HALCION®

125 and 250 microgram Tablets

(Triazolam)

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 Halcior

if you feel worse.

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

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 'mvasthenia' 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), o or other medicines that strongly reduce the
- activity of certain liver enzymes (see section "Other medicines and Halcion").

Warnings and precautions

Halcion

throughout your treatment with this medicine. Halcion increase the risk of such behaviours. If you believe up to 7-10 days in general. Your condition will be tell your doctor, as your treatment may need to be reviewed by your doctor if you need more than two discontinued due to the risk to yourself and others. weeks of treatment. Your dose will be lowered gradually A small number of people being treated with triazolam as you progress through the course of this treatment. may have thoughts of harming or killing themselves, Halcion must be used with caution if you have mild to if at any time you have these thoughts, immediately moderate liver problems or you suffer with breathing contact your doctor. 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

PACKAGE LEAFLET: INFORMATION FOR THE USER 2. What you need to know before you take Halcion 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 star you off with a lower dose of Halcion (125 micrograms) Halcion may cause memory loss in some patients severa 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 Talk to your doctor, pharmacist or nurse before taking taking Halcion at the correct dosage. Use of alcohol or taking Halcion at higher doses than prescribed, Your doctor will assess your condition before and or use of other drugs similar to Halcion appear to tablets are for short-term treatment of insomnia, for 🛛 that you have experienced this after taking Halcion, 🔤

> Tell your doctor immediately if you notice a change in your behaviour, for example agitation, rage, aggressiveness, false beliefs and hallucinations,

藰 treatment may need to be discontinued.

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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 f you are using alcohol or this type of medicines. The use of benzodiazepines, including Halcion, If you have a history of alcohol or drugs abuse your may lead to dependence. The risk of dependence doctor may want to give you special help when you is increased with higher doses and continuous use. need to stop taking these tablets. 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 Other medicines and Halcion your doctor should agree for how long you will take Tell your doctor or pharmacist if you are taking, have the medicine before starting the treatment. dosage rapidly, withdrawal reactions can occur. Do when taken at the same time. doctor for advice on how to discontinue the treatment. other medicines may change the effect of Halcion. Withdrawal reactions can range from mild depressed medicines: with muscle pain, cramps in the muscles and abdomen, infections) tension, restlessness, confusion and irritability. More • efavirenz and other medicines used to fight HIV life threatening reactions, can include: feeling of • other medicines that strongly reduce the activity detachment or alienation from oneself and the outside of certain liver enzymes

 Allergic (hypersensitivity) reactions such as skin You should always consult your doctor prior to switching
inability to calm the mind or body 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

<u>Dependence</u> 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. <u>Withdrawal</u>

• 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 • double or blurred vision, or a burning sensation of unreality or detachment, being unusually sensitive to sound, light or physical contact, numbness and Rare: may affect up to 1 in 1,000 people tingling of the feet and hands, shaking or epileptic fits. Rebound insomnia

Rebound insomnia is a temporary condition that may Not known: frequency cannot be estimated from the occur, whereby you have even greater difficulty in sleeping after you stop taking Halcion. You may also • allergic reaction (including facial/mouth/throat experience other reactions including mood changes, anxiety or sleep disturbances and restlessness. These aggression reactions are greater if you stop taking Halcion abruptly. • hallucinations Your doctor should gradually reduce your dose before treatment with Halcion is stopped.

rash or reddening, shortness of breath or a swollen from one benzodiazepine to another, as individual benzodiazepines have different duration of action. Switching from one to another can cause withdrawal • uncontrolled anger 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 If any of the above side effects gets serious of vou have 7 to 8 hours uninterrupted sleep.
- confusion
- being unable to sleep

- available data

- sleep walking
- loss of memory prior to or after an event or activity 5. How to store Halcion inability to relax
- irritable

being in a state of false belief despite proof or

- evidence of the truth
- 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
- in patients with breathing problems further reductions
- in breathing
- confusion
- drug abuse
- drug dependence
- drug withdrawal syndrome

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. By reporting side effects you can help provide more information on the safety of this medicine.

 Keep this medicine out of the sight and reach of children.

outer carton. Store in the original package.

is stated on the carton and blister after EXP. The 30 tablets. expiry date refers to the last day of that month. Not all pack sizes may be marketed. 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, Company contact address sodium benzoate (E211) (see section 2 Halcion contains For any information about this medicine contact sodium benzoate), and magnesium stearate. he 125 microars 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.

History of dependence

seizures and suicidality

Your symptoms for which this medicine was prescribed

may also return for a short time (rebound phenomena).

this medicine safely so it does not cause harm to

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 • oral contraceptives taking your tablets lack of sleep and increased anxiety.

recently taken or might take any of the following If you stop taking the drug abruptly or reduce the medicines, as the effect of Halcion may be stronger not stop taking this medicine suddenly. Ask your Halcion may change the effect of other medicines, and

Some withdrawal reactions can be life-threatening. Halcion must not be used together with the following mood, sleeplessness and headaches to a major syndrome • ketoconazole, itraconazole (medicines for fungal

- vomiting, sweating, trembling, convulsions, anxiety, nefazodone (medicine for depression)
- severe withdrawal signs and symptoms, including virus infections (for example ritonavir)

inappropriate actions and restlessness, as your world, excessive perception of noise, numbness and Sometimes it may be necessary to reduce the dose tingling in the extremities, increased sensitivity to light, of Halcion if you are taking:

- noise and physical contact, hallucinations, delirium antibiotics, such as clarithromycin, erythromycin tremens, depression, mania, psychosis, epileptic and troleandomycin
 - other antifungals used to treat fungal infections • medicines to reduce the natural production of acid in the stomach e.g. cimetidine
- You must not give Halcion to family or friends. Store 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

 - 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

affect the developing baby

Your doctor will tell you if you should continue to take Halcion during pregnancy. In these cases babies may **Do not take your tablets with alcohol.** symptoms and breathing and feeding difficulties. Breast-feeding

may pass into breast milk.

Driving and using machines

fully awake with no memory of the event afterwards) in some cases (see section 2). medicine may need to be changed.

Halcion contains lactose (a type of sugar)

ntolerance to some sugars, please tell your doctor before taking this medicine.

Halcion contains sodium

per tablet, that is to say essentially 'sodium-free'.

Halcion contains benzoic acid or benzoates

This medicine contains 0.15 mg sodium benzoate in **Children and adolescents** each tablet. Sodium benzoate may increase levels of Halcion tablets are not recommended for use in a substance called bilirubin. High levels of bilirubin children and adolescents below the age of 18 years. 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 symptoms of an overdose include feeling drowsy and Tell your doctor immediately if you are pregnant, Always take this medicine exactly as described in dizzy so do not drive. You may also feel or be sick. think you are pregnant, or are planning to become this leaflet or as your doctor, pharmacist or nurse. If you take more tablets than prescribed along with pregnant, before you take this medicine as it can has told you. Check with your doctor, pharmacist other medication, including alcohol, you may be at me or nurse if you are not sure. risk of more severe symptoms such as difficulty in breathing, decrease in blood pressure, decrease in coordination of muscle movement, seizures and rarely have a low body temperature, floppiness, withdrawal The dose and duration of administration should be in very severe cases coma and death.

adjusted to your individual situation. Your doctor will advise you on the dose and the number of times a If you forget to take Halcion Do not breast-feed while taking Halcion as the drug day to take the medicine and the duration of your If you forget a dose, take it as soon as you remember. treatment with Halcion, so that you take the lowest Do not take a double dose to make up for the forgotten dose possible for the shortest possible time as there is dose, take your next dose as usual the next day a risk of becoming dependent. You should not change before you go to bed. If you think you have missed Taking Halcion can affect your ability to drive or operate or exceed the dose prescribed for you. To discontinue more than one dose, contact your doctor for advice. machinery safely as it may cause you to feel drowsy the treatment, the dose should be gradually reduced or dizzy. You must seek advice before you drive or in consultation with your doctor. This reduces the risk If you stop taking Halcion operate machinery. 'Sleep driving' (driving whilst not of withdrawal reactions, which can be life threatening Always see your doctor before you stop taking Halcion

tablets as the dose needs to be reduced gradually has been reported as a side effect. Tell your doctor Halcion tablets should be used for short term treatment. If you stop taking the tablets or reduce the dose immediately if you suffer from this side effect as your of insomnia for 7-10 days in general, including a suddenly you can get withdrawal effects (see Section period where the dose is gradually reduced. 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 been told by your doctor that you have an The usual dose is one tablet to be taken once a day. If you have any further questions on the use of this before going to bed. The tablet may be swallowed medicine, ask your doctor or pharmacist.

with a glass of water or milk.

Older people This medicine contains less than 1 mmol sodium (23 mg) Your doctor will start you on a low starting dose and Like all medicines, this medicine can cause side gradually increase the dosage as needed to obtain effects, although not everybody gets them. the desired effect.

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 • Sleep driving - driving whilst not fully awake with tablets seek medical attention straight away. The no memory (amnesia) of the event.

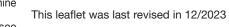
• Do not store above 25°C. Keep the blister in the Halcion 125 microgram tablets come in packs containing 7, 10 and 30 tablets. • Do not use this medicine after the expiry date which Halcion 250 microgram tablets come in packs containing

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24.

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

Medical Information at the following address: Pfizer Healthcare Ireland 9 Riverwalk National D (E127 aluminium lake) and Indigo Carmine (E132 Park, Citywest Business Campus, Dublin 24, Ireland Telephone: 1800 633 363



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4. Possible side effects

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.
- Continued over

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