PACKAGE INSERT

Remedica

NAME OF THE PRODUCT
Mianserin-Remedica 10 mg film-coated tablets
Mianserin-Remedica 30 mg film-coated tablets

NAME AND STRENGTH OF ACTIVE INGREDIENT
Mianserin-Remedica 10 mg film-coated tablets contain 10 mg Mianserin Hydrochloride
Mianserin-Remedica 30 mg film-coated tablets contain 30 mg Mianserin Hydrochloride

PRODUCT DESCRIPTION
White, round, scored, film-coated tablets.
The tablet can be divided into equal doses using pill cutter.

DOSAGE FORM
Film-coated tablets.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic
Pharmacotherapeutic group: Antidepressants-Tetracyclic derivatives
ATC Code: N06AX03 (Mianserin)
Mianserin, the active component of Mianserin-Remedica, belongs to the piperazino azepine group of compounds which are chemically not related to the tricyclic antidepressants (TCAs). Its structure lacks the basic side-chain which is considered to be responsible for the anticholinergic activity of the TCAs. Mianserin-Remedica is a centrally active presynaptic alpha-2-antagonist, which increases noradrenergic transmission. It does not increase central serotonin function but modulates ongoing serotonergic activity via antagonism at 5-HT2 and 5-HT3 receptors. Human pharmaco-EEG studies have confirmed the antidepressant profile of mianserin hydrochloride. The antidepressant efficacy of mianserin hydrochloride has been demonstrated in placebo-controlled trials and has been shown to be similar to other currently used antidepressants.
Moreover, it possesses anxiolytic and sleep improving properties which are of value in treating patients with anxiety or sleep disturbances associated with depressive illness. The histamine H1 and alpha-1-antagonistic activity of mianserin hydrochloride are thought to be responsible for its sedative properties.
Pharmacokinetic
After oral administration of Mianserin-Remedica, the active constituent, mianserin hydrochloride, is rapidly and well absorbed, reaching peak plasma levels within 3 hours. The bioavailability is approximately 20%. Binding of Mianserin-Remedica to plasma protein is approximately 90-95%.
The half-life of elimination (21 – 61 hours) is sufficient to justify once a-day dosing. Steady state plasma levels are reached within 6 days. Mianserin-Remedica is extensively metabolized and eliminated via the urine and faeces within 7 – 9 days. Two of the metabolites are active. Major pathways of biotransformation are demethylation and oxidation, followed by conjugation.

CLINICAL PARTICULARS
Indications
Depressive illness, particularly with anxiety.
Posology and method of administration
In the treatment of depression Mianserin-Remedica is given orally in doses of 30mg daily for the first few days. The effective daily dosage is usually between 30 and 90mg. The daily dosage may be divided throughout the day or given as a single dose at night. The recommended initial daily dose in the elderly is not more than 30mg, which may be slowly increased if necessary.
The drug is not recommended for use in children.
Route Of Administration
Oral
Contra-indications
Mianserin-Remedica is contra-indicated in patients with hypersensitivity to the active substance or any of the excipients, with mania and in patients with severe liver disease. Should not be used during pregnancy or breast feeding. Mianserin-Remedica should not be used in the treatment of children and adolescents under the age of 18 years, except for patients with depressive illness with or without anxiety.
Warnings and Precautions
It should be used with caution in patients with cardiovascular disorders, such as heart block, or after recent myocardial infarction. It should be used with caution in patients with diabetes mellitus, epilepsy and hepatic or renal insufficiency. This drug may precipitate hypomania in susceptible subjects with bipolar effective illness.
Patients with suicidal tendencies should be carefully supervised during treatment. Patients with narrow angle glaucoma or prostatic hypertrophy should be monitored even though antimuscarinic effects are rare. A full blood count is recommended every 4 weeks during the first 3 months of treatment, due to the risk of bone-marrow depression. Similarly, if a patient receiving Mianserin-Remedica develops fever, sore throat, stomatitis, or other signs of infection, treatment should be stopped and a full blood count obtained. The elderly are considered to be at special risk of blood disorders from Mianserin-Remedica.
Use in children and adolescents under 18 years of age:
Mianserin-Remedica should not be used in the treatment of children and adolescents under the age of 18 years, except for patients with depressive illness with or without anxiety. Suicide-related behaviours (suicide attempt and suicidal thoughts), and hostility (predominantly aggression, oppositional behavior and anger) were more frequently observed in clinical trials among children and adolescents treated with antidepressants compared to those treated with placebo. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth,

maturation and cognitive and behavioural development are lacking.
These products contain Lactose, so patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Depression is associated with an increased risk of suicidal thoughts, self harm and suicide (suiciderelated events). The risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.
Patients with a history of suicide-related events, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal attempts, and should receive careful monitoring during treatment. A meta-analysis of placebo-controlled clinical trials of antidepressant drugs in adult patients with psychiatric disorders showed an increased risk of suicidal behaviour with antidepressants compared to placebo in patients less than 25 years old.
Close supervision of patients and in particular those at high risk should accompany drug therapy especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behavior or thoughts and unusual changes in behavior and to seek medical advice immediately if these symptoms present.
Interactions With Other Medicaments
It is recommended that Mianserin-Remedica should not be given to patients receiving monoamine oxidase inhibitors or within 14 days of cessation of therapy with MAO. Mianserin-Remedica does not diminish the effects of the antihypertensive agents. It is to be expected that on pharmacological grounds there will be an interaction between mianserin hydrochloride and clonidine and mianserin hydrochloride and alphamethyldopa. Limited clinical experience to date has shown that mianserin hydrochloride does not interact with propanolol or with propranolol and hydralazine. Further clinical studies have shown that mianserin hydrochloride does not interact with guandethidine or bethanidine. However, it is still recommended that blood pressure is monitored when Mianserin-Remedica is prescribed with antihypertensive therapy. Phenytoin plasma concentrations should be watched carefully in patients treated concurrently with Mianserin-Remedica. The sedative effects of Mianserin-Remedica may be enhanced by concurrent administration with alcohol. Drowsiness is often experienced at the start of Mianserin-Remedica antidepressant therapy and patients if affected should not drive or operate machinery.
Pregnancy and Lactation
Pregnancy:
There is no evidence of safety of mianserin hydrochloride in human pregnancy. Therefore, Mianserin-Remedica should not be used during pregnancy unless there are compelling reasons.
Lactation:
Mianserin-Remedica should not be used during breast-feeding.
Side Effects
The most common adverse effect associated with mianserin hydrochloride is drowsiness. Mianserin hydrochloride also causes bone-marrow depression with leucopenia, and agranulocytosis; aplastic anaemia has been reported. The elderly are considered to be especially sensitive. Other side-effects reported include convulsions, disturbances of liver function and jaundice, breast disorders (gynaecomastia, nipple tenderness, and non puerperal lactation), dizziness, orthostatic hypotension, oedema, polyarthropathy, skin rash, sweating, and tremor. Antimuscarinic and cardiac side-effects are fewer and milder than with tricyclic antidepressants. Headache, diarrhoea, nausea, vomiting, hyperkinesias (restless legs) and exanthema have occasionally been reported.
Cases of suicidal ideation and suicidal behaviors have been reported during mianserin hydrochloride therapy or early after treatment discontinuation.
Symptoms And Treatment of Overdose
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 function.

PHARMACEUTICAL PARTICULARS
Storage Condition
Store below 30 ^{0}C. Protect from light and moisture.
Shelf Life
5 years
Pack Size Available
Mianserin-Remedica 10 mg film-coated tablets: Blister pack size of 100 (10x10) tablets.
Mianserin-Remedica 30 mg film-coated tablets: Blister pack size of 20 (2x10) tablets.

MANUFACTURER
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