PRODUCT INFORMATION
HALCION® triazolam

NAME OF THE MEDICINE

Halcion (triazolam), a triazolobenzodiazepine, is chemically 8-chloro-6-(o-chlorophenyl)-1-methyl-4H-S-triazolo-[4,3-alpha][1,4] benzodiazepine. It has a molecular weight of 343.21 and the following structural formula:

![Structural formula of triazolam](image)

The CAS number is 28911-01-5

DESCRIPTION

It is a white crystalline powder, soluble in ethanol and poorly soluble in water (less than 0.1%). Halcion tablets contain 0.125 mg triazolam with lactose, microcrystalline cellulose, colloidal anhydrous silica, maize starch, magnesium stearate, docusate sodium with sodium benzoate, indigo carmine (CI 73015) and erythrosine (CI 45430).

PHARMACOLOGY

Pharmacodynamics

Halcion is a potent short-acting hypnotic agent. In sleep laboratory studies in man, Halcion reduced sleep latency, increased duration of sleep and decreased the number of nocturnal awakenings compared to baseline. Other manifestations of effect included inco-ordination, impaired equilibrium, ataxia, muscle weakness, and amnesia. The duration and intensity of the CNS depression was dose-related. At usual therapeutic doses there was no significant respiratory or cardiovascular depression.

After two weeks of consecutive nightly administration, the drug's effect on total wake time is decreased, and the values recorded in the last third of the night approach baseline levels. On the first night after drug discontinuance (first post-drug night), total time asleep, percentage of time spent sleeping, and rapidity of falling asleep frequently were significantly less than on baseline (pre-drug) nights. This effect is often called "rebound" insomnia.

The type and duration of hypnotic effects and the profile of unwanted effects during administration of benzodiazepine drugs may be influenced by the biologic half-life of administered drug, the dose given, and any active metabolites formed. When half-lives are long, or the dosage increased, drug or metabolites may accumulate during periods of nightly administration and be associated with impairments of cognitive and motor performance during waking hours; the possibility of interaction
with other psychoactive drugs or alcohol will be enhanced. In contrast, if half-lives are short, or dosage reduced, drug and metabolites will be cleared before the next dose is ingested, and carry-over effects related to excessive sedation or CNS depression should be minimal or absent. However, during nightly use for an extended period, pharmacodynamic tolerance or adaptation to some effects of benzodiazepine hypnotics may develop. If the drug has a short half-life of elimination, it is possible that a relative deficiency of the drug or its active metabolites (i.e., in relationship to the receptor site) may occur at some point in the interval between each night's use. This sequence of events may account for two clinical findings reported to occur after several weeks of nightly use of rapidly eliminated benzodiazepine hypnotics: 1) increased wakefulness during the last third of the night, and 2) the appearance of increased daytime anxiety after 10 days of continuous treatment.

**Pharmacokinetics**

**Absorption**

Following an oral dose of 0.88 mg of Halcion (triazolam$^{14}$C) in man, the mean peak plasma concentration of Halcion occurred at a mean time of 1.5 ± 0.7 hours. Halcion levels decreased with a mean apparent plasma half-life ($t_{1/2}$) of 2.7 ± 0.5 hours. Halcion is extensively and rapidly metabolised. Metabolite levels peaked at 1.6 ± 0.7 hours, decreased by a biphasic process, with a mean apparent half-life for the initial phase of 3.4 ± 0.9 hours and 7.8 ± 1.5 hours for the terminal phase. The mean recovery of $^{14}$C by 240 hours was 89.6% (81.8% of urine and 7.9% of faeces).

**Distribution**

*In vitro*, Halcion is loosely bound (89%) to human serum proteins, and is rapidly dissociated, as shown by a relatively short plasma half-life of 2.7 hours. Although Halcion might be expected to dissociate rapidly, the serum concentration of free drug at any given time was extremely low (approximately 4%). Binding to serum albumin amounted to 49%. Halcion, equivalent to or greater than 100 times the therapeutic dose, does not displace bilirubin bound to human serum albumin *in vitro*.

The systemic availability of oral Halcion is increased in geriatric patients, probably due to a diminished first-pass hepatic metabolism (see PRECAUTIONS).

**Metabolism**

The major metabolites are a-hydroxymethyl triazolam (8-chloro-6-(o-chlorophenyl)-1-hydroxymethyl-4H-S-triazolo-[4,3-a][1,4] benzodiazepine), and 4-hydroxy triazolam (8-chloro-6-(o-chlorophenyl)-4-hydroxy-1-methyl-4H-S-triazolo-[4,3-a][1,4] benzodiazepine). These two metabolites accounted for 69% and 11% respectively of the urinary excretion in man. The pharmacological activity of Halcion metabolites has not been determined in man.

Pharmacokinetic interactions can occur when triazolam is administered along with drugs that interfere with its metabolism. Compounds which inhibit certain hepatic enzymes (particularly cytochrome P450IIIA4) may increase the concentration of triazolam and enhance its activity. Specific examples, documented with evidence from clinical pharmacokinetic studies, include the following: cimetidine, erythromycin (a macrolide antibiotic), nefazodone, ketoconazole, and itraconazole. Inhibition of the metabolism of other benzodiazepines metabolised by pathways similar to those for triazolam has been reported for a number of drugs, for example, diltiazem and verapamil. There is the possibility of similar interactions with triazolam.

In a clinical pharmacokinetic study conducted in healthy volunteers, co-administration of grapefruit juice increased the maximum plasma concentration of triazolam by 25%, increased the area under
the curve by 48% and increased half life by 18% (see INTERACTION WITH OTHER MEDICINES).

**Excretion**

Excretion of $^{14}$C in urine, faeces, and urine plus faeces appeared to be biphasic. The excretion half-times for urine plus faeces, corresponding to the initial and terminal excretion phases, were $3.4 \pm 0.5$ hours and $30 \pm 8$ hours. Only small amounts (approximately 2%) of unmetabolised Halcion appear in the urine.

**INDICATIONS**

Halcion is indicated for the short-term treatment of insomnia (generally 7-10 days). Use for more than 2-3 weeks requires complete re-evaluation of the patient (see PRECAUTIONS).

Prescriptions for Halcion should be written for short-term use (7-10 days) and it should not be prescribed in quantities exceeding a 1-month supply.

**CONTRAINDICATIONS**

- Pregnancy
- Depressed patients with suicidal tendencies
- Myasthenia gravis
- Co-administration with nefazodone, ketoconazole, itraconazole and HIV protease inhibitors (see PRECAUTIONS and INTERACTIONS WITH OTHER MEDICINES)
- Lactation
- Hypersensitivity to benzodiazepines or any of the excipients contained in Halcion tablets (see PRESENTATION)
- Chronic obstructive airways disease with incipient respiratory failure.

**PRECAUTIONS**

Because some of the adverse effects of Halcion appear to be dose-related (see DOSAGE AND ADMINISTRATION), it is important to use the smallest possible effective dose, especially in the elderly (see Use in the Elderly or Debilitated Patients).

In general, benzodiazepines should be prescribed for short periods only. Halcion is indicated in the short-term treatment of insomnia (generally 7-10 days). Use of Halcion for more than 2-3 weeks requires complete re-evaluation of the patient. Continuous long-term use of Halcion is not recommended. There is evidence that tolerance develops to the sedative effect of benzodiazepines. When Halcion is used at recommended doses for short-term treatment, the dependence potential is low. However, as with all benzodiazepines, the risk of dependence increases with higher doses and long-term use and is further increased in patients with a history of alcoholism or drug abuse (see Dependence).

After as little as one week of therapy with recommended doses, withdrawal symptoms can appear following cessation of treatment, e.g., rebound insomnia following cessation of a hypnotic benzodiazepine. Caution patients not to take Halcion in circumstances where a full night's sleep and clearance of the drug from the body are not possible before they would again need to be active and functional, e.g., an overnight flight of less than 7-8 hours, since amnestic episodes have been reported in such situations.
Transient amnesia or memory impairment has been reported in association with the use of benzodiazepines.

**Severe anaphylactic and anaphylactoid reactions**

Rare cases of angioedema involving the tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of sedative-hypnotics. Some patients have had additional symptoms such as dyspnoea, throat closing, or nausea and vomiting that suggest anaphylaxis. Some patients have required medical therapy in the emergency department. If angioedema involves the tongue, glottis, or larynx, airway obstruction may occur and be fatal. Patients who develop angioedema after treatment with Halcion should not be re-challenged with the drug.

**Sleep Disturbance**

Sleep disturbance may be the presenting manifestation of a physical and/or psychiatric disorder. Consequently, a decision to initiate symptomatic treatment of insomnia should only be made after the patient has been carefully evaluated.

The failure of insomnia to remit after 7-10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.

Worsening of insomnia or the emergence of new abnormalities of thinking or behaviour may be the consequence of an unrecognised psychiatric or physical disorder. These have also been reported to occur in association with the use of Halcion.

**Psychiatric Effects**

An increase in daytime anxiety has been reported for Halcion after as few as 10 days of continuous use. In some patients this may be a manifestation of interdose withdrawal (see **PHARMACOLOGY**). If increased daytime anxiety is observed during treatment, discontinuation of treatment may be advisable.

A variety of abnormal thinking and behaviour changes have been reported to occur in association with the use of benzodiazepine hypnotics including Halcion. Some of these changes may be characterised by decreased inhibition, e.g., aggressiveness and extroversion that seem excessive, similar to that seen with alcohol and other CNS depressants (e.g., sedative/hypnotics). Other kinds of behavioural changes have also been reported, for example, bizarre behaviour, agitation, hallucinations, depersonalisation. In primarily depressed patients, the worsening of depression, including suicidal thinking, has been reported in association with the use of benzodiazepines.

It can rarely be determined with certainty whether a particular instance of the abnormal behaviours listed above is drug induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioural sign or symptom of concern requires careful and immediate evaluation.

As with all patients taking CNS-depressant medications, patients receiving Halcion should be warned not to operate dangerous machinery or motor vehicles until it is known that they do not become drowsy or dizzy from Halcion therapy (see **Effects on Ability to Drive and Use of Machines**). Patients should also take care as pedestrians. Abilities may be impaired on the day following use. Patients should be advised that their tolerance for alcohol and other CNS-depressants will be diminished and that these medications should either be eliminated or given in reduced dosage in the presence of Halcion.
“Sleep-driving” and other complex behaviours

Complex behaviours such as “sleep-driving” (i.e., driving while not fully awake after ingestion of a sedative-hypnotic, with amnesia for the event) have been reported. These events can occur in sedative-hypnotic-naive as well as in sedative-hypnotic-experienced persons. Although behaviours such as sleep-driving may occur with sedative-hypnotics alone at therapeutic doses, the use of alcohol and other CNS depressants with sedative-hypnotics appears to increase the risk of such behaviours, as does the use of sedative-hypnotics at doses exceeding the maximum recommended dose. Due to the risk to the patient and the community, discontinuation of sedative-hypnotics should be strongly considered for patients who report a “sleep-driving” episode.

There have been reports of people getting out of bed after taking a sedative-hypnotic and driving their cars while not fully awake, often with no memory of the event. If a patient experiences such an episode, it should be reported to his or her doctor immediately, since “sleep-driving” can be dangerous. This behaviour is more likely to occur when sedative-hypnotics are taken with alcohol or other central nervous system depressants or when sedative-hypnotics are used at doses exceeding the maximum recommended dose.

Other complex behaviours (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with “sleep-driving”, patients usually do not remember these events.

Depression, Psychosis and Schizophrenia

Halcion is not recommended as primary therapy for patients with depression and psychosis. In such conditions, psychiatric assessment and supervision are necessary if benzodiazepines are indicated. Benzodiazepines may increase depression in some patients and may contribute to deterioration in severely disturbed schizophrenics with confusion and withdrawal. Suicidal tendencies may be present or uncovered and protective measures may be required.

Paradoxical Reactions

Paradoxical reactions such as acute rage, stimulation or excitement may occur; should such reactions occur, Halcion should be discontinued.

Impaired Respiratory Function

Caution in the use of Halcion is recommended in patients with respiratory depression or sleep apnoea. In patients with chronic obstructive pulmonary disease, benzodiazepines can cause increased arterial carbon dioxide tension and decreased oxygen tension. In patients with compromised respiratory function, respiratory depression and apnoea have been reported infrequently.

Hypotension

Although hypotension may occur only rarely, benzodiazepines should be administered with caution to patients in whom a drop in blood pressure might lead to cardiac or cerebral complications. This is particularly important in the elderly patient.

Abuse

Caution must be exercised in administering Halcion to individuals known to be addiction prone, or those whose history suggests they may increase the dosage on their own initiative. It is desirable to limit repeat prescriptions without adequate medical supervision.
Dependence
The use of benzodiazepines may lead to dependence as defined by the presence of a withdrawal syndrome on discontinuation of the drug. Tolerance as defined by a need to increase the dose in order to achieve the same therapeutic effect seldom occurs in patients receiving the recommended dose under medical supervision. Tolerance to sedation may occur with benzodiazepines, especially in those with drug seeking behaviour. Tolerance may develop during 1 to 2 weeks of therapy.

Withdrawal symptoms, similar in character to those noted with barbiturates and alcohol have occurred following abrupt discontinuance with benzodiazepines, including Halcion. These symptoms range from insomnia, anxiety, dysphoria, palpitations, panic attacks, vertigo, myoclonus, akinesia, hypersensitivity to light, sound and touch, abnormal body sensations (e.g., feelings of motion, metallic taste), depersonalisation, derealisation, delusional beliefs, hyperreflexia and loss of short term memory, to a major syndrome which may include convulsions, seizures, tremor, abdominal and muscle cramps, confusional state, delirium, hallucinations, hyperthermia, psychosis, vomiting and sweating. Such manifestations of withdrawal, especially the more serious ones are more common in patients who have received excessive doses over a prolonged period. However, withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines taken continuously at therapeutic levels. Accordingly, Halcion should be terminated by tapering the dose to minimise occurrence of withdrawal symptoms. Patients should be advised to consult with their physician before either increasing the dose or abruptly discontinuing the medication.

Rebound phenomena have been described in the context of benzodiazepine use. Rebound insomnia and anxiety mean an increase in the severity of these symptoms beyond pre-treatment levels following the cessation of benzodiazepines. Rebound phenomena in general possible reflect the re-emergence of pre-existing symptoms combined with withdrawal symptoms described earlier. Some patients prescribed benzodiazepines with very short half-lives (in the order of 2 to 4 hours) may experience relatively mild rebound symptoms between their regular doses. Withdrawal/rebound symptoms may follow the use of high doses for relatively short periods.

Acute Narrow-Angle Glaucoma
Caution should be used in the treatment of patients with acute-narrow glaucoma (because of atropine-like side effects).

Epilepsy
Abrupt withdrawal of benzodiazepines in persons with convulsive disorders may be associated with a temporary increase in the frequency and/or severity of seizures.

Patients with convulsive disorder should not be abruptly withdrawn from Halcion.

Use in Pregnancy: Category C
Halcion is contraindicated in pregnant women.

Benzodiazepines cross the placenta and may cause hypotonia, respiratory depression and hypothermia in the newborn infant. Continuous treatment during pregnancy and administration of high doses in connection with delivery should be avoided. Withdrawal symptoms in newborn infants have been reported with this class of drug.
**Non-Teratogenic Effects**

It is to be considered that the child born of a mother who is on benzodiazepines may be at some risk for withdrawal symptoms from the drug during the postnatal period. Also, neonatal flaccidity has been reported in an infant born of a mother who had been receiving benzodiazepines.

Radioactive studies in pregnant mice have demonstrated that the drug and its metabolites cross the placenta and are present at maternal concentrations in the foetuses. In rats or rabbits, Halcion 10 mg and 30 mg per kg per day given during gestation is considered to be associated with retarded or impaired skeletal formation. In rabbits given 5 mg per kg per day, the viability and weight gain of the neonates was impaired. These findings do not exclude the possibility of embryotoxicity and teratogenicity in pregnant women.

**Use in Lactation**

Halcion is contraindicated in breast feeding mothers.

Human studies on the excretion of Halcion in breast milk have not been performed. Studies in rats have, however, indicated that Halcion and its metabolites are excreted in breast milk. Benzodiazepines generally show increased toxicity in neonates, and the excretion of benzodiazepines in breast milk may cause drowsiness and/or feeding difficulties in the infant.

**Paediatric Use**

Benzodiazepines and other hypnotic drugs may impair mental alertness in children. Halcion is not recommended as safety and effectiveness in patients under the age of 18 has not been established.

**Use in the Elderly or Debilitated Patients**

Such patients may be particularly susceptible to the sedative effects of benzodiazepines and associated giddiness, ataxia and confusion, which may increase the possibility of a fall. For this reason, the dosage should be limited to the smallest effective amount to preclude such effects (see DOSAGE AND ADMINISTRATION).

The systemic availability of oral Halcion is increased in elderly patients probably due to a diminished first-pass hepatic metabolism.

**Use in Renal Impairment**

Patients with impaired renal function should use benzodiazepine medication with caution and a reduction in dosage, or decision not to prescribe, may be necessary in such patients.

**Use in Hepatic Impairment**

Patients with impaired renal or liver function should use benzodiazepine medication with caution and a reduction in dosage, or decision not to prescribe, may be necessary in such patients. In rare instances some patients taking benzodiazepines have developed blood dyscrasias, and some have had elevations of liver enzymes. As with other benzodiazepines, periodic blood counts and liver function tests are recommended. Caution must be used in treating patients with impaired hepatic function, severe pulmonary insufficiency, or sleep apnoea.

**Effects on Ability to Drive and Use of Machines**

Patients receiving Halcion should be warned not to operate dangerous machinery or motor vehicles until it is known that they are fully awake and no longer feeling drowsy.
There have been reports of people driving their cars while not fully awake after taking a sedative-hypnotic, often with no memory of the event. Due to the risk to the patient and the community, discontinuation of Halcion therapy should be strongly considered if a patient experiences such an episode (see PRECAUTIONS, “Sleep-driving” and other complex behaviours).

**INTERACTIONS WITH OTHER MEDICINES**

The benzodiazepines, including Halcion, produce additive CNS depressant effects when co-administered with alcohol or other medication which themselves produce CNS depression e.g., barbiturates, sedatives, tricyclic antidepressants, non-selective MAO inhibitors, phenothiazines and other antipsychotics, skeletal muscle relaxants, antihistamines, narcotic analgesics and anaesthetics (see PRECAUTIONS).

Halcion undergoes oxidative metabolism, and consequently may interact with disulfiram or cimetidine resulting in increased plasma levels of Halcion. Increased levels of Halcion have also been observed with co-administration of erythromycin. Patients should be observed closely for evidence of enhanced benzodiazepine response during concomitant treatment with disulfiram, verapamil, diltiazem isoniazid, fluvoxamine, sertraline, paroxetine, cimetidine or macrolide antibiotics such as erythromycin, troleandomycin and clarithromycin; some patients may require a reduction in the dosage of Halcion. In the cases of nefazodone, ketoconazole and itraconazole, the magnitude of the interaction is such that co-administration of triazolam with these drugs is contraindicated. The co-administration of triazolam with otherazole-type antifungals is not recommended. In general, caution should be used when triazolam is used in combination with a drug that is known to inhibit cytochrome P450III A4.

The pharmacokinetics of triazolam may be altered by co-administration of grapefruit juice (see Pharmacokinetics).

The anticholinergic effects of other drugs, including atropine and similar drugs, antihistamines and antidepressants may be potentiated when taken in conjunction with benzodiazepines.

Interactions have been reported between some benzodiazepines and anticonvulsants, with changes in the serum concentration of the benzodiazepine or the anticonvulsant. It is recommended that patients be observed for altered responses when benzodiazepines and anticonvulsants are prescribed together, and that serum level monitoring of the anticonvulsant be performed more frequently.

Interactions involving HIV protease inhibitors (e.g., ritonavir) and triazolam are complex and time dependent. Short-term low doses of ritonavir resulted in a large impairment of triazolam clearance, prolonged its elimination half-life and enhanced clinical effects. The co-administration of triazolam with HIV protease inhibitors is contraindicated (see CONTRAINDICATIONS).

Minor EEG changes, usually low voltage fast activity, of no known clinical significance, has been reported with benzodiazepine administration.

**ADVERSE EFFECTS**

During clinical trials in which 5,420 patients received Halcion, the most common adverse effects were drowsiness/sedation 19.4%, dizziness/lightheadedness 8.1%, headache 8.1%, and impaired co-ordination/impaired equilibrium/ataxia 5.9%, nervousness/anxiety 5.4%, nausea/vomiting 3.8%, tiredness/lethargy 2.4%, concentration difficulty 1.4%. The incidence and severity of these events
is generally dose-related. Severe sedation and impaired co-ordination are indicative of drug intolerance and overdosage.

Adverse reactions which have been reported less frequently (less than 1.5%) are depression, euphoria, confusional states, memory impairment, anterograde amnesia, visual disturbances, pains/cramps, palpitations/tachycardia, hiccups, taste alterations, skin rash, pruritus, paraesthesia, constipation/diarrhoea.

Paradoxical reactions such as acute rage, stimulation, excitement, agitation, sleep disturbances, hallucinations, disorientation in time or place, paranoia and other adverse behavioural or psychotic effects have been reported with benzodiazepines, including Halcion. Additionally, somnambulism, syncope, falling, hostility, aggressiveness, bizarre behaviour, depersonalisation and abnormal dreams have been reported.

Post-Marketing Experience

Immune system disorder

Hypersensitivity reactions including angioneurotic oedema, anaphylactoid reaction, allergic oedema and anaphylactic shock have been reported.

DOSAGE AND ADMINISTRATION

It is important to individualise the dosage of Halcion in patients within various population groups in order to obtain maximum therapeutic effect while using the smallest effective dose.

The recommended dose for most adults is 0.25 mg before retiring. A dose of 0.125 mg may be found to be sufficient for some patients (e.g., low body weight). A dose of 0.5 mg should be used only for exceptional patients who do not respond adequately to a trial of a lower dose since the risk of several adverse reactions increases with the size of the dose administered. A dose of 0.5 mg should not be exceeded.

In geriatric and/or debilitated patients the recommended dosage range is 0.125 mg to 0.25 mg. Therapy should be initiated at 0.125 mg in this group and the 0.25 mg dose should be used only for exceptional patients who do not respond to a trial of the lower dose. A total dose of 0.25 mg should not be exceeded in these patients.

Instructions to be given to the patient

As with any hypnotic, the prescribing doctor should:

- warn patients about the possibility of decreased alertness and consequent risk as a pedestrian or whilst driving or operating dangerous machinery or any other activity requiring alertness
- warn patients (especially elderly ones) about ataxia and muscle weakness which may impair mobility or increase the possibility of a fall
- warn patients about reduced tolerance to alcohol, and the additive effects of other CNS depressants
- advise patients of the potential for the development of habituation in the form of nightly reliance on sleeping pills. Tell patients that they may experience "rebound" insomnia on the first night or two after discontinuing the drug
- warn patients that an increase in dosage, or discontinuation of therapy, should not be made without the advice of a doctor
advise women of childbearing age not to use the tablets in future episodes of insomnia unless they are certain they are not pregnant.

OVERDOSAGE

Because of the potency of triazolam, some manifestations of overdose may occur at 2 mg, four times the maximum recommended therapeutic dose (0.5 mg)

Symptoms

Symptoms of overdose with triazolam are extensions of its pharmacological action, including respiratory depression and degrees of central nervous system depression, ranging from drowsiness to coma. In mild cases symptoms include drowsiness, mental confusion, slurred speech, motor incoordination and lethargy. In more serious cases symptoms may include ataxia, hypotonia, hypotension, respiratory depression, apnoea, hypothermia, rhabdomyolysis, coma and very rarely death. Seizures have occasionally been reported after overdosages. In terms of duration, most obtunded patients become arousable within 12 to 36 hours following an acute overdose. Serious sequelae are rare unless other drugs and/or ethanol are concomitantly ingested. Benzodiazepine and alcohol levels seen in some cases have been lower than those usually associated with reports of fatality with either substance alone.

Treatment

In the management of overdose with any medication it should be borne in mind that multiple agents may have been taken.

Triazolam plasma concentrations are not clinically useful and specific lab work (CBC, electrolytes, urinalysis) is not needed unless otherwise indicated.

Treatment of overdose is primarily supportive of respiratory and cardiovascular function. Activated charcoal may reduce absorption of the drug and it is most effective when administered within one hour of ingestion. In patients who are not fully conscious or have impaired gag reflex, consideration should be given to administering activated charcoal via nasogastric tube once the airway is protected.

The benzodiazepine antagonist flumazenil may be useful in hospitalised patients for the reversal of acute benzodiazepine effects. Flumazenil is intended as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. Patients treated with flumazenil should be monitored for resedation, respiratory depression, and other residual benzodiazepine effects for an appropriate period after treatment. The prescriber should be aware of a risk of seizure in association with flumazenil treatment, particularly in long-term benzodiazepine users and in cyclic antidepressant overdose. Please consult the flumazenil product information prior to use.

Haemoperfusion, haemodialysis and forced diuresis are generally not useful in benzodiazepine intoxication.

Contact the Poisons Information Centre, on 13 11 26, for advice on the management of an overdose.
PRESENTATION AND STORAGE CONDITIONS

Presentation
Halcion 0.125 mg tablets are available as violet tablets in bottles of 50.

Storage conditions
Store below 30°C.

NAME AND ADDRESS OF THE SPONSOR
Pfizer Australia Pty Ltd
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WEST RYDE NSW 2114.

POISON SCHEDULE
Schedule 4, Prescription Only Medicine.

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

DATE OF MOST RECENT AMENDMENT
12 December 2013.

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