May be habit-forming.

Pregnancy Category C:
Plasma protein binding: 45% (mean), with a large degree of variation. Butalbital is well distributed to most tissues and organs, including the placenta (see below).

Acetaminophen may alter drug concentrations and/or therapeutic effects and thereby influence the plasma protein binding of butalbital. The clinical significance of these findings is not known.

Drug Interactions:

CNS Depression: Butalbital and acetaminophen may produce additive CNS depression when taken with this combination product, and such tasks should be avoided. Patients should be cautioned against driving or operating machinery while taking this product.

Drug/Liquid Interactions: When this combination product is taken with alcohol, general anesthetics, sedative-hypnotics, tranquilizers such as chloral hydrate, meprobamate (Equanil®), secobarbital sodium, and antihistamines, the effects of therapy may be increased. Such tasks should be avoided.

Drug/Other Substances Interactions: Several studies have compared the pharmacokinetic characteristics of butalbital with those of other barbiturates  such as phenobarbital. Overlap between the plasma concentration-time profiles of these drugs is evident, but the overlap with butalbital is less extensive than that with secobarbital and is reduced to a varying degree and binds to plasma and tissue proteins to a varying degree and binds to plasma and tissue proteins. The plasma half-life is 2-4 hours.

Acetaminophen (4′-hydroxyacetanilide) is an antipyretic. It has the following structural formula:

\[
\text{C}_8\text{H}_9\text{NO}_2 \quad \text{MW}=151.16
\]

It consists of a fixed combination of butalbital and acetaminophen. Butalbital (5-allyl-5-isobutyl barbituric acid), a slightly beta-barbiturate, is supplied in tablet form for oral administration.

Each tablet contains:

- Butalbital ............... 50 mg
- Acetaminophen ......... 325 mg

Warnings and Precautions:

This product is contraindicated in patients with a known allergy to any component of this product.

Patients with porphyria should be warned against taking this product. It is also not known whether butalbital and acetaminophen may produce additive CNS depression when taken with this combination product, and such tasks should be avoided.

Drug/Liquid Interactions: When this combination product is taken with alcohol, general anesthetics, sedative-hypnotics, tranquilizers such as chloral hydrate, meprobamate (Equanil®), secobarbital sodium, and antihistamines, the effects of therapy may be increased. Such tasks should be avoided.

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Acetaminophen is principally by liver metabolism (conjugation, most as the glucuronide conjugate, with excretion of urea (about 17%) and subsequent renal excretion of metabolites. The plasma half-life is 1-2 hours. The excretion products include dehydrogenase (MAO) inhibitors. The clinical significance of these findings is not known.

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Barbiturates may be habit-forming. The risk is higher if used long-term or in high doses. It is not known if this drug is safe for use by children, adults, or during pregnancy. The drug may cause harm if taken at too high a dose, which may make you feel drowsy or confused. Do not discontinue the drug abruptly; withdrawal symptoms may develop. The use of this drug during pregnancy should be avoided. Other considerations include:

- It is not known if this drug is safe for use by children, adults, or during pregnancy.
- The drug may be harmful if taken in high doses.
- It is not known if this drug is safe for use during pregnancy.
- Do not discontinue the drug abruptly.

Indications:
- This drug is used to relieve pain and fever.
- It is also used to prevent and treat seizures.

Contraindications:
- This drug is not recommended for use in patients with a history of sensitivity to barbiturates, children, or adults.
- It is not recommended for use in pregnant women.
- It is not recommended for use in patients with a history of sensitivity to acetaminophen.
- It is not recommended for use in patients with a history of sensitivity to aspirin.

Adverse Reactions:
- The most common adverse reactions include dizziness, sedation, and confusion.
- Other adverse reactions include:
  - Nervous system: Dizziness, sedation, confusion, and coma.
  - Gastrointestinal: Heartburn, nausea, and vomiting.
  - Cardiovascular: Hypotension.
  - Autonomic nervous system: Heart rate change.
  - Respiratory: Hyperventilation.
  - Hematologic: Methemoglobinemia.
  - Other: Rhinorrhea, rash, thrombocytopenia, and methemoglobinemia.

Dosage and Administration:
- The recommended dosage is:
  - Adults: One to two tablets every 4 hours as needed.
  - Children: One tablet every 4 hours as needed.

Administration:
- This drug may be taken orally, intramuscularly, or intravenously.
- The manufacturer may administer the drug for additional control as needed.

Overdosage:
- Overdosage may result in:
  - Coma
  - Convulsions
  - Respiratory depression
  - Hypotension
  - Shock

Treatment:
- Treatment may include:
  - Inducing emesis
  - Activated charcoal
  - Antidotes
  - Supportive care

Antidotes:
- The recommended antidotes are:
  - Activated charcoal
  - Barbiturate antagonist
  - Methemoglobinemia corrector

Supportive Care:
- Supportive care includes:
  - Admission to hospital
  - Intravenous administration
  - Oxygen supplementation

References:

Manufactured by:
- H22001

Address:
- 5550 MacArthur Boulevard
- Atlanta, GA 30318

Telephone:
- 1-800-635-3350

Fax:
- 404-328-3338

Website:
- www.takeda.com

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- May 2017