PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

HALCION 0,125 tablets

HALCION 0,25 tablets

Triazolam

Contains sugar

Each 0,125 or 0,25 mg tablet contains 72 mg lactose

Read all of this leaflet carefully before you start taking HALCION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- HALCION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 belongs to a group of medicines known as benzodiazepines. It is used for the short-term management of sleep problems (insomnia). Insomnia is not always the same. It may be seen as the difficulty of falling asleep, frequent awakening during the night, and/or early morning awakening.

2. What you need to know before you take HALCION

Do not take HALCION

- if you are hypersensitive (allergic) to triazolam, benzodiazepines or any of the other ingredients of HALCION (listed in section 6)
- if you suffer from or have suffered from mental depression or any kind of psychotic illness
- if you are taking medicines like ketoconazole, itraconazole, nefazodone or ritonavir (see Other medicines and HALCION)
- if you are pregnant, trying to become pregnant or breastfeeding. Your baby may become dependent on this medicine or experience breathing problems, difficulty in feeding, body temperature problems or muscle weakness. Breastfed babies may become drowsy as HALCION may pass into the breast milk.

HALCION should not be used for long-term treatment of insomnia and in patients younger than 18 years of age.

Warnings and precautions

Take special care with HALCION

- if you have liver or kidney problems
- if you have breathing problems
- if you are elderly or debilitated, you may be given a lower starting dose. HALCION can cause drowsiness, sleepiness, dizziness, difficulty in controlling movements and depression and elderly patients are at higher risk of falls
- if you have a history of alcohol abuse or drug abuse
- if you have a history of seizures
- if you develop any unusual or disturbing thoughts such as harming or killing yourself) or if you notice a change in your behaviour, for example loss of memory, inappropriate behaviour, confusion, disorientation, false beliefs, agitation, restlessness and irritability during treatment, tell your doctor immediately

- driving while not fully awake after taking HALCION can occur. The use of alcohol and other CNS depressants with HALCION can increase the risk of “sleep-driving”. Tell your doctor immediately if this occurs, as your treatment may need to be discontinued
- if you suffer from psychotic illness, depression, or anxiety with depression as the risk of suicide may be increased
- if you have arteriosclerosis (thickening and hardening of the arteries)

If you take HALCION for a long time, you may become physically dependent on it, especially if you have a history of alcohol or drug abuse. In this case, if HALCION is stopped suddenly, withdrawal symptoms like sleeplessness, mood changes, anxiety and restlessness may occur. Your doctor will gradually reduce your HALCION dose, and the duration of treatment should be as short as possible but should not exceed 4 weeks including a tapering-off process.

Other medicines and HALCION

Always tell your health care provider if you are taking other medicines. (This includes all complementary or traditional medicines).

When taking HALCION with certain other medicines, HALCION may affect the blood levels of those medicines or those medicines may affect the blood levels of HALCION. Tell your doctor if you are taking any of the following:

- Opioids (strong pain killers) or other antidepressants
- Cimetidine (medicine used to reduce stomach acid) may double the HALCION levels in the body
- Erythromycin (antibiotic) may double the HALCION levels in the body
- Clarithromycin (antibiotic) may result in HALCION not been cleared properly from the body
- Troleandomycin (antibiotic): The HALCION dose may need to be reduced
- The co-administration with ketoconazole, itraconazole (medicines used to treat fungal infections), nefazodone (medicine used to treat depression) and ritonavir (medicine used to treat HIV) is contraindicated.
- Co-administration with other azole-type antifungals is not recommended.

- Caution is recommended when HALCION is co-administered with isoniazid (antibiotic used to treat tuberculosis), fluvoxamine, paroxetine, sertraline (medicines used to treat depression), diltiazem, verapamil (medicines used to treat heart conditions or high blood pressure).

HALCION with food, drink and alcohol

You should not drink alcohol while on treatment with HALCION as it increases the effects of this medicine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

HALCION should not be used during pregnancy or if you are trying to become pregnant. You should not breastfeed if you are taking HALCION (see Do not take HALCION).

Driving and using machines

Be cautious when your occupation requires mental alertness such as operating machinery or driving a motor vehicle, the day after a night-time dose of HALCION, until it is established that you do not exhibit daytime drowsiness or dizziness.

It is not always possible to predict to what extent HALCION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which HALCION affects them.

HALCION contains lactose

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

3. How to take HALCION

Do not share medicines prescribed for you with any other person.

Always take HALCION exactly as your doctor has told you. Your doctor will decide what dose is right for you. Check with your doctor or pharmacist if you are not sure.

Adults

The recommended dose is 0,25 mg before going to sleep. A dose of 0,5 mg should be reserved for those patients who do not respond adequately to a lower dose.

A dose of 0,125 mg may be found to be sufficient for selected, elderly and/or debilitated patients. Therapy should be initiated at 0,125 mg in this group until individual response is determined and can then be increased to 0,25 mg if necessary. The lowest effective dose should be used.

Treatment should be as short as possible. Generally, the duration of treatment varies from a few days to two weeks, with a maximum, including tapering off process, of four weeks. In certain cases, extension beyond the recommended treatment period may be necessary; if so, it should not take place without re-evaluation of the patient's status.

Try to take the medicine at the same time every day.

Do not alter the dose yourself without your doctor's advice. Do not stop taking the HALCION unless told to do so by your doctor. Should you need to stop taking HALCION, your doctor will decide which is the best method for you.

Your doctor will tell you how long your treatment with HALCION will last. If you have the impression that the effect of HALCION is too strong or too weak, tell your doctor or pharmacist.

If you take more HALCION than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any HALCION tablets left or not.

These are the possible signs and symptoms of overdosage: drowsiness, slurred speech, motor-incoordination, coma and respiratory depression.

If you forget to take HALCION

Do not take a double dose to make up for forgotten individual doses.

If you stop taking HALCION

The dosage of HALCION needs to be gradually reduced towards the end of your treatment. If HALCION is stopped abruptly, withdrawal symptoms may occur. These may include headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases, feelings or experiences that seem unreal, sensitivity to sound, numbness and tingling of hands and feet, sensitivity to light, noise and physical contact, hallucinations or epileptic seizures may occur.

4. Possible side effects

HALCION can have side effects.

Not all side effects reported for HALCION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HALCION, please consult your health care provider for advice.

If any of the following happens, stop taking HALCION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to HALCION. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- drowsiness
- sleepiness
- headache
- depression
- dizziness
- impaired coordination
- light-headedness
- visual disturbances
- blurred vision
- fast heartbeat (palpitations)

Less frequent side effects:

- fainting
- changes in the sense of taste
- slurred speech
- stomach discomfort
- loss of bladder control
- confusional states
- memory impairment
- aggressiveness
- hallucinations
- sleepwalking
- feeling of excitement (euphoria)

- agitation
- temporary insomnia (inability to sleep) after discontinuing HALCION
- memory loss
- lack of muscle coordination
- tremor
- low blood pressure
- excessive salivation
- diarrhoea
- jaundice (yellowing of the skin and eyes)
- allergic reactions including itching and skin rash
- muscular weakness
- inability to urinate
- changes in sex drive
- falling

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of HALCION.

5. How to store HALCION

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Keep blister in the carton until required for use.
- Protect from moisture and light.
- Do not use HALCION after the expiry date which is printed on the label.

- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HALCION contains

The active substance is triazolam.

Each tablet contains 0,125 mg or 0,25 mg triazolam.

The other ingredients are corn starch, colloidal silicon dioxide, docusate sodium with sodium benzoate, lactose, magnesium stearate, microcrystalline cellulose, and FD&C Blue No. 2 aluminium lake and erythrosine sodium aluminium lake (HALCION 0,125) as colourants.

What HALCION looks like and contents of the pack

HALCION 0,125

Lavender elliptical, flat, tablet with length 7,9 mm and width 5,6 mm, with bevelled edges and "Upjohn 10" on the one side.

HALCION 0,125 tablets are available in transparent PVC/aluminium blister packs of 10, 30 and 100 tablets, packed into an outer carton.

HALCION 0,25

Powder blue elliptical tablet with length 7,9 mm and width 5,6 mm, scored on the one side and "Upjohn 17" impressed on the other side.

HALCION 0,25 tablets are available in transparent PVC/aluminium blister packs of 10, 30 and 100 tablets, packed into an outer carton.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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