dementia-related psychosis and caution should be exercised with elderly patients with Parkinson's disease. Physicians should be cautious in prescribing high doses to adults with low body weight (50Kg) and patients with a history of alcohol or drug abuse. Excipient warnings: Contains methyl and propyl parahydroxybenzoate, propylene glycol (E1520) and sodium. **Any warning from the MC, CHM CSM or MHRA: No. Black Triangle notice:** not applicable. **Legal Category:** Prescription only medicine. The very common and commonly reported adverse events are as follows: *Very common:* Decreased haemoglobin, elevated serum triglyceride and total cholesterol (predominantly LDL cholesterol) levels, decreased HDL cholesterol, weight gain, dizziness, somnolence, headache, extrapyramidal symptoms, dry mouth, and withdrawal symptoms. *Common:* Leucopenia , decreased neutrophil count, eosinophils increased, Hyper-prolactinaemia, decreases in total T_4, free T_4, total T_3, and increased TSH, Increased appetite, blood glucose increased to hyperglycaemic levels, abnormal dreams and nightmares, suicidal ideation, suicidal behaviour, dysarthria, tachycardia, palpitations, vision blurred, orthostatic hypotension, dyspnoea, constipation, dyspepsia, vomiting, elevated serum alanine aminotransferase and gamma-GT levels., mild asthenia, peripheral oedema, irritability, and pyrexia (Refer to SmPC for other reported events). **Pack Size and NHS Price:** 150ml - £208.95. **Marketing Authorisation Number:** PL 00427/0240. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. **Date of Preparation:** July 2024.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

Abbreviated Prescribing Information: Chlorpromazine Hydrochloride 25mg/5ml and 100mg/5ml Oral Syrup. Consult Summary of Product Characteristics before prescribing. Presentation: Oral Solution containing either 25mg/5ml or 100mg/5ml Chlorpromazine Hydrochloride. **Therapeutic Indications:** Schizophrenia and other psychoses (especially paranoid), mania and hypomania; as an adjunct in psychomotor agitation, excitement and violent or dangerously impulsive behaviour; nausea and vomiting of terminal illness; childhood schizophrenia and autism; intractable hiccups. **Posology and Method of Administration:** Dosage for schizophrenia, other psychoses, mania, hypomania, anxiety, psychomotor agitation, excitement, violent or dangerously impulsive behaviour: Initially 25mg three times daily or 75mg at bedtime increasing daily by 25mg to maintenance dose 70 to 300mg, but may be up to 1g daily in some patients. Elderly or disabled patients: Start with 1/3 to 1/2 the usual adult dose with a more gradual increase in dosage. Dosage for Intractable Hiccup: 25 - 50mg tds or qds. Dosage for Vomiting and Nausea of Terminal Illness 10 - 25mg every 4 - 6 hours. Elderly or disabled patients: Initially 1/3 to 1/2 the adult dose. **Paediatric population:** Childhood schizophrenia Children under 1 year: Not recommended unless the need is lifesaving. Children 1 - 5 years: 0.5mg/Kg bodyweight every 4 - 6 hours to a maximum of 40mg daily. Children 6 - 12 years: 1/3 to 1/2 the adult dose up to a maximum of 75 mg daily. Dosage for Intractable Hiccup: Not recommended. Vomiting and Nausea of Terminal Illness: Children under 1 year: Do not use unless need is lifesaving.

Children 1 - 5 years: 0.5mg/Kg every 4 - 6 hours. Maximum daily dosage 40 mg. Children 6 - 12 years: 0.5mg/Kg every 4 - 6 hours. Maximum daily dosage 75mg. **Contra-indications:** Hypersensitivity to chlorpromazine or to any of the excipients, comatose states, severe CNS depression, history of blood dyscrasias including bone marrow depression and agranulocytosis, severe cardiovascular disease, risk of angle-closure glaucoma, risk of urinary retention related to urethroprostatic disorders, dopaminergic antiparkinsonism agents, nursing mothers, and citalopram and escitalopram. **Special Warnings and Precautions for use:** Caution in patients with cardiac arrhythmias, cardiac disease, severe respiratory disease, renal failure, Parkinson's disease, history of narrow angle glaucoma, prostatic hypertrophy, epilepsy, myasthenia gravis, phaeochromocytoma and hypersensitivity to phenothiazines. Caution in the elderly, as they are particularly susceptible to postural hypotension, sedation, extrapyramidal effects, chronic constipation, and potentially prostatic hypertrophy. Close monitoring is required in patients with epilepsy or a history of seizures. Avoid in patients with liver dysfunction, hypothyroidism, cardiac failure and agranulocytosis. In patients with impaired liver function, regular monitoring is necessary. If signs of blood dyscrasia appear, regular blood counts should be carried out. All patients with blood disorder must be advised that, if they experience fever, sore throat or any other infection, they should inform their physician immediately and undergo a complete blood count. Treatment will be discontinued if any marked changes are observed. Withdrawal should be gradual and closely monitored. In schizophrenia, the response may be delayed. Conversely, if treatment is withdrawn, the recurrence of symptoms may not become apparent for some time. Treatment to be discontinued in the event of signs of neuroleptic malignant syndrome. Chlorpromazine should not be used alone where depression is predominant. Patients should be advised to avoid exposure to direct sunlight. Care must be taken to avoid contact of the drug with the skin. Chlorpromazine should be used with caution in patients with risk factors for stroke. May potentiate QT interval prolongation. The absence of any factors favouring the onset of ventricular arrhythmias should be ensured before administration. It is recommended that the initial work up of patients should include an ECG. All possible risk factors for VTE should be identified before and during treatment with chlorpromazine and preventive measures undertaken. Except under exceptional circumstances, this drug must not be administered to patients with Parkinson's disease. Use with lithium, other QT prolonging agents, and dopaminergic anti-parkinsonism agents is not recommended. The onset of paralytic ileus must be treated as an emergency. Use with other neuroleptics should be avoided. Elderly Patients with Dementia: Elderly patients with dementia-related psychosis treated with antipsychotics drugs are at an increased risk of death. Chlorpromazine is not licensed for the treatment of dementia-related behavioural disturbances. Hyperglycaemia or intolerance to glucose has been reported. Patients with an established diagnosis of diabetes mellitus or with risk factors for the development of diabetes should get appropriate glycaemic monitoring during treatment. Patients are strongly advised not to consume alcohol and alcohol-containing drugs throughout treatment. Children should undergo a yearly clinical examination to evaluate learning capacity. Severe liver toxicity, resulting sometimes in death, has been reported with chlorpromazine use. Drug reaction with eosinophilia and systemic symptoms (DRESS) can be life-threatening or fatal, have been reported in association with chlorpromazine treatment. If signs and symptoms suggestive of these reactions appear, chlorpromazine should be withdrawn immediately and not be restarted. **Any warning from the MC, CHM CSM or MHRA. Black Triangle notice:** Not applicable. **Legal Category:** POM. **A list of very common and common reactions is presented below and refer the SmPC for other reactions:** *Very common:* Weight increased, sedation, somnolence, dyskinesia (Acute dystonias or dyskenias, usually transitory are more common in children and young adults and usually occur within the first 4 days of treatment or after dosage increases), tardive dyskinesia, extrapyramidal disorder, akathisia-often after large initial dose, orthostatic hypotension, dry mouth, constipation. ***Common:*** Hyperprolactinaemia, amenorrhoea, glucose tolerance impaired, anxiety, hypertonia, convulsion, ECG changes include Electrocardiogram QT prolonged, ST depression, and U-Wave and T-Wave changes. **Pack Size and NHS Price:** 25mg/5ml 150ml - £2.35 and 100mg/5ml 150ml - £5.50. **Marketing Authorisation Number:** 25mg/5ml PL 0427/5017R and 100mg/5ml PL 00427/0072. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. **Date of Preparation:** 20 October 2023.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

Abbreviated Prescribing Information. Consult Summary of Product Characteristics before prescribing. Promazine hydrochloride 25mg/5ml & 50mg/5ml oral syrup. Presentation: Syrups containing 25mg/5ml or 50mg/5ml Promazine Hydrochloride. **Therapeutic Indications:** As an adjunct to short-term management of moderate to severe psychomotor agitation. Agitation and restlessness in the elderly. **Posology and Method of Administration:** For oral administration. *Psychomotor Agitation:* Adults: 100mg to 200mg, QDS. Elderly: Half the normal dose. *Agitation and Restlessness:* Elderly: 25mg initially, increasing, if necessary, up to 50mg, QDS. Initial doses should be low. **Paediatric population:** Not recommended for children. **Contra-indications:** Hypersensitivity to promazine or other phenothiazines, coma, CNS depression, bone marrow depression, phaeochromocytoma, lactation, and pregnancy. **Special Warnings and Precautions for use:** Acute withdrawal symptoms can occur after abrupt cessation. Caution in patients with a history of jaundice, existent liver dysfunction, blood dyscrasias, coronary insufficiency, cardiac disease, severe respiratory disease and renal failure. Prolonged use requires regular and careful monitoring of eye changes, effects on haemopoiesis, liver dysfunction, and myocardial conduction effects. Use at high doses may induce extrapyramidal side effects. Caution in patients also taking anti-parkinson agents. Prolonged administration may result in persistent or tardive dyskinesia particularly in the elderly. Therapy should be withdrawn if dyskinesia develops. Use with care in treatment of patients with cerebral arteriosclerosis, coronary heart disease or other conditions in which a fall in blood pressure might be undesirable. Caution in epilepsy or conditions predisposing to epilepsy, those with a history of narrow angle glaucoma, use in extreme weather as body temperature regulation potentially impaired, hypothyroidism, myasthenia gravis, phaeochromocytoma and prostatic hypertrophy. Promazine may increase prolactin secretion. Venous thromboembolism may occur hence preventative measures recommended in those with risk factors. There is an increased risk of cerebrovascular events in the dementia population. Mortality is also increased in elderly dementia patients and promazine is not licensed to treat dementia-related behavioural disturbances. Elderly are particularly susceptible to hypotension, sedation and temperature regulation effects. Photosensitisation may occur; avoid direct sunlight. Use with caution in patients with a history of cardiovascular disorders. Avoid concomitant use with other antipsychotics or neuroleptics. **Any warning from the MC, CHM CSM or MHRA. No. Black Triangle notice:** Not applicable. **Legal Category:** POM. **The reported adverse reactions are:** Sensitivity reactions including agranulocytosis, leucopenia, haemolytic anaemia, apathy, confusional state, effects of excitement, agitation or insomnia, withdrawal symptoms, drowsiness, dizziness, headache, sedation, epileptic fits, extrapyramidal symptoms, neuroleptic malignant syndrome, blurred vision, precipitation of glaucoma, corneal and lens opacities and purplish pigmentation of the skin, cornea, conjunctiva and retina, tachycardia, cardiovascular effects, prolongation of QT interval, T-wave changes, ventricular arrhythmias (VF, VT (rare)), sudden unexplained death, cardiac arrest and torsades de pointes, nasal stuffiness, gastrointestinal disturbances, dry mouth, constipation. Transient abnormalities of liver function tests, rarely - obstructive jaundice associated with stasis in biliary canaliculi, allergic skin reactions, rashes, photosensitisation and contact sensitization, urinary hesitancy or retention when due to enlarged prostate, menstrual disturbances, galactorrhoea, gynaecomastia, impotence, hypothermia, hyperpyrexia, drug withdrawal syndrome neonatal (not known), and weight gain. **Pack Size and NHS Price:** 25mg/5ml – 150ml, £70.00; 50mg/5ml – 150ml, £80.00. **Marketing authorisation number:** 25mg/5ml: PL 00427/0054; 50mg/5ml: PL 00427/5014R. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE. **Date of Preparation:** December 2022.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

Abbreviated Prescribing Information: Risperidone 1mg/ml Oral Solution **Consult Summary of Product Characteristics before prescribing. Presentation:** A clear colourless solution containing 1mg risperidone per ml. **Therapeutic Indications:** Schizophrenia. Moderate to severe manic episodes associated with bipolar disorders. Short-term treatment of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches & when there is a risk of harm to self or others. Short-term treatment of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. **Posology and Method of Administration:** Schizophrenia: Starting dose of 2 mg/day. Typical dose 4-6 mg/day. Elderly: Starting dose of 0.5mg twice daily, which can be titrated to 1-2 mg twice daily. Manic episodes in bipolar disorder: Starting on a 2 mg once daily dose, adjusted to dose range of 1-6 mg once per day. Elderly: Starting dose of 0.5 mg twice daily, individually adjusted to 1-2 mg twice daily. Aggression in Alzheimer's dementia: Starting dose of 0.25 mg twice daily, individually adjusted to optimum dose of 0.5 mg twice daily, up to 1 mg in some patients for up to 6 weeks. **Paediatric population:** Conduct disorder in children from 5-18 years: Starting dose of 0.25 - 0.5 mg depending on patient weight. The optimum dose is 0.5 mg once daily for most patients. Some patients may benefit from 0.25 mg once daily while others may require 0.75 mg once daily. For oral use diluted with water or orange juice and to be used immediately. This liquid should not be mixed with coffee and tea. **Contra-**

indications: Hypersensitivity to the active substance or to any of the excipients. **Special Warnings and Precautions for use:** Elderly patients with dementia: increased risk of mortality with atypical antipsychotics & increased risk of mortality with concomitant use of furosemide. Increased risk of cerebrovascular adverse events, orthostatic hypotension, leukopenia, neutropenia and agranulocytosis, tardive dyskinesia/extrapyramidal symptoms, patients receiving both psychostimulants and risperidone, neuroleptic malignant syndrome (NMS), worsening of Parkinson's disease and dementia with Lewy bodies, hyperglycaemia, diabetes mellitus and exacerbation of pre-existing diabetes. Increased risk of weight gain, hyperprolactinaemia, known cardiovascular disease & QT prolongation, a history of seizures and in patients with renal & hepatic impairment, priapism, disruption of body temperature regulation, antiemetic effect, venous thromboembolism, intraoperative floppy iris syndrome. Close monitoring of use in the paediatric population is recommended. **Any warning from the MC, CHM CSM or MHRA. Black Triangle notice:** Not applicable. **Legal Category:** POM. The undesirable effects reported for memantine are: *Very common:* insomnia, sedation/somnolence, Parkinsonism, and headache. *Common:* pneumonia, bronchitis, upper respiratory tract infection, sinusitis, urinary tract infection, ear infection, influenza, hyperprolactinaemia, weight increased, increased appetite, decreased appetite, sleep disorder, agitation, depression, anxiety, akathisia, dystonia, dizziness, dyskinesia, tremor, vision blurred, conjunctivitis, tachycardia, hypertension, dyspnoea, pharyngolaryngeal pain, cough, epistaxis, nasal congestion, abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhoea, dyspepsia, dry mouth, toothache, rash, erythema, muscle spasms, musculoskeletal pain, back pain, arthralgia, urinary incontinence, oedema,pyrexia, chest pain, asthenia, fatigue, pain, and fall; *Uncommon:* respiratory tract infection, cystitis, eye infection, tonsillitis, onychomycosis, cellulitis localised infection, viral infection, acarodermatitis, neutropenia, white blood cell count decreased, thrombocytopenia, anaemia, haematocrit decreased, eosinophil count increased, hypersensitivity, diabetes mellitus, hyperglycaemia, polydipsia, weight decreased, anorexia, blood cholesterol increased, mania, confusional state, libido decreased, nervousness, nightmare, tardive dyskinesia, cerebral ischaemia, unresponsive to stimuli, loss of consciousness, depressed level of consciousness, convulsion, syncope, psychomotor hyperactivity, balance disorder, coordination abnormal, dizziness postural, disturbance in attention, dysarthria, dysgeusia, hypoaesthesia, paraesthesia, photophobia, dry eye, lacrimation increased, ocular hyperaemia, vertigo, tinnitus, ear pain, atrial fibrillation, atrioventricular block, conduction disorder, electro-cardiogram QT prolonged, bradycardia, electro-cardiogram abnormal, palpitations, hypotension, orthostatic hypotension, flushing, pneumonia aspiration, pulmonary congestion, respiratory tract congestion, rales, wheezing, dysphonia, respiratory disorder, faecal incontinence, faecaloma, gastroenteritis, dysphagia, flatulence, urticaria, pruritus, alopecia, hyperkeratosis, eczema, dry skin, skin discolouration, acne, seborrhoeic dermatitis, skin disorder, skin lesion, blood creatine phosphokinase increased, posture abnormal, joint stiffness, joint swelling muscular weakness, neck pain, pollakiuria, urinary retention, dysuria, erectile dysfunction, ejaculation disorder, amenorrhoea, menstrual disordered, gynaecomastia, galactorrhoea, sexual dysfunction, breast pain, breast discomfort, vaginal discharge, face oedema, chills, body temperature increased, gait abnormal, thirst, chest discomfort, malaise, feeling abnormal, discomfort, transaminases increased, gamma-glutamyltransferase increased, hepatic enzyme increased, procedural pain; ***Rare:*** Infection, agranulocytosis, anaphylactic reaction, inappropriate antidiuretic hormone secretion, glucose urine present, water intoxication, hypoglycemia, hyper-insulinaemia, blood triglycerides increased, catatonia, somnambulism, sleep related eating disorder, blunted affect, anorgasmia, neuroleptic malignant syndrome, cerebrovascular disorder, diabetic coma, head titubation, glaucoma, eye movement disorder, eye rolling, eyelid margin crusting, floppy iris syndrome (intraoperative), sinus arrhythmia, pulmonary embolism, venous thrombosis, sleep apnoea syndrome, hyperventilation, pancreatitis, intestinal obstruction, swollen tongue, cheilitis, drug eruption, dandruff, rhabdomyolysis, drug withdrawal syndrome neonatal, priapism, menstruation delayed, breast engorgement, breast enlargement, breast discharge, hypothermia, body temperature decreased, peripheral coldness, drug withdrawal syndrome, induration, jaundice; *Very rare:* diabetic ketoacidosis, ileus, Angioedema; *Not Known:* Stevens-Johnson syndrome / toxic epidermal necrolysis. **Pack Size and NHS Price:** 100ml - £9.46 **Marketing authorisation number:** PL00427/0239 **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. **Date of Preparation:** 28 September 2023.

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard
Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

Abbreviated Prescribing Information: Trifluoperazine 5mg/5ml Oral Solution. Consult Summary of Product Characteristics before prescribing. Presentation: Oral solution containing 5mg trifluoperazine per 5ml. **Therapeutic Indications:** *Low dosage:* Adjunct in the short-term management of anxiety states, depressive symptoms secondary to anxiety, and agitation. Symptomatic treatment of nausea and vomiting. *High Dosage:* treatment of symptoms and prevention of relapse in schizophrenia and in other psychoses (especially of the paranoid type, but not in depressive psychoses). Adjunct in the short-term management of severe psychomotor agitation and of dangerously impulsive behaviour. **Posology and Method of Administration:** *Low Dosage:* 2- 4 mg a day given in divided doses. May be increased to 6mg a day. *High dosage:* Starting dose for physically fit adults is 5mg twice a day; after a week this may be increased to 15mg a day. Further increases of 5mg at three-day intervals and then reduced gradually until an effective maintenance level has been established. Reduce initial dose in elderly by at least half. **Paediatric population:** *Low dosage:* 3-5 years up to 1mg/day, 5-12 years up to 4mg/day in divided doses. *High dosage:* under 12 years - the initial oral dosage should not exceed 5mg a day, given in divided doses and any increase made with caution at intervals of not less than three days. For oral administration only. **Contra-indications:** Hypersensitivity to trifluoperazine or to any of the excipients. Comatose patients, or in those with existing blood dyscrasias, or known liver damage. Patients with uncontrolled cardiac decompensation. **Special warnings and Precautions for use:** Trifluoperazine should be discontinued at the first sign of clinical symptoms of tardive dyskinesia and Neuroleptic Malignant Syndrome. Patients on long term therapy require regular and careful surveillance especially for tardive dyskinesia and possible eye changes, blood dyscrasias, liver dysfunction and myocardial conduction defects. Care should be taken when treating elderly patients, and initial dosage should be reduced. Patients with cardiovascular disease including arrhythmias and angina pectoris should also be treated with caution. Patients who have demonstrated bone marrow suppression or jaundice with a phenothiazine should not be re-exposed unless justified. In patients with Parkinson's disease, symptoms may be worsened, and the effects of levodopa reversed. Patients with epilepsy should be treated with caution, and metrizamide avoided. Caution with patients with narrow angle glaucoma, myasthenia gravis or prostatic hypertrophy. Nausea and vomiting as a sign of organic disease may be masked. Caution in patients with risk factors for stroke, cardiovascular disease or family history of QT prolongation. Concomitant use of neuroleptics should be avoided. Venous thromboembolism (VTE) has been reported with antipsychotic drugs. All possible risk factors for VTE should be identified before and during treatment and preventive measures undertaken. Gradual withdrawal is advisable. Care should be used in extremes of temperature. Increased Mortality in Elderly people with Dementia. Trifluoperazine is not licensed for the treatment of dementia-related behavioural disturbances. **Any warning from the MC, CHM CSM or MHRA. No. Black Triangle notice:** Not applicable. **Legal Category:** POM. **The reported adverse reactions are:** Blood dyscrasias such as Agranulocytosis, Pancytopenia, Leucopenia and Thrombocytopenia, Hyperprolactinaemia, Galactorrhoea, Amenorrhoea, Gynaecomastia, Anorexia, Weight gain, Unpleasant symptoms, Confusion, Extrapyramidal symptoms, Neuroleptic malignant syndrome, Tardive dyskinesia, Drowsiness, Dizziness, Transient restlessness, Insomnia, Retinopathy, Lenticular opacities, Blurred vision, Serious arrhythmias, Unexplained death, Cardiac arrest and Torsades de pointes, Tachycardia, Mild postural hypotension, Venous thromboembolism, Pulmonary embolism, Deep vein thrombosis, Constipation, Dry mouth, Cholestatic jaundice, Skin pigmentation, Photosensitivity reactions, Muscular weakness, Urinary hesitancy and retention, Drug withdrawal syndrome neonatal, Hyperpyrexia, Lassitude, Oedema, Withdrawal reactions, and ECG changes with prolongation of the QT interval and T-wave changes. **Pack Size and NHS Price:** 150ml £56.19. **Marketing Authorisation Number:** PL 00427/0118. **Marketing Authorisation Holder:** Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK. **Date of Preparation:** December 2022.

Adverse events should be reported.
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