Package leaflet: Information for the user

Delipam 5 mg tablets
Delipam 10 mg tablets
Delipam 15 mg tablets
oxazepam

Read all of this leaflet carefully before you start using 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 [Product name] is and what it is used for

[Product name] contains the active substance oxazepam and belongs to a group of medicines called benzodiazepines. These work by enhancing the effect of an inhibiting substance (GABA) in the brain. Thus, [Product name] has anxiety relieving, muscle-relaxing and calming effects.

[Product name] is used for agitation, anxiety, restlessness and sleeping difficulties in connection with nervous conditions. [Product name] may be used together with antidepressants for depression with episodes of anxiety.

[Product name] may also be used for the treatment of withdrawal symptoms related to alcohol abuse such as confusion, anxiety, excitation, and agitation.

2. What you need to know before you take [Product name]

Do not take [Product name]
- if you are allergic to oxazepam or any of the other ingredients of this medicine (listed in section 6).
- if you have sleep apnoea (pauses in your breathing during your sleep).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking [Product name] if:
- you are elderly. Confusion may occur in the elderly following too high doses.
- your liver function is impaired.
- your kidney function is impaired.
- you have a disease causing muscle weakness (myasthenia gravis).
- you have breathing difficulties (respiratory insufficiency).
- your general condition is impaired.
- you have a substance abuse (e.g. drug or alcohol abuse).

- you have had sleeping difficulties for a longer period of time.
- you are taking other medicines for psychological problems (e.g. tranquilizers, sleep medication, medicines for depression or psychosis).

Tolerance development, dependence, withdrawal symptoms and drug abuse
You may experience a reduced effect of this medicine (tolerance development) after continuous use. This medicinal product is recommended for short-term use.

Treatment with this medicine increases also the sensitivity to the effects of alcohol and other medicines that affect brain function. Talk to your doctor if you drink alcohol or if you are taking this type of medicine.

The use of benzodiazepines, including [Product name], may lead to the development of dependence. The risk for dependence increases with higher doses and long-term use. The risk is also greater if you have in the past abused alcohol, medicines or drugs, or if you are at risk for abuse of medicines or drugs.
You must talk to your doctor if
- you have used or are using illegal medicines or drugs
- you regularly consume alcohol, or you have in the past often consumed large amounts of alcohol
- you have or have had in the past a desire to take large amounts of medicines.

Benzodiazepines should usually be used for short periods only and the dose should be reduced gradually when the treatment is discontinued. Before the treatment begins, you and your doctor should agree on how long you will take this medicine.

If you suddenly stop taking this medicine or reduce the dose rapidly, you may get withdrawal symptoms. You should not stop taking this medicinal product suddenly. Ask your doctor for advice on how to discontinue the treatment. Some withdrawal symptoms can be life-threatening.

Withdrawal symptoms may range from headache, mild dysphoria and insomnia to more severe reactions like abdominal and muscle cramps, muscle pain, vomiting, sweating, anxiety, tension, restlessness, irritability, tremor and convulsions. More severe acute signs and symptoms of withdrawal, including life-threatening reactions, are disorientation, depersonalization, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, *delirium tremens* (severe withdrawal symptoms including confusion, shaking and hallucinations), depression, hallucinations (seeing, hearing and feeling things that don't exist), mania (mental condition with excessive excitement and overactivity), psychosis (altered perception of reality), epileptic seizures (convulsions) and suicidal tendencies. Convulsions/seizures may appear more commonly if you have pre-existing seizure disorder, or if you are taking other medicines, such as antidepressants, which increase the risk of convulsions.

The symptoms that were originally the cause of treatment with this medicine may recur for a short time (withdrawal/rebound phenomena).

Do not give [Product name] to family members or friends. Keep this medicine in a safe place which is inaccessible to other persons, as it can be harmful for them. Any unused medicine should be returned to the pharmacy.

Children and adolescents
The effect and safety in children below the age of 18 years have not been established. [Product name] should not be given to children, unless considered necessary by the doctor. The duration of treatment should be as short as possible.

Other medicines and [Product name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular:

- Opioid medicines (such as strong painkillers, medicines for the treatment of opioid addiction, and certain cough medicines). Concomitant use increases the risk of drowsiness, breathing difficulties (respiratory depression), and coma, and may be life-threatening. Therefore, concomitant use should only be considered by the doctor when there are no other treatment options. Contact your doctor if you experience signs such as drowsiness or breathing difficulties (respiratory depression).
- Contraceptives (the pill).

[Product name] with alcohol
You must avoid drinking alcohol during treatment with this medicine since it may increase the effects of [Product name] and alcohol.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
There is a risk of an effect on the foetus. Therefore, you should always consult your doctor *before* using [Product name] during pregnancy.

Breast-feeding
Passes into breast milk but is not expected to affect the breastfed child. However, you should always consult your doctor *before* using [Product name] during breast-feeding.

Driving and using machines
During treatment with [Product name], your ability to react may be reduced, and you may experience side effects such as dizziness, drowsiness, hallucinations, and aggression that may impair your ability to drive or use machines.

[Product name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take [Product name]

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

The dose and the duration of treatment is decided and adjusted individually for you by your doctor. The doctor will tell you the dose, how many times a day and how long you should take [Product name]. This is to ensure you take the lowest effective dose for the shortest possible time because there is a risk of dependence. You should not change or exceed the dose prescribed for you.

The doctor will regularly evaluate the need to continue the treatment. At the end of the treatment, the dose must be gradually reduced according to your doctor’s instructions. This reduces the risk of withdrawal symptoms, which may in some cases be life-threatening (see section 2).

The tablets should be swallowed with a glass of water.
The 5 mg and 10 mg tablets can be divided into equal doses.

If you take more [Product name] than you should
Symptoms of overdosing may include:
Difficulties coordinating muscle movements, dizziness, speech difficulties, muscle weakness, sleepiness or unconsciousness, agitation (restlessness), aggression, hallucinations (seeing and hearing things that are not real), larger or smaller pupils, breathing difficulties, drop in blood pressure, faster heartbeat, low body temperature, nausea, or vomiting.

If you forget to take [Product name]
If you forget to take a dose, you should take it as soon as you remember, unless it is almost time to take your next dose. Do not take a double dose to make up for a forgotten dose. If in doubt, contact your doctor.

If you stop taking [Product name]
Do not stop the treatment without talking to your doctor first.
The treatment should not be stopped abruptly, but by reducing the dose gradually to reduce the risk of withdrawal symptoms. Abrupt discontinuation of the treatment or too rapid dose reduction may cause withdrawal symptoms (see section 2 “Warnings and precautions”).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects are dose-dependent, and the elderly are more sensitive.

Common side effects (may occur in up to 1 out of 10 users):
- Drowsiness (occurs in approximately 10-15% of all patients, but usually subsides after a few days of treatment)

Uncommon side effects (may occur in up to 1out of 100 users):
- Headache
- Dizziness
- Difficulties coordinating muscle movements
- Muscle weakness
- Memory problems with high doses

Rare side effects (may occur in up to 1 out of 1,000 users):
- Allergic skin reactions
- Breathing difficulties (respiratory depression)
- Sleeplessness
- Nightmares
- Agitation
- Aggression
- Seeing and hearing things that are not real (hallucinations)

Not known side effects (frequency cannot be estimated from the available data):
- Abuse of medicines, dependence
- Withdrawal syndrome

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

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

Blisters: Do not store above 30°C.

Bottles: This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the package 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 protect the environment.

6. Contents of the pack and other information

What [Product name] contains
- The active substance is oxazepam. One tablet contains 5 mg, 10 mg, or 15 mg of oxazepam, respectively.
- The other excipients are microcrystalline cellulose, pregelatinised starch, calcium hydrogen phosphate dihydrate (E341ii), anhydrous colloidal silica, sodium laurilsulfate (E487), croscarmellose sodium (E468), magnesium stearate (E470b).

What [Product name] looks like and contents of the pack
5 mg: White to yellowish, round, bevelled-edged, convex tablet, with ‘5’ debossed on one side and ‘score line’ on the other side. The tablet is 6 mm in diameter and can be divided into equal doses.

10 mg: White to yellowish, round, bevelled-edged, convex tablet, with ‘10’ debossed on one side and ‘score line’ on the other side. The tablet is 8 mm in diameter and can be divided into equal doses.

15 mg: White to yellowish, round, bevelled-edged, convex tablet, with ‘15’ debossed on one side. The tablet is 9 mm in diameter.

[Product name] tablets are packed in Al/PVC/PVDC blisters and white plastic bottles with PE screw cap.

Pack sizes:
25, 30, 50 and 100 tablets in blisters.
49x1 and 50x1 tablets in unit-dose blisters.
250 and 500 tablets in bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
2care4 Generics ApS
Stenhuggervej 12-14
6710 Esbjerg V
Denmark

Manufacturer
SANTA S.A.
Str. Panselelor nr. 25, nr. 27, nr. 29
Braşov, jud. Braşov, 500419,
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This leaflet was last revised in 2024-02-15

Detailed information on this medicine is available on the website of (name of MA Agency (hyperlink)).