Tolvon®
10 mg or 30 mg Tablets

(Mianserin Hydrochloride)

Film coated tablets

For oral use only

ٹولون®

(میانسرین ہائیڈروکلورائیڈ)

فلم کوٹیڈ گولیاں

صرف کھانے کے لئے

Composition

Each film-coated tablet contains: 10 or 30 mg of mianserin hydrochloride (B.P.).

Characteristics

TOLVON is an antidepressant. Its active substance belongs to the piperazino-azepine group of compounds which are chemically not related to the tricyclic antidepressants (TCA's). Its structure lacks the basic side-chain which is considered to be responsible for the anticholinergic activity of the TCA's. The overall antidepressant efficacy of **TOLVON** is comparable with that of other currently used antidepressants. Moreover, it possesses anxiolytic properties which are of value in treating patients with anxiety associated with depressive illness.
TOLVON is well tolerated, in particular by the elderly and by patients with cardiovascular disease. At therapeutically effective dosages **TOLVON** is devoid of anticholinergic action and does not produce significant effects on the cardiovascular system. As compared to the TCA's, it causes less cardiotoxic effects on overdosage. **TOLVON** does not antagonize the action of sympathomimetic agents and antihypertensive drugs which block adrenergic neurons (e.g. bethanidine) or α 2-receptors (e.g. clonidine, methyldopa), nor does it affect the action of coumarin type anticoagulants such as phenprocoumon.

Indications

For relief of symptoms of depression in those cases of depressive illness where drug therapy is indicated.

Dosage

-	Adults	Treatment should begin with 30-40 mg daily and dosage should be adjusted according to the clinical response. The effective dose usually lies between 30 and 90 mg (mostly 60 mg) daily.
-	Elderly	Not more than 30 mg daily initially. The dose should be slowly increased under close supervision. A lower than the normal maintenance dose may be sufficient for a satisfactory clinical response.
-	Children	A dosage scheme cannot be given as there is no clinical experience.
N.B:		The daily dose can be taken either in divided doses or preferably (in view of a favourable effect on sleep) as a single dose at night. It is often advantageous to maintain antidepressant treatment for several months after clinical improvement has occurred.

Administration

The tablets should be swallowed without chewing, preferably with some fluid.

Contra-indications

- Mania.
- Severe liver disease.

Use during pregnancy and breast-feeding

Although animal experiments indicate that the drug does not cause foetal harm and is excreted in the milk in negligible amounts, the benefits of the use of **TOLVON** during pregnancy or breast-feeding should be weighed against the possible hazards to the foetus or the new born child.

Warnings and precautions

- **TOLVON** may impair psychomotor performance for the first few days of treatment. In general, depressed patients treated with antidepressants should avoid the performance of such hazardous tasks as driving a motor vehicle or operating machinery.
- **TOLVON** like other antidepressants, may precipitate hypomania in susceptible subjects with bipolar depressive illness. In such a case treatment with **TOLVON** should be withdrawn.
- Treatment should be discontinued if jaundice or convulsions occur. Bone-marrow depression, usually presenting as granulocytopenia or agranulocytosis, has been reported during treatment with **TOLVON.** These reactions have occurred most commonly after 4-6 weeks of treatment and were generally reversible on stopping treatment. If a patient shows fever, sore throat, stomatitis or other signs of infection, a full blood count should be obtained. This adverse reaction has been observed in all age groups but appears to be more common in the elderly.
- When treating patients with diabetes or cardiac, hepatic or renal insufficiency, normal precautions should be exercised and the dosage of any concomitant therapy kept under review. Patients with narrow angle glaucoma or symptoms suggestive of prostatic hypertrophy should also be monitored even though anticholinergic side-effects are not anticipated with **TOLVON** therapy.

Interactions

- **TOLVON** may potentiate the central nervous depressant action of alcohol central nervous system, and patients should be advised to avoid taking alcohol during treatment.
- **TOLVON** should not be administered concomitantly with or within two weeks of cessation of therapy with MAO inhibitors.
- **TOLVON** does not interact with bethanidine, clonidine, methyldopa, guanethidine or propranolol (either alone or in combination with hydralazine). Nevertheless, it is recommended to monitor the blood pressure of those patients who are concomitantly treated with antihypertensive drugs.

Adverse reactions

Blood dyscrasias, convulsion, hypomania, hypotension, disturbances of liver function, arthralgia, oedema and gynaecomastia have occasionally been reported. Drowsiness has been reported to occur in the first days of treatment. In order to ensure an optimal antidepressant effect, the dosage of **TOLVON** should not be reduced.

The frequency and severity of depression related symptoms such as blurred vision, dry mouth and constipation do usually not increase during treatment with **TOLVON** in fact an actual decrease has been observed in many cases.

Overdosage

Symptoms of acute overdosage are normally confined to prolonged sedation. Cardiac arrhythmias, convulsions, severe hypotension and respiratory depression are unlikely to occur. There is no specific antidote. Treatment is by gastric lavage with appropriate symptomatic and supportive therapy for vital functions.

Presentation

Tolvon 10 mg: Pack of 1x30's Blister.
Tolvon 30 mg: Pack of 3x10's Blisters.

Dosage

As directed by the physician.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

Instructions

Store at 2-30 °C. Protect from sunlight and moisture.
Keep out of reach of children.

ہدایات: ۲ تا ۳۰ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
N. V. Organon, Oss,
The Netherlands.

Marketed by:
Organon Pakistan (Pvt.) Ltd.
36-A/1, Lalazar, near M.T. Khan Road,
Karachi, Pakistan.

Mfg. Org. Spec.

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