PRESCRIBING INFORMATION

PRIMIDONE

Primidone Tablets USP

125 mg and 250 mg

Anticonvulsant
**PRESCRIBING INFORMATION**

**PRIMIDONE**

Primidone Tablets USP

125 mg and 250 mg

**THERAPEUTIC CLASSIFICATION**

Anticonvulsant

**INDICATIONS**

For the control of grand mal and psychomotor seizure. May be used alone or in combination with other anticonvulsants.

**CONTRAINDICATIONS**

Porphyria; patients hypersensitive to phenobarbital.

**PRECAUTIONS**

The abrupt withdrawal of antiepileptic medication may precipitate status epilepticus.

The therapeutic efficacy of a dosage regime takes several days before it can be assessed.

Recent reports strongly suggest an association between the use of anticonvulsant drugs by women with epilepsy and elevated incidence of birth defects in children born to these women. Reference has been made to primidone in several cases in which it was used in combination with other anticonvulsants, but its teratogenicity has not been demonstrated conclusively. The possibility exists that other factors, e.g. genetic factors of the epileptic condition, may contribute to the higher incidence of birth defects. The data also indicate that the great majority of mothers receiving anticonvulsant medication deliver normal infants.
Anticonvulsant drugs should not be discontinued in patients in whom the drugs are administered to prevent major seizures because of the strong possibility of precipitating status epilepticus with attendant hypoxia and risk to both mother and foetus. When the nature, frequency and severity of the seizures do not pose a clear threat to the patient, good medical practice requires that the physician weigh the expected therapeutic benefit against possible risk on an individual basis. Neonatal haemorrhage, with coagulation defect resembling vitamin K deficiency, has been described in newborns whose mothers were taking primidone or other anticonvulsants. Pregnant women under anticonvulsant therapy should receive prophylactic vitamin K therapy for one month prior to, and during delivery.

**Pregnancy:** The physician should weigh all of the foregoing considerations when treating and counselling epileptic women of childbearing potential.

The total daily dosage should not exceed 2 g. Since primidone therapy generally extends over prolonged periods, a complete blood count and sequential multiple analysis test (e.g. SMA-12) should be made every six months.

**Lactation:** There is evidence that in mothers treated with primidone, the drug, or its metabolites, appear in the milk in substantial quantities. Since tests for the presence of primidone in biological fluids are too complex to be carried out in the average clinical laboratory, it is suggested that the presence of undue somnolence and drowsiness in nursing newborns of primidone-treated mothers be taken as an indication that nursing should be discontinued.

**ADVERSE EFFECTS**

Adverse effects are minor and infrequent, tending to disappear with continued therapy or reduction of dosage. The isolated occurrence of the following, particularly in the early treatment program, have been reported: nausea, anorexia, vomiting, fatigue, hyperirritability, emotional disturbances, diplopia,
nystagmus, drowsiness, dizziness, and ataxia. Morbiliform skin eruptions are occasionally seen. Oedema, impaired sexual potency, polyuria and thirst occur only rarely. On rare occasions, persistent or severe side effects may necessitate withdrawal of the drug.

Megaloblastic anaemia may occur as a rare idiosyncrasy to primidone and to other anticonvulsants. The anaemia usually responds to folic acid 15mg daily, without the necessity of discontinuing therapy.

**OVERDOSAGE**

Symptoms and Treatment: As for barbiturate poisoning; general supportive therapy is recommended.

**DOSAGE**

<table>
<thead>
<tr>
<th>Week</th>
<th>Adults and Children over 8 years</th>
<th>Children under 8 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>250 mg hs</td>
<td>125 mg hs</td>
</tr>
<tr>
<td>2</td>
<td>250 mg bid</td>
<td>125 mg bid</td>
</tr>
<tr>
<td></td>
<td>(morning &amp; evening)</td>
<td>(morning &amp; evening)</td>
</tr>
<tr>
<td>3</td>
<td>250 mg tid</td>
<td>125 mg tid</td>
</tr>
<tr>
<td>4</td>
<td>250 mg qid</td>
<td>125 mg qid</td>
</tr>
</tbody>
</table>

If necessary, continue similar weekly increments until seizures are controlled. Dosage exceeding 2 g daily is not recommended. In patients already receiving other anticonvulsants, usual dosage range: Adults and children 8 years and older: 125 mg to 1500 mg daily in divide doses. Dosage is gradually increased while the dosage of other drug (s) is gradually decreased. When therapy with primidone alone is the objective, the transition should not be completed in less than two weeks.
AVAILABILITY OF DOSAGE FORMS

Round, white, flat-faced, bevelled edge, scored tablets containing primidone USP; 125 mg, identified “125”; 250 mg identified “250”.

Bottles of 100 and 500.