

## COMPOSITION:

Risperidone USP ... 1mg, 2mg, 3mg or 4mg. [USP Specs.]

**DESCRIPTION:** BUZON (Risperidone) is a novel antipsychotic belonging to a new class of antipsychotic agent, the benzisoxazole derivatives.

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PHARMACODYNAMICS: 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 α1-adrenergic receptors, and with lower affinity b1-histaminergic and α₂-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 neuroleptics. Balanced central serotonin and dopamine antagonism may reduce extrapyramidal side effect liability and extend the therapeutic activity to the negative and affective symptoms of schizophrenia.

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PHARMACOKINETICS: Risperidone is completely absorbed after oral administration, reaching peak plasma concentration within 1 to 2 hours. The absorption is not affected by food and thus Risperidone can be given with or without meals. Risperidone is metabolized by cytochrome P-450 2D6 to 9-hydroxy-risperidone, which has a similar pharmacological activity as Risperidone. Risperidone plus 9-hydroxy-risperidone form the active antipsychotic fraction. Another metabolic pathway of Risperidone is Nedelkylation. Risperidone is rapidly distributed. The volume of distribution is 1-2L/kg. In plasma, Risperidone is bound to albumin and α₁-acid glycoprotein. The plasma protein binding of Risperidone is 88% and that of 9-hydroxy-risperidone is 77%.

INDICATIONS: BUZON (Risperidone) Tablet is indicated for the treatment of acute and INDICATIONS: BUZON (Risperidone) Tablet is indicated for the treatment of acute and chronic schizophrenic psychosis, and other psychotic conditions, in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness) and/or negative symptoms (such as blunted effect, emotional and social withdrawal, and poverty of speech) are prominent. BUZON Tablet also alleviates affective symptoms such as depression, guilt feelings, anxiety associated with schizophrenia. BUZON Tablet is also indicated for the treatment of autistic children. Risperidone showed significant improvement in behaviour in autistic children. BUZON Tablet is also indicated as long-term therapy for the prevention of relapse (acute exacerbation) in chronic schizophrenic patients. In addition, BUZON Tablet is indicated for the treatment of behavioural disturbances in patients with dementia in whom symptoms such as aggressiveness (verbal outbursts, physical violence), activity disturbances (agitation, wandering) or psychotic symptoms are prominent.

CONTRA-INDICATIONS: Risperidone is contra-indicated in patients with a known

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hypersensitivity to the product. WARNINGS AND PRECAUTIONS: Due to the  $\alpha$ -blocking activity of Risperidone orthostatic hypotension may occur, especially during the initial dose-titration period. Risperidone should be used with caution in patients with known cardiovascular disease (e.g. heart failure, myocardial infarction, conduction abnormalities, hypovolemia, or cerebrovascular disease), and the dosage should be gradually titrated as recommended. A dose reduction should be considered if hypotension occurs. It is recommended to halve both the starting dose and the subsequent dose increments in geriatric patients and in patients with renal or liver insufficiency. Caution is also due when prescribing Risperidone to patients with Parkinson's disease since, theoretically, it might cause a deterioration of the disease. Classical neuroleptics are known to lower the seizure threshold. Caution is recommended when treating patients with epileoxy. Patients may threshold. Caution is recommended when treating patients with epilepsy. Patients may be advised to refrain from excessive eating in view of the possibility of weight gain.

INTERACTIONS: Risperidone should be used with caution in combination with other INTERACTIONS: Risperidone should be used with caution in combination with other centrally acting drugs. Risperidone may antagonize the effect of levodopa and other dopamine-agonists. Carbamazepine has been shown to decrease the plasma levels of the active antipsychotic fraction of Risperidone. Similar effects may be observed with other hepatic enzyme inducers. On discontinuation of carbamazepine or other hepatic enzyme inducers the dosage of Risperidone should be re-evaluated and if necessary decreased. Phenothiazines, tricyclic antidepressants and some beta-blockers may increase the plasma concentrations of Risperidone but not those of the antipsychotic fraction. When Risperidone is taken together with other highly protein-bound drugs, there is no clinically relevant displacement of either drug from the plasma proteins.

EFFECTS ON DRIVING ABILITY AND USE OF MACHINERY: Risperidone may interfere with activities requiring mental alertness. Therefore, patients should be advised not to drive or operate machinery until their individual susceptibility is known.

DOSAGE AND ADMINISTRATION:
Adults: BUZON Tablets may be given in 1 or 2 divided doses daily. The usual initial daily dose of BUZON Tablets is 2mg on the first day, 4mg on the second day, and 6mg on the third day. From then the dosage can be maintained unchanged, or further individualized, if needed. The usual maintenance doses are 4 to 8mg daily.

Elderly: A starting dose of 0.5mg bid is recommended. This dosage can be individually adjusted with 0.5mg bid increments to 1 to 2mg bid.

Renal and liver disease: A starting dose of 0.5mg bid is recommended. This dosage can be individually adjusted with 0.5mg bid increments to 1 to 2mg bid.

ADVERSE REACTIONS: Risperidone is generally well tolerated and in many instances it has been difficult to differentiate adverse events from symptoms of the underlying disease. Adverse events observed in association with the use of Risperidone are insomnia, agitation, anxiety, and headache.

Less Common: Somnolence, fatigue, dizziness, impaired concentration, constipation, dyspepsia, nausea/vomiting, abdominal pain, blurred vision, priapism, erectile dysfunction, ejaculatory dysfunction, orgastic dysfunction, urinary incontinence, rhinitis, rash and other allergic reactions.

Symptoms: In general, reported signs and symptoms have been those resulting from an exaggeration of the drug's known pharmacological effects. These include drowsiness and sedation, tachycardia and hypotension, and extrapyramidal symptoms. Treatment: Establish and maintain a clear airway and ensure adequate oxygenation and ventilation. Gastric lavage (after intubation, if the patient is unconscious) and administration of activated charcoal together with a laxative should be considered. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

**INSTRUCTIONS:** Store below 30°C. Protect from heat, light and moisture. Keep out of the reach of the children.

PRESENTATION:
BUZON 1mg & 2mg tablets available in a blister packs of 10'sx2 tablets.
BUZON 3mg & 4mg tablets available in a blister packs of 10'sx1 tablets.

بُرز آن الوليان

اجزاءتر كيب: بُزآن كى برگولى بين رئيريدون الى گرام، ٢ لى گرام، ٣ لى گرام اور ٢ لى گرام موجود بــ

فوائد: بُزآن گولیاں ایک مخصوص Monoaminergic antagonist ہے۔

معلومات: بزان گولیاں برخم کے Schizophrenia اورنشیاتی بیاریوں جس کی علامات کا نوں ش ایس آواز وں کا سانگار بنا جس کی کوئی حقیقت ندہو دیٹیوں کا سانگار بنا ، سوچے اور غورو فوض کرنے کی صلاحیت کا متاثر ہونا، ہر بات کومشکوک جھنا، بے وجدکا غصہ اور جذباتی ہونا، کی بھی کام میں منٹی پہلوکوزیا دوا ہمیت دینا، بےجاخوف، پر ججوم جگدے فرار، بولنے میں ایکچاہٹ وغیرہ میں ان بیار یوں کے علاج اور بیاؤ کے لئے تجویز کی جاتی ہیں۔ بڑآن ایسے مریضوں میں بھی استعمال کی جاتی ہیںجن سے محلے کی اوجہ سے سوچنے محصے کی صلاحیت میں کی آئی ہو۔اس کےعلاوہ Autistic child کے لئے بھی ایک مؤثر دواہے۔ (ایسے بچے جو ماحول سے بیز ارمفہوم کی ادایکل سے قاصراور تنہائی پیند ہوں) مانع علامات: رسيريدُون سے پيشگي حساسيت \_

احتیاط: کچیم لیفنوں میں Low blood pressure کی شکایت ہوگئی ہے۔ رسپریڈون کا استعال دل کے عارضہ میں مبتلام لیفنوں میں احتیاط کے ساتھ کریں۔ مثلاً دل کے دورہ میں جتنا ہونے والے مریشن، Conduction abnormality ، تہم ٹیں پانی کی کی بھون کے تم ٹیں کی ، دہا تی امراش۔ اگر Hypotension کی تکلیف ہوتو دوا کی خوراک شن کی ک جا تھی ہے۔ جگراورگردے کی ناتص کارکردگی کے م لیفوں ٹیں دوااحتیا کا بھی ساتھ ال کریں۔ مرگی اور Parkinsonism کے مریضوں ٹیں بیووااحتیا کا بھی استعمال کریں۔ دومري دواوّن كيرياتهدر وعمل: اعصابي نظام پرغل كرنے والي دوائيس ربيرية ون كيرياته استعمال مذكرين - ربيريله ون Levodopa اور دوسرے Dopamine agonist کی اثر پزیری کو کم کرتا ہے۔ وہ مریض جو پہلے ہے کوئی Antipsychotic دوا استعمال کررہے ہووہ اس دوا کا استعمال ترک کرویں۔

خوراک اورطریقة استعلی : برول کے لئے: رپریلون کی ابتدا کی خوراک املی گرام دن میں دومرتبہ کیلے روزے۔ آیا مرض شدیدہ یاضد کی دوا کی خوراک میں بتدرتنا اضافہ ۲ ملی گرام

دن میں دو مرتبہ دوسرے روز دی جاتی ہے اور پھر ۳ ملی گرام دن میں دومرتبہ تیسرے روز دی پھر دوا ای طرح جاری رھی جاتی ہے۔ رسپریڈون کی انتہائی خوراک استعمال ۴ سے ۸ ملی گرام روزا نہ ہے۔

ضعیف مریضوں کے لئے: 0.5 کمی گرام دومرتبدروزاندےابتداءکریں۔ دواٹیںاضافہ 0.5 کمی گرام دن ٹیں دومرتبد کی ٹری سے کریکتے ہیں اورخوراک ہے ۲ ملی گرام دن ٹیں دومرتبہ تک مقرر کی جاسکتی ہے۔

جگراورگردے کی ناقص کارکردگی والے مریض: الیے مریضوں ٹی خوراک کی ابتداء 0.5 ملی گرام ہے کریں۔ نالېنىدىيە يانا خوشگواراراترات: يول ۋر پېرىلەن ايك قائل قول دوا بېكىن ئىچىم يىغىول بىل ناخشگواراترات مرتب بوسكتە بىن، بىغوالى، جارھانىدوىيە دېخىلابىمىن، مايوى، مركادرد

جبكه شاذو نادر كچه مريضوں ميں تھكاوٹ، چكرآ نا «اكتاب قبض، ببغضى «ائى، پيپ كا درد، دھندلانظر آ نا ياالر جك ري ايكشن ہوسكتہ ہيں۔ مقرر کروه خوراک ہے تجاوز اورعلاج: حادثاتی یا اتفاق طور پرضرورت ہے زیادہ دوالینے کی صورت میں مند کا ختک ہونا ، مغزوگی ، دل کی دھڑ کن کا تیز ہونا، بلڈ پریشر کا کم ہونا یا

Extrapyramidal علامات ہو محق ہیں۔ اگر مریض کی حالت زیاد وخراب ہوتو فوراً قریبی ڈاکٹرے رجوع کریں۔ ہدایات: ۳۰ ڈگری سنٹی گریڈے کم درجہ حرارت پر بھیں۔ گری روٹنی اور فی سے بچاکس بچول کی بھی ہے۔ دور رکھیں۔

طریقة فراجمی: بُزآن المی گرام اور ۲ لی گرام 10'sx2 کیلسٹر پیک میں دستیاب ہے۔ بُرْ آن ٣ مَلْ گرام اور ١٥ مَلْ گرام 10'sx1 كيلسٹر پيك مِين دستياب بـ

Manufactured by: NABIQASIM INDUSTRIES (PVT) LTD. 17/24, Korangi Industrial Area, Karachi-Pakistan.