reach the target dose of 60 mg/kg/day, 50% of patients reached a final dose of at least
Clinical Pharmacology (12.3)].

CONTRAINDICATIONS

2.6 Initiation of Monotherapy for Pediatric Patients (Aged 4-16 Years)

The recommended total daily dose of Oxcarbazepine is shown in the table below.

<table>
<thead>
<tr>
<th>Weight Range (kg)</th>
<th>Dose Range (mg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 16</td>
<td>600 mg/day</td>
</tr>
<tr>
<td>16-30</td>
<td>600 mg/day to 1,200 mg/day</td>
</tr>
</tbody>
</table>

Oxcarbazepine may be increased as clinically indicated by a maximum increment of

2.7 Adjunctive Therapy for Pediatric Patients (Aged 2-16 Years)

Adjunctive Patients (Aged 2-16 Years): For patients aged 4-16 years, target maintenance dose should be achieved over 2 weeks (2.4). For patients aged 2 - <4 years, maximum maintenance dose should be achieved

<table>
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</tr>
</tbody>
</table>

Oxcarbazepine Tablets should be kept out of the reach and sight of children.

FULL PRESCRIBING INFORMATION

This represents the full prescribing information for Oxcarbazepine Tablets and should be referred to in conjunction with the Package Insert. The following sections are included:

1. INDICATIONS AND USES
2. DOSAGE AND ADMINISTRATION
3. DOSAGE FORMS AND STRENGTHS
4. CONTRAINDICATIONS
5. WARNINGS AND PRECAUTIONS
6. ADVERSE REACTIONS
7. DRUG INTERACTIONS
8. USE IN SPECIFIC POPULATIONS
9. STUDIES
10. USE IN SPECIFIC PATIENTS
11. CLINICAL PHARMACOLOGY
12. FULL PRESCRIBING INFORMATION

Adverse reactions were monitored in a controlled clinical study of oxcarbazepine in adults with partial seizures, compared to patients treated with placebo or active control. In this study, oxcarbazepine was administered in a twice-a-day regimen, and the recommended daily dose for adults was 2,400 mg, which was reached after approximately weekly increments. In this study, the most commonly reported adverse events associated with oxcarbazepine treatment were:

- 5% of patients experienced at least one severe adverse event
- 15% of patients discontinued treatment due to adverse events

The most common adverse events reported in this study were:

- Dizziness 22 6
- Constipation 2 2 6 4

In addition to these adverse events, there were also reports of:

- Nervous System: Insomnia 4 2 3 1
- Dermatological: Rash 12 3 7 6
- Gastrointestinal: Abdominal pain 10 2 3 8
- Musculoskeletal: Back pain 9 6 2 8

Other adverse events reported in the study included:

- Cardiac: Bradycardia 13 1 6 4
- Hematologic: Anemia 17 2 7 2
- Respiratory: Dyspnea 16 2 8 4

In conclusion, oxcarbazepine treatment was associated with a higher incidence of adverse events compared to placebo treatment. However, the incidence of severe adverse events was relatively low, and the majority of patients who discontinued treatment did so due to adverse events.

The full prescribing information for Oxcarbazepine Tablets should be referred to for complete information regarding the indications, dosages, and adverse events associated with this medication.

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