

## **CONSUMER MEDICINE INFORMATION**

## OX-PAM™

Oxazepam 10mg and 15mg Tablets

- This leaflet answers some common questions about OX-PAM™ Tablets. It does not contain all the available information. It does not replace talking to your doctor or pharmacist.
- If you have any questions or concerns, talk to your doctor or pharmacist.

### In this leaflet:

- 1. What is OX-PAM™ and what is it used for
- Before you take OX-PAM™
- How to take OX-PAM™
- 4. Possible side effects
- How to store OX-PAM™
- 6. Further information

#### What is OX-PAM™ and what is it used for?

OX-PAM™ contains the active ingredient oxazepam. It belongs to a group of medicines known as benzodiazepines. OX-PAM™ is used for the short term treatment of anxiety or to provide relief from alcohol withdrawal symptoms.

## Before you take OX-PAM™

# Do not take OX-PAM™ Tablets if you:

- are allergic (hypersensitive) to oxazepam or other benzodiazapines or any of the other ingredients in OX-PAM™ Tablets.
- suffer from lung disease.
- suffer from myasthenia gravis (severe muscle tiredness).

- are suffering from a psychiatric illness or a personality disorder.
- suffer from sleep apnoea (a condition where you stop breathing whilst asleep).
- suffer from head injury.
- have severe liver disorders.

# Tell your doctor before you take OX-PAM™ if you:

- have a long-term lung, liver or kidney disease.
- suffer from depression.
- are suffering or have suffered from a mental illness.
- drink alcohol regularly. Do not drink alcohol while taking OX-PAM™.
- have a history of drug abuse or dependence.
- have glaucoma.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from the pharmacy, supermarket or health food shops.

Some medicines may interfere with the effects of OX-PAM™, particularly:

- Tranquillisers, antidepressants, hypnotics (sleeping tablets), anaesthetics or other medicines acting on the brain or nerves.
- Analgesics (pain killers), particularly opioidbased pain killers. It can make you very sleepy.
- Medicines for allergies (antihistamines).
- Medicines for epilepsy (anti-epileptics).
- Cimetidine (a medicine used to treat stomach problems).
- Rifampicin (an antibiotic).

 Others, in particular probenecid, levodopa, and zidovudine.

**Elderly patients** should take extra care when taking OX-PAM<sup>™</sup> Tablets as it can increase the risk of falls.

### Pregnancy and breast-feeding:

Tell your doctor if you are or intend to become pregnant. Your doctor will discuss the risks and benefits of taking this medicine with you.

If you need to take OX-PAM<sup>™</sup> during late pregnancy or during labour, your baby might have floppiness, a low body temperature, breathing and feeding difficulties. Your unborn baby may be at risk of developing dependency to this medicine and may be at some risk of developing withdrawal symptoms after birth.

Tell your doctor before taking OX-PAM™ if you are breastfeeding. Avoid taking OX-PAM™ if you are breast-feeding as it passes into the breastmilk.

## **Driving and using machines:**

OX-PAM™ Tablets may cause blurred vision, dizziness and impaired concentration. This may affect your ability to operate machinery or drive. Do not drive or operate machinery while taking this medicine until you know how it affects you. Talk to your doctor or pharmacist if you have any concerns.

### How to take OX-PAM™

Follow the directions given to you by your doctor carefully.

- The usual starting dose is 10mg up to three to four times daily. However, your starting dose may be different. Your doctor will prescribe the most suitable dose for you.
- Take OX-PAM™ exactly as your doctor has prescribed.
- Swallow the tablet whole with water.
- Do not change the prescribed dose yourself.
   If you think the effect of your medicine is too strong or too weak, talk to your doctor.
- Treatment with OX-PAM<sup>™</sup> should be short term. Treatment duration should not exceed 4 weeks.
- There is a risk of dependence with taking OX-PAM™. This risk increases with the dose and treatment duration.
- Never give your prescribed OX-PAM™ Tablets to other people. It may harm them even if their symptoms are the same as yours.

**Alcohol:** do not take with OX-PAM<sup>™</sup> as alcohol may increase the sedative effect of OX-PAM<sup>™</sup>.

If you forget to take OX-PAM<sup>™</sup>, do not take a double dose to make up for the missed dose. Take the next dose when it is due.

If you take more OX-PAM™ than you should, contact your doctor, pharmacist or nearest hospital straight away

# When to stop taking OX-PAM™

Your doctor will advise you when to stop taking OX-PAM™. Do not stop taking OX-PAM™ Tablets suddenly. If you suddenly stop your treatment you may experience unpleasant withdrawal effects such as: anxiety, depression, headache,

insomnia, irritability and, dizziness, abdominal cramps and sweating.

If you have been taking benzodiazepines for a long time, it will take a longer period of time to reduce your dose when you stop taking this medicine. You may need additional help. Your doctor will be able to discuss this with you.

#### Possible side effects of OX-PAM™

OX-PAM™, like all medicines, can cause side effects, although not everybody gets them.

# You must inform your doctor immediately if you notice any of the following symptoms:

- Restlessness, agitation, irritability, aggressiveness, delusion, experiencing rages, nightmares, hallucinations (seeing or hearing things that are not there), psychoses (loss of contact with reality), inappropriate behaviour, depression with feelings of suicide
- Allergic reaction: skin rashes, itching, swelling of the tongue or throat

# Tell your doctor if you notice any of the following side effects:

- Light-headedness and mild drowsiness may occur during the first few days of treatment
- Dizziness, loss of co-ordination, fainting, or headache with or without drowsiness, tiredness
- becoming less alert, excitement, disorientation, dreams, confusion, slurred speech and lack of muscle co-ordination
- changes in sex drive
- blurred or double vision
- low blood pressure

 yellowing of the skin or whites of the eyes (jaundice)

This is not a complete list of all possible side effects.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side affects you can help provide more information on the safety of this medicine.

#### How to store OX-PAM™ Tablets

Store at or below 25°C and protect from light Keep this medicine out of the reach of children. Do not use this medicine after the expiry date (EXP) printed on the pack.

Return any left-over medicine to your pharmacist.

#### **Further information**

OX-PAM™ 10mg Tablets are white, round and flat with a score on one side.

OX-PAM™ 15mg Tablets are yellow, round and flat with a score on one side.

Both tablets contain the active ingredient oxazepam and inactive ingredients **lactose** monohydrate, maize starch and magnesium stearate.

OX-PAM™ 15mg Tablets also contain quinoline yellow and sunset yellow FCF.

## **New Zealand Sponsor:**

Douglas Pharmaceuticals Ltd P O Box 45 027, Auckland 0651, New Zealand Phone: (09) 835 0660

Date of revision: May 2017