ORIDONE 1 mg Tablet
(Risperidone USP)
(USP Specifications)

اوریڈون ۱ ملی گرام ٹیبلیٹ
(رسپیریڈون یو ایس پی)

ORIDONE 2 mg Tablet
(Risperidone USP)
(USP Specifications)

اوریڈون ۲ ملی گرام ٹیبلیٹ
(رسپیریڈون یو ایس پی)

ORIDONE 3 mg Tablet
(Risperidone USP)
(USP Specifications)

اوریڈون ۳ ملی گرام ٹیبلیٹ
(رسپیریڈون یو ایس پی)

ORIDONE 4 mg Tablet
(Risperidone USP)
(USP Specifications)

اوریڈون ۴ ملی گرام ٹیبلیٹ
(رسپیریڈون یو ایس پی)

ORIDONE Oral Solution 1mg / ml
(Risperidone USP)
(USP Specifications)

اوریڈون اورل سلوشن ۱ ملی گرام / ملی لیٹر
(رسپیریڈون یو ایس پی)

PRESCRIBING INFORMATION

ORIDONE (Risperidone) is an anti-psychotic agent belonging to a new chemical class, the benzisoxazole derivative.

USP Specs:
Composition:
Each tablet contains: Risperidone USP ... 1mg.
Each tablet contains: Risperidone USP ... 2mg.
Each tablet contains: Risperidone USP ... 3mg.
Each tablet contains: Risperidone USP ... 4mg.
Each ml contains : Risperidone USP ... 1mg.

Indications:
ORIDONE is indicated for the management of broad range of patients with acute and chronic schizophrenia, psychosis, other psychotic conditions in which positive symptoms and or negative symptoms are prominent. ORIDONE also alleviates effective symptoms. In addition,ORIDONE is also indicated as long term therapy for the prevention of relapse in chronic schizophrenic patients. Moreover, ORIDONE is also indicated for the treatment of behavioural disturbances in patients with dementia in whom symptoms such as aggressiveness, activity disturbances or psychotic symptoms are prominent.

Dosage and Administration: Switching from other Antipsychotic agents: There are no systematically collected data to specifically address switching from other antipsychotics to ORIDONE, or concerning concomitant administration with other antipsychotics. While immediate discontinuation of the previous antipsychotic treatment may be acceptable for some patients, moreover gradual discontinuation may be most appropriate for majority of patients. In all cases the period of overlapping antipsychotic administration should be minimized.

Adults: ORIDONE (Risperidone) may given once daily or twice daily. Patients should be titrated to 6mg gradually over three days. Oridone Oral Solution may be given undiluted or mixed with non alcoholic beverages such as orange juice, low fat milk, not to be mixed with tea and cola. **Acute or Chronic Schizophrenia:** For acute or chronic patients of schizophrenia the usual initial daily dose of ORIDONE is 2mg on the first day , 4mg on the second day and 6mg on the third day in two divided doses. Further dosage adjustment may be needed and should generally be made ainterval of not less than one week, usual maintenance doses are 4 to 8mg daily. The maximum recommended dose is 16mg daily. However, patients may benefit from lower doses. A slower titration phase may be medically appropriate. Since the safety of doses above 16mg/day has not been evaluated doses above this level should not be used. If additional sedation is required a benzodiazepine may be added with ORIDONE. **Elderly:** In such cases it is advisable to use half of the recommended dose, with ainitial dose of 0.5mg twice daily, with slowly increased in steps of 0.5mg twice daily to a dose 1 to 2mg twice daily or as advised by the physician. In such patients slower titration may be medically appropriate.

Children: Experience is lacking in children aged less than 15 years.
Renal and Hepatic Insufficient Patients: In such type of patients it is advisable to use half of the recommended dose with an initial dose of 0.5mg twice daily with slowly increased in steps of 0.5mg twice daily to a dose of 1 to 2mg twice daily or as advised by the physician. In such patients slower titration may be medically appropriate.

Contra-Indications:
ORIDONE (Risperidone) is contra-indicated in patients with a known hypersensitivity to contents of the product.

Warnings and Precautions: Cardiovascular Disease: Due to alpha-blocking activity of ORIDONE, patients with cardiovascular disease should use ORIDONE with caution. It may also cause orthostatic hypotension especially during the initial dose. In such cases the dose should be reduced and adjusted accordingly.

Pregnancy and lactation:
Safety of ORIDONE during human pregnancy and lactation has not been established, so it should be used in these conditions only when clearly indicated and benefits out weigh the hazards. Elevated plasma prolactin levels in female patients can lead to side effects such as irregular menstrual cycle, amenorrhoea and galactorrhoea. Woman receiving ORIDONE should not be breast feed.

Epilepsy:
Epileptic patients should be given ORIDONE under close medical supervision.

During driving vehicles and operating machines: ORIDONE may interfere with activities requiring mental alertness. Therefore, patients should be advised not to drive vehicles or operate machinery until their individual susceptibility is known.

Drug Interaction: ORIDONE (Risperidone) should be used with caution when given along with other centrally acting drugs. ORIDONE may antagonize the effect of levodopa and other dopamine agonists. Carbamazepine has been shown to decrease the plasma levels of the active anti psychotic fraction of ORIDONE. Similar effects may be observed with other hepatic enzyme inducers. Phenothiazines, tricyclic antidepressants and some betablokers may increase the plasma concentration of Risperidone but not those of the antipsychotic fraction. When ORIDONE is taken together with other highly protein bound drugs there is no clinically relevant displacement of either drug from the plasma proteins.

Adverse Effects:
Based on extensively clinical experience including long term use, ORIDONE is generally well tolerated in majority of the patients. ORIDONE is reported to be less likely to cause sedation or extrapyramidal effect, however, agitation., insomnia, anxiety and headache have been commonly reported. Dyspepsia, nausea, abdominal pain, constipation, impaired mental concentration, somnolence, fatigue, dizziness, erectile dysfunction, rhinitis, rash, orthostatic hypotension, reflex tachycardia and hypertension have been reported less commonly. Weight gain, oedema and increased in hepatic enzyme levels have also been observed during treatment with ORIDONE.

Over Dosage:
There is no specific antidote to ORIDONE. In case of overdosage, vital signs should be carefully monitored and supportive and symptomatic measures should be used. Cardiovascular monitoring should be done to detect possible arrhythmia. Gastric lavage, administration of activated charcoal in addition to a laxative should be instituted.

Storage Condition:
Tablet store at room temperature (25ºC - 30ºC).

Oral Solution store below 30ºC.

Protect from sunlight, heat & moisture. Keep all medicines
out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

Manufactured by:
LISKO
Lisko Pakistan (Pvt.) Ltd.
L-10-D, Block-21, Shaheed
Rashid Minhas Road,
F. B. Industrial Area,Karachi.

Marketed by:
ORGANIC Pharmaceuticals