BREVITAL® (methohexital sodium) for injection, USP

**INDICATIONS AND USAGE**

BREVITAL® (methohexital sodium, USP) for injection, 3.0 mg/3 mL (10 mg/mL methohexital sodium) for injection, 1.5 mg/1.5 mL (10 mg/mL methohexital sodium) for injection, and 0.6 mg/0.6 mL (5 mg/mL methohexital sodium) for injection, is a freeze-dried, plug that is freely soluble in water.

Methohexital sodium is a rapid, ultrashort-acting barbiturate anesthetic. Methohexital sodium for injection is a freeze-dried, plug that is freely soluble in water.

**CLINICAL PHARMACOLOGY**

Compared with thiopental and thalidomide, methohexital is at least twice as potent on a weight basis, and its duration of action is only about half as long. Although the metabolic half-life of methohexital in the body is not clear, the drug does not appear to concentrate in fat deposits to the extent that other barbiturate anesthetics do. Thus, cumulative effects are few and necessary is more rapid with methohexital than with thalidomide. In experimental animals, the drug is excreted in the first 24 hours after administration.

Methohexital differs chemically from the established barbiturate anesthetics in that it contains no sulfur. Little enolization is conferred by barbiturates; their use in the presence of pain may result in excitation.

Intramuscular administration of methohexital results in a rapid onset by the brain within 30 seconds and rapid induction of sleep. Following intramuscular administration to pediatric patients, the onset of sleep occurs in 1 to 10 minutes. A plasma concentration of 3 mcg/mL, was achieved in pediatric patients 15 minutes after an intramuscular dose (10 mcg/kg) of a 5% solution. Following rectal administration to pediatric patients, the onset of sleep occurs in 10 to 15 minutes. Plasma concentration levels achieved following rectal administration tend to be lower than with the use of the more dilute solution concentrations when using the same dose. A 25 mcg/kg dose of 10% methohexital sodium yields plasma concentrations up to 9.9 to 7.9 mcg/mL, 15 minutes after dosing. Tissue concentrations in children are similar to those in adults. 

With simple ales, the time of resolution determines duration of pharmacologic effect. Methohexital occurs in the liver through deactivation and enterohepatic circulation is the rapid disintegration in vivo because of metabolism or binding to plasma proteins. Metabolism occurs in the liver through deactivation and enterohepatic circulation is the rapid disintegration in vivo because of metabolism or binding to plasma proteins.

**INDICATIONS AND USAGE**

**For Intravenous Use in Adults**

1. As an agent for inducing a hypnotic state.

2. As an agent for inducible anesthesia and as an adjunct to subpotent inhalational anesthetic agents for short surgical procedures; BREVITAL® may be given by infusion or intermittent injection. 

3. As an agent for inducing and maintaining anesthesia for short surgical, diagnostic or therapeutic procedures involving minor to moderately painful or stressfull procedures (see WARNINGS).

4. As an agent for inducing and maintaining anesthesia for short surgical, diagnostic or therapeutic procedures involving minor to moderately painful or stressfull procedures (see WARNINGS).

5. As an agent for inducing a hypnotic state.

6. As an agent for inducing and maintaining anesthesia for short surgical, diagnostic or therapeutic procedures involving minor to moderately painful or stressfull procedures (see WARNINGS).

**For Intravenous Use in Pediatric Patients Only**

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2. **As an agent for inducing and maintaining anesthesia for short surgical, diagnostic or therapeutic procedures involving minor to moderately painful or stressfull procedures (see WARNINGS).**

**WARNINGS/Pediatric Neurotoxicity, PRECAUTIONS/Pediatric Use, and USES IN SPECIFIC POPULATIONS/Pediatric Use**, suggest that 1 or more of the following may be of benefit in reducing the area of necrosis:

1. drone flying (see description that may result in excitation.

2. drone flying (see description that may result in excitation.

3. drone flying (see description that may result in excitation.

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**For Intravenous Use in Adults**

1. The extent of injury is related to concentration. Concentrations of 1% methohexital will usually suffice; higher concentrations should only be used in emergency situations.

2. Check the site to ensure that the catheter is in the lumen of a vein before injection. Injection through a running catheter is highly inefficient and may result in the administration of drug other than the desired one.

3. Intravenous (i.v.) injection of the site of injury, followed by systemic steroids. An i.v. injection (25%).

**For Intravenous Use in Pediatric Patients Only**

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4. For Intravenous Use in Pediatric Patients Only

**WARNINGS**

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Due to a variety of limitations such as study design, biopharmaceutics issues, and the wide range of effects observed with barbiturate analgesics, substantial differences in interindividual responses to barbiturates are not unexpected. Published juvenile animal studies demonstrated that the administration of anesthetics and sedative drugs, such as BREVITAL, isoflurane, and diazepam, administered intravenously, produces a dose-related impairment of visual-motor and sensory-motor function parameters, results in widespread necrotic and oligodendroglial cell loss in the developing brain and alterations in synaptic morphology and neurotransmitter levels, and results in neuronal cell death. Data in rodents and in primates suggest that the neuronal and oligodendroglial cell associations are associated with profound neurodevelopmental defects in learning and memory. The clinical significance of these neurodevelopmental findings is not known, and healthcare providers should balance the benefits of appropriate anesthesia in neonates and young children, who have a high neuronal and oligodendroglial cell population, against the potential risks suggested by the animal studies.

In primates, exposure to 3 hours of anesthesia that produced a light surgical plane of anesthesia did not increase neuronal cell loss. However, treatment regimens of 5 hours or longer of isoflurane increased neuronal cell loss. Data from isoflurane-treated rodents and rat brains indicate that either block NMDA receptors or potentiate the activity of GABA during the period of rapid brain growth or synaptogenesis, may be associated with subtle but prolonged cognitive deficits in learning and memory.

Neurobehavioral (including auditory, respiratory, cardiovascular, gastrointestinal, and behavioral) monitoring should be performed at the operator’s discretion. 

Administration

Dilution

When the first dilutor is made with the 2.5 g, the solution in the vid be yellow. When further diluted to make 1% solution, it must be clear and colorless or should not be used.

FOR CONTINUOUS INTRAVENOUS ADMINISTRATION

For intravenous administration, prepare a 5% solution by adding 50 mL of BREVITAL to 250 mL of diluent. For this infusion, either 5% glucose solution or 0.9% sodium chloride solution (1% w/v) are recommended as the diluent of choice.

The preferred diluent for intramuscular administration is Sterile Water for Injection, 0.9% Sodium Chloride Injection or 5% Dextrose Injection is also an acceptable diluent.

For Intramuscular Administration

The strength of BREVITAL is 10 mg/mL. Each mL contains 10 mg of sodium pentobarbital, and 0.1 mL contains 1 mg. The preferred diluent for intramuscular administration is Sterile Water for Injection. 0.9% Sodium Chloride Injection is also an acceptable diluent.

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