ZISPER MD

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for ZISPER **MD** (Risperidone Orally Disintegrating Tablets U.S.P.) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: **Risperidone** is a selective monoaminergic antagonist with unique properties. It has a high affinity for serotoninergic 5-HT2 and dopaminergic D2 receptors. Risperidone binds also to alpha1-adrenergic receptors, and, with lower affinity, to H1-histaminergic and alpha2-adrenergic receptors. Risperidone has no affinity for cholinergic receptors. Although risperidone is a potent D2 antagonist, which is considered to improve the positive symptoms of schizophrenia, it causes less depression of motor activity and induction of catalepsy than classical antipsychotics. **INDICATIONS**: for the treatment of schizophrenia., moderate to severe manic episodes associated with bipolar disorders., 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. , for 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 sub average intellectual functioning or mental retardation diagnosed according to DSM-IV criteria, in whom the severity of aggressive or other disruptive behaviours require pharmacologic treatment. Pharmacological treatment should be an integral part of a more comprehensive treatment programme, including psychosocial and educational intervention. It is recommended that risperidone be prescribed by a specialist in child neurology and child and adolescent psychiatry or physicians well familiar with the treatment of conduct disorder of children and adolescents. **DOSAGE AND ADMINISTRATION**: Dosage: As directed by the Physician. **CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients **WARNINSGS & PRECAUTION**: **Risperidone** *Elderly patients with dementia Increased mortality in elderly people with dementia* In a meta-analysis of 17 controlled trials of atypical antipsychotics, including RISPERIDONE, elderly patients with dementia treated with atypical antipsychotics have an increased mortality compared to placebo. In placebo-controlled trials with oral RISPERIDONE in this population. *Concomitant use with furosemide* in the RISPERIDONE placebo-controlled trials in elderly patients with dementia, a higher incidence of mortality was observed in patients treated with furosemide plus risperidone (7.3%; mean age 89 years, range 75-97) when compared to patients treated with risperidone alone (3.1%; mean age 84 years, range 70-96) or furosemide alone (4.1%; mean age 80 years, range 67-90). The increase in mortality in patients treated with furosemide plus risperidone was observed in two of the four clinical trials. Cerebrovascular adverse events (CVAE) An approximately 3-fold increased risk of cerebrovascular adverse events have been seen in randomised placebo-controlled clinical trials in the dementia population with some atypical antipsychotics. Tardive dyskinesia/extrapyramidal symptoms (TD/EPS) Medicines with dopamine receptor antagonistic properties have been associated with the induction of tardive dyskinesia characterised by rhythmical involuntary movements, predominantly of the tongue and/or face. **DRUG INTERACTIONS**: **Risperidone** Pharmacodynamic-related interactions *Drugs known to prolong the QT interval* As with other antipsychotics, caution is advised when prescribing risperidone with medicinal products known to prolong the QT interval, such as antiarrhythmics (e.g., quinidine, dysopiramide, procainamide, propafenone, amiodarone, sotalol), tricyclic antidepressants (i.e., amitriptyline), tetracyclic antidepressants (i.e., maprotiline), some antihistamines, other antipsychotics, some antimalarials (i.e., quinine

and mefloquine), and with medicines causing electrolyte imbalance (hypokalaemia, hypomagnesaemia), bradycardia, or those which inhibit the hepatic metabolism of risperidone. **ADVERSE REACTIONS Very common side effects (may affect more than 1 in 10 people):** • Difficulty falling or staying asleep • Parkinsonism: This condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face • Feeling sleepy, or less alert • Headache. **Common side effects (may affect up to 1 in 10 people):** • Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu. **Uncommon side effects (may affect up to 1 in 100 people):** • Infection of the breathing passages, bladder infection, 'eye infection, tonsillitis, fungal infection of the nails, infection of the skin, an infection confined to a single area of skin or part of the body, viral infection, skin inflammation caused by mites. Rare side effects (may affect up to 1 in 1,000 people):• Infection• Inappropriate secretion of a hormone that controls urine volume• Sleep walking• Sleep-related eating disorder• Sugar in the urine, low blood sugar, high blood triglycerides (a fat)• Lack of emotion, inability to reach orgasm **Very rare side effects (may affect up to 1 in 10,000 people):** • Life threatening complications of uncontrolled diabetes • Serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing • Lack of bowel muscle movement that causes blockage.

MARKETED BY:

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(Additional information is available on request)