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 OXYCODONE HYDROCHLORIDE EXTENDED-RELEASE TABLETS 80 mg
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PATIENT INFORMATION



OXYCODONE HYDROCHLORIDE EXTENDED-RELEASE TABLETS, 80 mg

Read this information carefully before you take oxycodone hydrochloride extended-release tablets. Also read the information you get with your refills. There may be something new. This information does not take the place of talking with your doctor about your medical condition or your treatment. Only you and your doctor can decide if oxycodone hydrochloride extended-release tablets are right for you. Share the important information in this leaflet with members of your household.

What Is the Most Important Information I Should Know About Oxycodone Hydrochloride Extended-Release Tablets?

- Use oxycodone hydrochloride extended-release tablets only for the condition for which they are prescribed.
- Oxycodone hydrochloride extended-release tablets are not for occasional ("as needed") use.
- Swallow the tablets whole. Do not break, crush, dissolve, or chew them before swallowing. Oxycodone hydrochloride extended-release tablets work properly over 12 hours only when swallowed whole. If a tablet is broken, crushed, dissolved, or chewed, the entire 12 hour dose will be absorbed into your body all at once. This can be dangerous, causing an overdose, and possibly death.
- Keep oxycodone hydrochloride extended-release tablets out of the reach of children. Accidental overdose by a child is dangerous and may result in death.
- Prevent theft and misuse. Oxycodone hydrochloride extended-release tablets contain a narcotic painkiller that can be a target for people who abuse prescription medicines. Therefore, keep your tablets in a secure place, to protect them from theft. Never give them to anyone else. Selling or giving away this medicine is dangerous and against the law.

What are Oxycodone Hydrochloride Extended-Release Tablets?
 Oxycodone hydrochloride extended-release tablets come in several strengths and contain the medicine oxycodone (ox-ə-KOY-done). This medicine is a painkiller like morphine. Oxycodone hydrochloride extended-release tablets treat moderate to severe pain that is expected to last for an extended period of time. Use oxycodone hydrochloride extended-release tablets regularly during treatment. They contain enough medicine to last for up to twelve hours.

Who Should Not Take Oxycodone Hydrochloride Extended-Release Tablets?

- Do not take oxycodone hydrochloride extended-release tablets if
- your doctor did not prescribe oxycodone hydrochloride extended-release tablets for you.
 - your pain is mild or will go away in a few days.
 - your pain can be controlled by occasional use of other painkillers.
 - you have severe asthma or severe lung problems.
 - you have had a severe allergic reaction to codeine, hydrocodone, dihydrocodeine, or oxycodone (such as Tylox™, Tylenol with Codeine®, or Vicodin™). A severe allergic reaction includes a severe rash, hives, breathing problems, or dizziness.
 - you had surgery less than 12 to 24 hours ago and you were not taking oxycodone hydrochloride extended-release tablets just before surgery.

Your doctor should know about all your medical conditions before deciding if oxycodone hydrochloride extended-release tablets are right for you and what dose is best. Tell your doctor about all of your medical problems, especially the ones listed below:

- trouble breathing or lung problems
- head injury
- liver or kidney problems
- adrenal gland problems, such as Addison's disease
- convulsions or seizures
- alcoholism
- hallucinations or other severe mental problems
- past or present substance abuse or drug addiction

If any of these conditions apply to you, and you haven't told your doctor, then you should tell your doctor before taking oxycodone hydrochloride extended-release tablets.

If you are pregnant or plan to become pregnant, talk with your doctor. Oxycodone hydrochloride extended-release tablets may not be right for you. **Tell your doctor if you are breast feeding.** Oxycodone hydrochloride extended-release tablets will pass through the milk and may harm the baby.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. They may cause serious medical problems when taken with oxycodone hydrochloride extended-release tablets, especially if they cause drowsiness.

How Should I Take Oxycodone Hydrochloride Extended-Release Tablets?

- Follow your doctor's directions exactly. Your doctor may change your dose based on your reactions to the medicine. Do not change your dose unless your doctor tells you to change it. Do not take oxycodone hydrochloride extended-release tablets more often than prescribed.
- Swallow the tablets whole. Do not break, crush, dissolve, or chew before swallowing. If the tablets are not whole, your body will absorb too much medicine at one time. This can lead to serious problems, including overdose and death.
- If you miss a dose, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once unless your doctor tells you to.
- In case of overdose, call your local emergency number or poison control center right away.
- Review your pain regularly with your doctor to determine if you still need oxycodone hydrochloride extended-release tablets.

If you continue to have pain or bothersome side effects, call your doctor.

Stopping oxycodone hydrochloride extended-release tablets. Consult your doctor for instructions on how to stop this medicine slowly to avoid uncomfortable symptoms. You should not stop taking oxycodone hydrochloride extended-release tablets all at once if you have been taking it for more than a few days.

After you stop taking oxycodone hydrochloride extended-release tablets, flush the unused tablets down the toilet.

What Should I Avoid While Taking Oxycodone Hydrochloride Extended-Release Tablets?

- Do not drive, operate heavy machinery, or participate in any other possibly dangerous activities until you know how you react to this medicine. Oxycodone hydrochloride extended-release tablets can make you sleepy.
- Do not drink alcohol while using oxycodone hydrochloride extended-release tablets. It may increase the chance of getting dangerous side effects.
- Do not take other medicines without your doctor's approval. Other medicines include prescription and non-prescription medicines, vitamins, and supplements. Be especially careful about products that make you sleepy.

What are the Possible Side Effects of Oxycodone Hydrochloride Extended-Release Tablets?

Call your doctor or get medical help right away if

- your breathing slows down
- you feel faint, dizzy, confused, or have any other unusual symptoms

Some of the common side effects of oxycodone hydrochloride extended-release tablets are nausea, vomiting, dizziness, drowsiness, constipation, itching, dry mouth, sweating, weakness, and headache. Some of these side effects may decrease with continued use.

There is a risk of abuse or addiction with narcotic painkillers. If you have abused drugs in the past, you may have a higher chance of developing abuse or addiction again while using oxycodone hydrochloride extended-release tablets. We do not know how often patients with continuing (chronic) pain become addicted to narcotics, but the risk has been reported to be small.

These are not all the possible side effects of oxycodone hydrochloride extended-release tablets. For a complete list, ask your doctor or pharmacist.

General Advice About Oxycodone Hydrochloride Extended-Release Tablets

- Do not use oxycodone hydrochloride extended-release tablets for conditions for which it was not prescribed.
- Do not give oxycodone hydrochloride extended-release tablets to other people, even if they have the same symptoms you have. Sharing is illegal and may cause severe medical problems, including death.
- Store oxycodone hydrochloride extended-release tablets at controlled room temperature, between 20° and 25°C (68° and 77°F) (see USP).

This leaflet summarizes the most important information about oxycodone hydrochloride extended-release tablets. If you would like more information, talk with your doctor. Also, you can ask your pharmacist or doctor for information about oxycodone hydrochloride extended-release tablets that is written for health professionals.

*Tylox and Tylenol with Codeine are brand names of ORTHO-MCNEIL PHARMACEUTICAL.

**Vicodin is a brand name of ABBOTT LABORATORIES.

Rx only

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