

Package leaflet: Information for the user
Centrax® 10mg Tablets
prazepam

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 Centrax is and what it is used for
2. What you need to know before you take Centrax
3. How to take Centrax
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1. What Centrax is and what it is used for

Centrax is a tranquilliser containing the active ingredient prazepam. It belongs to a group of medicines called benzodiazepines. Benzodiazepines affect chemical activity in the brain and may help to reduce anxiety and stress.

It is used for short term relief of severe or disabling anxiety or when anxiety is causing great distress.

The overall length of your treatment should not be more than 4 to 6 weeks including a period where the dose is gradually reduced.

It is not suitable for children and adolescents under 18 years.

2. What you need to know before you take Centrax

Do not take Centrax:

- If you are allergic to prazepam or other similar benzodiazepine medicines, or any of the other ingredients of this medicine (listed in section 6)
- If you suffer from an autoimmune disease called ‘myasthenia gravis’ where you suffer from very weak and tired muscles
- If you have severe breathing difficulties
- If you have severe liver problems
- If you have ‘sleep apnoea’- this is a condition where your breathing becomes irregular, even stopping for short periods, while you are asleep.

Warning and precautions

Talk to your doctor or pharmacist before taking Centrax.

Your doctor will assess your condition before and throughout your treatment with this medicine. Centrax tablets are for short term use only for over a period of 4 to 6 weeks. Your condition will be reviewed if you need more than the recommended duration of treatment. Your dose will be lowered gradually as you progress through the course of this treatment. If you take Centrax for a long period of time, you may need to have regular blood tests.

Centrax 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 Centrax 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 of uninterrupted sleep.

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. 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 prazepam, 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, once dependence has developed, 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 headaches, convulsions, trembling, cramps in the muscles and abdomen, vomiting, nausea, sweating, diarrhoea, loss of appetite, muscle pain, feeling anxious, tension, sleeplessness, restlessness, depressed mood, dizziness, vertigo, 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, involuntary movements, agitation, palpitations, tachycardia, panic attacks, hyperactive reflexes, short term memory loss, hyperthermia, delirium tremens, hallucinations, 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 Centrax 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.**

Centrax needs to be gradually reduced towards the end of your treatment. Do not stop taking your tablets suddenly, especially if you have been taking a high dose. You may experience withdrawal symptoms (“rebound effects”) like headache, depression, nervousness, feeling stressed or worried, difficulty in sleeping, restlessness, irritability, tension and muscle pain. (see section 4 – Dependence and withdrawal symptoms).

Elderly Patients

Centrax may cause the muscles to feel relaxed or weak, therefore elderly patients taking Centrax are more at risk of falling, which may lead to hip fractures. Elderly patients should therefore take care when moving around if they experience any muscles problems.

Other medicines and Centrax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, in particular any of the following medicines, as the effect of Centrax may be stronger when taken at the same time. Sometimes it may be necessary to reduce the dose of Centrax if you are taking:

- 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 Centrax 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
- sedative antihistamines for relief of allergies that also make you sleepy
- oral contraceptives (‘the pill’)
- anaesthetics (medicines that aid loss of sensation to prevent pain during surgery).

Centrax with food and drink

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

Pregnancy and Breast-feeding

Pregnancy

Centrax is not recommended during pregnancy and in women of childbearing potential not using birth control

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

If you do become pregnant while taking this medicine, your doctor will advise you of the risks involved and may advise you to stop taking the tablets. Occasionally, your doctor may assess your condition and it may be necessary to give you Centrax during late pregnancy or during labour. In these cases babies may have a low body temperature, floppiness, withdrawal symptoms, breathing and feeding difficulties.

Breast-feeding

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

Driving and using machines

Centrax can cause blurred vision, drowsiness during the day, lack of coordination, forgetfulness and loss of concentration. It is very important you do not drive or operate machinery until you know how the tablets affect you.

Centrax contains lactose

Centrax contains an ingredient known as lactose which is a type of sugar. 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 Centrax

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how many tablets to take and when to take them. This information is also on the label on the carton of the tablets. **Do not take your tablets with alcohol.**

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 Centrax, 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).

Adults

Your doctor will have decided on the most suitable dose for you. The recommended dose is 3 tablets a day, either as a single dose or divided into several doses. Your doctor may decide that a different dose is right for you; this will normally be between 1 and 6 tablets a day.

The elderly

You may be given half the adult dose if you are elderly (over 65), run down, or have kidney or liver problems.

Children

Centrax is not recommended for the treatment of children or adolescents under 18 years.

If you take more Centrax than you should

It is important that you do not take more tablets than you are told to. If you do accidentally take too many tablets, seek medical attention straight away.

If you forget to take Centrax

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

Length of treatment and stopping treatment with Centrax tablets

- Centrax tablets are only used for short-term treatment (not more than 6 weeks). You will be given a prescription for this medicine for a minimum of 4 weeks. Your doctor will assess your condition after this time and may put you on a further 2 weeks of treatment.
- Always see your doctor before you stop taking your tablets as the dose needs to be reduced gradually. If you stop taking the tablets or reduce the dose suddenly you can get 'rebound' 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 are worried, your doctor can tell you more about this.

4. Possible side effects

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

If any of the following happen, see your doctor immediately:

- Very occasionally treatment with this medicine may cause serious behavioural or psychiatric effects - for example agitation, restlessness, aggressiveness, irritability, violent anger, false beliefs, nightmares or vivid dreams and hallucinations or other inappropriate behaviour.

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

Use of benzodiazepines (even at therapeutic doses) can cause physical dependence. Consequently, discontinuation of treatment may induce a withdrawal or rebound phenomenon (see section 2 “Warnings and precautions”). Psychological dependence can also occur. Cases of benzodiazepine abuse have been reported (see section 2 “Warnings and precautions”).

Tell your doctor if you start to feel dependence on your treatment.

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

Other side effects

The frequency of possible side effects listed below is defined using the following convention:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

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

Very rare: may affect up to 1 in 10,000 people

Not known (frequency cannot be estimated from the available data)

Very common side effects

- drowsiness during the day

Common side effects

- confusion
- vivid dreams
- impaired balance or coordination
- dizziness
- headache
- hyperactivity (stimulation or excitability)
- light-headedness
- slurred speech
- tremor (shakiness or trembling)
- blurred vision
- abnormal heartbeat (palpitations)
- dry mouth
- stomach or intestinal problems
- sweating
- skin rash
- joint pains
- urinary and other genital complaints
- tiredness
- weakness

Uncommon side effects

- fainting
- itchy skin
- swelling of feet

Frequency unknown

- numbed emotions
- reduced alertness
- skin reactions
- muscle weakness
- decreased blood pressure
- abnormal liver function tests
- increases in body weight
- changes in libido
- 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 of uninterrupted sleep
- drug abuse, drug dependence (see section 2 Development of tolerance and dependence, withdrawal reactions and drug abuse)
- drug withdrawal syndrome (see section 2 Development of tolerance and dependence, withdrawal reactions and drug abuse).

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.

5. How to store Centrax

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

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.

No special storage precautions are required.

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 Centrax contains

The active substance is prazepam. Each tablet contains 10mg of prazepam.

The other ingredients are lactose monohydrate (see section 2, Centrax contains lactose), microcrystalline cellulose, maize starch, magnesium stearate and colloidal anhydrous silica.

What Centrax looks like and contents of the pack

Centrax are round white tablets with a breakline. The tablet can be divided into equal doses.

They are available in PVC/Aluminium blister packs of 60 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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

Manufacturer:

Pfizer Manufacturing Deutschland GmbH-
Betriebsstätte Freiburg
Mooswaldallee 1
D-79090
Freiburg
Germany.

Company contact address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24,
Ireland. Telephone 1800 633 363.

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