FIRST TIME GENERIC APPROVAL

Brand Name	Celontin®
Generic Name	methsuximide
Drug Manufacturer	Novitium Pharma LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

May 1, 2023

LAUNCH DATE

May 5, 2023

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 217213

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Methsuximide is indicated for the control of absence (petit mal) seizures that are refractory to other drugs.

MECHANISMS OF ACTION

Methsuximide suppresses the paroxysmal three cycle per second spike and wave activity associated with lapses of consciousness which is common in absence (petit mal) seizures. The frequency of epileptiform attacks is reduced, apparently by depression of the motor cortex and elevation of the threshold of the central nervous system to convulsive stimuli.

DOSE FORM AND STRENGTH

300 mg capsule

DOSE & ADMINISTRATION

Optimum dosage must be determined by trial. A suggested dosage schedule is 300 mg per day for the first week. If required, dosage may be increased thereafter at weekly intervals by 300 mg per day for the three weeks following a daily dosage of 1.2 g. Because therapeutic effect and tolerance vary among patients, therapy with methsuximide must be individualized according to the response of each patient. Optimal dosage is that amount of methsuximide which is barely sufficient to control seizures so that side effects may be kept to a minimum.

FIRST TIME GENERIC APPROVAL

Methsuximide may be administered in combination with other anticonvulsants when other forms of epilepsy coexist with absence (petit mal).