

Health Professional Summary: CALIQUIL™

ROUTE OF ADMINISTRATION: Oral

DOSAGE FORM/STRENGTH: Capsule of 500mg extract equivalent to 2.5g of the dried herb top of California poppy

NON MEDICINAL INGREDIENT: Micro-crystalline cellulose



CLINICAL USE

CaliQuil™ is recommended for the treatment of pain (analgesic) and/or the treatment of insomnia.

It is recommended that you prescribe 1 or 2 capsules of CaliQuil™ at night as an analgesic for night pain or as a sedative (hypnotic) for insomnia. Begin with 1 capsule and escalate to 2 capsules if needed. Do not exceed a single administration of 2 capsules.

For acute or chronic pain, use 1 capsule of CaliQuil™ in the morning and 1 capsule in the evening. It is important to advise your patient that this product may cause drowsiness and to avoid performing any tasks that require attention such as driving.

Children and Adolescents (< 18 years of age):

The product is only recommended for use in adults. There is no clinical data supporting the use in children and adolescents.

CONTRAINDICATIONS

Dependence/Tolerance

There is no known dependence or addiction to California poppy. CaliQuil™ is a dietary supplement and is not classified as a narcotic or controlled drug. There are no reports of a tolerance to the hypnotic or analgesic effects of California poppy.

General

Do not use CaliQuil™ in people with known allergy/hypersensitivity to California poppy (*Eschscholzia californica*), its constituents (codeine or morphine and their derivatives), or related members of the Papaveraceae (Poppy) family. Do not take while pregnant or breast feeding without consulting your physician.

Potential Adverse Drug Reactions

The following adverse drug reactions have been observed/ reported with other standardized California poppy extract products:

- Altered dreaming: frequently reported by people as peasant or strange dreams
- Drowsiness: frequently reported by people taking alcohol or other sedatives/tranquilizers
- Insomnia: low incidence, but excitation is known to occur in some people

Potential Drug Interactions

California poppy and its extracts may have an additive effect when used with sedatives, tranquilizers, hypnotics, and analgesics.

Drug-Drug Interactions

In vitro studies performed using pure synthetic forms of the known ingredients of California poppy revealed that Escholtzine (MM = 323 g/mole) had strong inhibition of CYP3A4 (ic50= 13.4± 4.7 uM); the other alkaloids only had weak inhibition. CaliQuil™ contains 0.4 to 1.2mg of Escholtzine. When given once or twice a day, CaliQuil™ should not cause significant CYP3A4 inhibition.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

CaliQuil™ is standardized to contain 0.8% of the three isoquinoline alkaloids califonidine, escholtzine, and protopine. The following is a summary of the animal pharmacology data that confirmed the sedative, anxiolytic, and some of the analgesic effects of a 5:1 extract of California poppy.

Pharmacodynamics/Pharmacokinetics

Onset of action: Oral: 15-30 minutes

Duration of action (based on observations in clinical trials): Oral: 4-6 hours

The absorption-distribution-metabolism and excretion (ADME) of California poppy extracts currently cannot be performed since these products contain hundreds of ingredients and the analytical methodology is not sufficiently sensitive to follow the three main isoquinoline alkaloids at the plasma levels found in the human body.

STORAGE AND STABILITY

CaliQuil™ capsules should be stored at room temperature. The product is stable for 2 to 3 years.