

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### HALCION® 125 and 250 microgram Tablets (Triazolam)

-----Pfizer

#### Logo

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

- 1. What Halcion is and what it is used for**
- 2. What you need to know before you take Halcion**
- 3. How to take Halcion**
- 4. Possible side effects**
- 5. How to store Halcion**
- 6. Contents of the pack and other information**

#### 1. What Halcion is and what it is used for

Halcion contains the active ingredient triazolam. Triazolam belongs to a group of medicines called benzodiazepines.

Halcion is used for the short-term treatment of severe insomnia (difficulty in falling asleep or sleeping properly).

You must talk to a doctor if you do not feel better or if you feel worse.

#### 2. What you need to know before you take Halcion

##### Do not take Halcion if you:

- are allergic to triazolam or other similar benzodiazepine medicines or any of the other ingredients of this medicine (listed in section 6)
- suffer from an autoimmune disease called ‘myasthenia gravis’ where you suffer from very weak and tired muscles
- have severe breathing difficulties
- have ‘sleep apnea’- this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep
- have severe liver problems
- are taking simultaneously
  - medicines for fungal infections containing ketoconazole or itraconazole,
  - medicines for depression containing nefazodone,
  - medicines for HIV infections containing efavirenz or HIV protease inhibitors (e.g. ritonavir),
  - or other medicines that strongly reduce the activity of certain liver enzymes (see section “Other medicines and Halcion”).

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Halcion.

Your doctor will assess your condition before and throughout your treatment with this medicine. Halcion tablets are for short-term treatment of insomnia, for up to 7-10 days in general. Your condition will be reviewed by your doctor if you need more than two weeks of treatment. Your dose will be lowered gradually as you progress through the course of this treatment.

Halcion must be used with caution if you have mild to moderate liver problems or you suffer with breathing difficulties. If you suffer with breathing difficulties, you may experience hypoventilation (shallow breathing whereby not enough oxygen enters the lungs) or apnea (temporarily stop breathing). If you have a mental illness, Halcion tablets are not to be used as the main treatment for this. If you suffer with depression or anxiety associated with depression, Halcion tablets are not to be used alone to treat this. If you are allergic to any of the ingredients listed in section 6 of this leaflet, let your doctor know as some allergic reactions can be serious, and in rare cases possibly fatal. Signs of an allergic reaction include a rash and breathing problems. There can also be swelling of the legs, arms, face, throat or tongue.

Because triazolam can cause sedation (drowsiness, sleepiness, dizziness and difficulty in controlling movements), patients, particularly the elderly, are at a higher risk of falls. If you are an older person or suffering from extreme weakness, your doctor may start you off with a lower dose of Halcion (125 micrograms).

Halcion may cause memory loss in some patients several hours after taking the tablets. If you believe that you could have suffered memory loss after taking Halcion tell your doctor. To reduce this risk your doctor may recommend that you take this medicine at a time which ensures you have 7 to 8 hours uninterrupted sleep.

Some patients may experience complex sleep behaviour-related events such as “sleep driving” (i.e. driving while not fully awake) after taking Halcion. These and other complex sleep behaviours may occur whilst you are taking Halcion at the correct dosage. Use of alcohol, or taking Halcion at higher doses than prescribed, or use of other drugs similar to Halcion appear to increase the risk of such behaviours. If you believe that you have experienced this after taking Halcion, tell your doctor, as your treatment may need to be discontinued due to the risk to yourself and others.

A small number of people being treated with triazolam may have thoughts of harming or killing themselves, if at any time you have these thoughts, immediately contact your doctor.

**Tell your doctor immediately if you notice a change in your behaviour, for example agitation, rage, aggressiveness, false beliefs and hallucinations, inappropriate actions and restlessness, as your treatment may need to be discontinued.**

#### **Development of tolerance and dependence, withdrawal reactions and drug abuse**

You may experience a reduction in the efficacy of this medicine (tolerance) after continued use. This medicine is recommended for short term treatment.

Treatment with this medicine also increases the sensitivity of the effects of alcohol and other medicines that affect brain function. Therefore, talk to your doctor if you are using alcohol or this type of medicines.

The use of benzodiazepines, including Halcion, may lead to dependence. The risk of dependence is increased with higher doses and continuous use. It is also increased if you have a history of alcohol or drug abuse.

You must tell your doctor if

- you have used or currently use any illegal drugs
- you regularly consume alcohol, or have in the past, frequently consumed large quantities of alcohol
- you have had in the past or currently have a craving to take large amounts of medicines

In principle, benzodiazepines should only be used for short periods and discontinued gradually. You and your doctor should agree for how long you will take the medicine before starting the treatment.

If you stop taking the drug abruptly or reduce the dosage rapidly, withdrawal reactions can occur. Do not stop taking this medicine suddenly. Ask your doctor for advice on how to discontinue the treatment.

Some withdrawal reactions can be life-threatening.

Withdrawal reactions can range from mild depressed mood, sleeplessness and headaches to a major syndrome with muscle pain, cramps in the muscles and abdomen, vomiting, sweating, trembling, convulsions, anxiety, tension, restlessness, confusion and irritability. More severe withdrawal signs and symptoms, including life threatening reactions, can include: feeling of detachment or alienation from oneself and the outside world, excessive perception of noise, numbness and tingling in the extremities, increased sensitivity to light, noise and physical contact, hallucinations, delirium tremens, depression, mania, psychosis, epileptic seizures and suicidality.

Your symptoms for which this medicine was prescribed may also return for a short time (rebound phenomena).

You must not give Halcion to family or friends. Store this medicine safely so it does not cause harm to others.

### **History of dependence**

If you have a history of alcohol or drugs abuse your doctor may want to give you special help when you need to stop taking these tablets.

**Tell your doctor** if you start to experience the following during your treatment with this medicine:

- **a decrease in the effects of the medicine**
- **feeling of dependence on your treatment (withdrawal symptoms) if you delay or miss taking your tablets**
- **lack of sleep and increased anxiety.**

### **Other medicines and Halcion**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines, as the effect of Halcion may be stronger when taken at the same time.

Halcion may change the effect of other medicines, and other medicines may change the effect of Halcion.

Halcion must not be used together with the following medicines:

- ketoconazole, itraconazole (medicines for fungal infections)
- nefazodone (medicine for depression)
- efavirenz and other medicines used to fight HIV virus infections (for example ritonavir)
- other medicines that strongly reduce the activity of certain liver enzymes

Sometimes it may be necessary to reduce the dose of Halcion if you are taking:

- antibiotics, such as clarithromycin, erythromycin, and troleandomycin
- other antifungals used to treat fungal infections
- medicines to reduce the natural production of acid in the stomach e.g. cimetidine
- any other medicines to treat anxiety or depression or to help you sleep
- strong pain killers (e.g., opioids, morphine or codeine - keep the dosages and duration of both medicines to a minimum as recommended by your doctor). Taking Halcion with these pain killers may make you more sleepy and in rare cases can cause breathing difficulty and death
- antipsychotic medicines such as clozapine - used to treat mental illnesses like schizophrenia which affects the way you think and feel
- medicines to treat epilepsy (e.g. carbamazepine)
- sedative antihistamines that also make you sleepy for relief of allergies such as hay fever
- oral contraceptives
- antineoplastics such as imatinib
- drugs used to treat tuberculosis (e.g. rifampicin)
- drugs used to treat heart conditions or high blood pressure (e.g. verapamil or diltiazem)
- drugs used to treat severe nausea (e.g. aprepitant)

Tell your doctor or pharmacist if you are taking any other medicines not listed above, including those bought without a prescription.

#### **Halcion with drink and alcohol**

Do not drink any alcohol whilst you are taking Halcion as alcohol increases the effects of this medicine.

You should not drink grapefruit juice while taking Halcion because it may affect the way your body breaks down Halcion.

#### **Pregnancy**

Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant, before you take this medicine as it can affect the developing baby.

Your doctor will tell you if you should continue to take Halcion during pregnancy. In these cases babies may have a low body temperature, floppiness, withdrawal symptoms and breathing and feeding difficulties.

#### **Breast-feeding**

Do not breast-feed while taking Halcion as the drug may pass into breast milk.

#### **Driving and using machines**

Taking Halcion can affect your ability to drive or operate machinery safely as it may cause you to feel drowsy or dizzy. You must seek advice before you drive or operate machinery. 'Sleep driving' (driving whilst not fully awake with no memory of the event afterwards) has been reported as a side effect. **Tell your doctor immediately** if you suffer from this side effect as your medicine may need to be changed.

#### **Halcion contains lactose (a type of sugar)**

If you have been told by your doctor that you have an intolerance to some sugars, please tell your doctor before taking this medicine.

#### **Halcion contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

#### **Halcion contains benzoic acid or benzoates**

This medicine contains 0.15 mg sodium benzoate in each tablet. Sodium benzoate may increase levels of a substance called bilirubin. High levels of bilirubin may lead to jaundice (yellowing of the skin and eyes) and may also lead to brain injury (encephalopathy) in newborn babies (up to 4 weeks old).

### **3. How to take Halcion**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

#### **Do not take your tablets with alcohol.**

The dose and duration of administration should be adjusted to your individual situation. Your doctor will advise you on the dose and the number of times a day to take the medicine and the duration of your treatment with Halcion, so that you take the lowest dose possible for the shortest possible time as there is a risk of becoming dependent. You should not change or exceed the dose prescribed for you. To discontinue the treatment, the dose should be gradually reduced in consultation with your doctor. This reduces the risk of withdrawal reactions, which can be life threatening in some cases (see section 2).

Halcion tablets should be used for short term treatment of insomnia for 7- 10 days in general, including a period where the dose is gradually reduced.

#### **Adults**

The usual dose is one tablet to be taken once a day before going to bed. The tablet may be swallowed with a glass of water or milk.

#### **Older people**

Your doctor will start you on a low starting dose and gradually increase the dosage as needed to obtain the desired effect.

#### **Children and adolescents**

Halcion tablets are not recommended for use in children and adolescents below the age of 18 years.

#### **If you take more Halcion than you should**

It is important that you do not take more tablets than you are told to. If you accidentally take too many tablets seek medical attention straight away. The symptoms of an overdose include feeling drowsy and dizzy so do not drive. You may also feel or be sick.

If you take more tablets than prescribed along with other medication, including alcohol, you may be at risk of more severe symptoms such as difficulty in breathing, decrease in blood pressure, decrease in coordination of muscle movement, seizures and rarely in very severe cases coma and death.

#### **If you forget to take Halcion**

If you forget a dose, take it as soon as you remember. Do not take a double dose to make up for the forgotten dose, take your next dose as usual the next day before you go to bed. If you think you have missed more than one dose, contact your doctor for advice.

### **If you stop taking Halcion**

Always see your doctor before you stop taking Halcion tablets as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get withdrawal effects (see Section 2) which might cause you to become temporarily more anxious or restless or to have difficulty sleeping. These symptoms will go away as your body re-adjusts.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### **Reasons for stopping Halcion treatment and seeing your doctor immediately**

- Very occasionally treatment with Halcion can cause serious behavioural or psychiatric effects - for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares and hallucinations or other inappropriate behaviour.
- ‘Sleep driving’ – driving whilst not fully awake with no memory (amnesia) of the event.
- Allergic (hypersensitivity) reactions such as skin rash or reddening, shortness of breath or a swollen face, lips, larynx (throat) or vocal cords.

**If you get any of these symptoms see your doctor straight away as treatment will need to be discontinued. Your doctor will then advise how treatment will be stopped.**

## **Dependence and Withdrawal Symptoms**

### Dependence

It is possible to become reliant (‘dependent’) on medicines like Halcion while you are taking them which increase the likelihood of getting withdrawal symptoms when you stop treatment. **Tell your doctor** if you start to feel dependence on your treatment.

### Withdrawal

- Withdrawal symptoms are more common if you stop treatment suddenly, have been taking high doses, have been taking Halcion for longer than recommended or have a history of alcohol or drug abuse. This can cause effects such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.
- In severe cases of withdrawal you can also get the following symptoms: nausea (feeling sick), vomiting, sweating, stomach cramps, muscle cramps, a feeling of unreality or detachment, being unusually sensitive to sound, light or physical contact, numbness and tingling of the feet and hands, shaking or epileptic fits.

### Rebound insomnia

Rebound insomnia is a temporary condition that may occur, whereby you have even greater difficulty in sleeping after you stop taking Halcion. You may also experience other reactions including mood changes, anxiety or sleep disturbances and restlessness. These reactions are greater if you stop taking Halcion abruptly. Your doctor should gradually reduce your dose before treatment with Halcion is stopped.

You should always consult your doctor prior to switching from one benzodiazepine to another, as individual benzodiazepines have different duration of action. Switching from one to another can cause withdrawal symptoms described above.

**Please see your doctor as soon as you can if any withdrawal symptoms get worse or don't go away.**

### **Other side effects**

You can also get the following side effects. Do not stop taking the tablets but contact your doctor if you are concerned about any side effect:

Common: may affect up to 1 in 10 people

- drowsiness during the day
- tiredness
- headache
- dizziness
- muscle spasms

Uncommon: may affect up to 1 in 100 people

- memory loss - Tell your doctor if you think you could have suffered this. Your doctor may recommend that you take this medicine at a time which ensures you have 7 to 8 hours uninterrupted sleep.
- confusion
- being unable to sleep
- double or blurred vision, or a burning sensation in the eyes

Rare: may affect up to 1 in 1,000 people

- muscle weakness
- rash

Not known: frequency cannot be estimated from the available data

- allergic reaction (including facial/mouth/throat swelling)
- aggression
- hallucinations
- sleep walking
- loss of memory prior to or after an event or activity
- inability to relax
- irritable
- inability to calm the mind or body
- being in a state of false belief despite proof or evidence of the truth
- uncontrolled anger
- nightmares
- changes in personality, impaired functioning and a distorted sense of reality
- inappropriate behaviour
- speech disorder (difficulties speaking)
- changed sense of taste
- loss of alertness or concentration
- fainting (syncope)
- numbed emotions
- changes in sex drive
- fall
- in patients with breathing problems - further reductions in breathing

- confusion
- drug abuse
- drug dependence
- drug withdrawal syndrome

**If any of the above side effects gets serious or if you notice any side effects not listed in this leaflet, do not stop taking the tablets but please tell your doctor.**

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Halcion**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Keep the blister in the outer carton. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Halcion contains**

The active substance is triazolam.

Each Halcion 125 microgram tablet contains 125 micrograms of triazolam.

Each Halcion 250 microgram tablet contains 250 micrograms of triazolam.

The other ingredients are:

lactose monohydrate, maize starch, microcrystalline cellulose, colloidal anhydrous silica, sodium docusate, sodium benzoate (E211) (see section 2 Halcion contains sodium benzoate), and magnesium stearate.

The 125 microgram tablets also contain erythrosine (E127 aluminium lake) and Indigo Carmine (E132 aluminium lake) as the colouring agents.

The 250 microgram tablets also contain Indigo Carmine (E132 aluminium lake) as the colouring agent.

For further information on lactose monohydrate, see section 2.

#### **What Halcion looks like and the contents of the pack**

Halcion 125 microgram tablets are lavender coloured, elliptical tablets, marked with “Upjohn10” on one side and plain on the other side.

Halcion 250 microgram tablets are powder blue coloured, elliptical tablets, marked with the 'UPJOHN' logo and '17' on one face and a single score (break) line on the other.

Halcion 125 microgram tablets come in packs containing 7, 10 and 30 tablets.

Halcion 250 microgram tablets come in packs containing 30 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Pfizer Healthcare Ireland Unlimited Company  
The Watermarque Building  
Ringsend Road,  
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#### **Manufacturer**

Pfizer Italia S.r.l.,  
Localita, Marino del Tronto,  
63100 Ascoli Piceno (AP),  
Italy.

#### **Company contact address**

For any information about this medicine contact Medical Information at the following address:

Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road,  
Dublin 4, D04 K7N3, Ireland.  
Telephone: 1800 633 363

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