Abtard® contains the active substance oxycodone hydrochloride which belongs to a group of medicines called opioids. These are strongly painkillers, is used to relieve severe pain, which can only be controlled by opioid analgesics in adults and adolescents 12 years and older.

1. What Abtard® is and what it is used for

Abtard® is an opioid analgesic of the prolonged-release type which contains oxycodone hydrochloride. Abtard® is used to relieve severe pain, which can only be controlled by opioid analgesics in adults and adolescents 12 years and older.

2. What you need to know before you take Abtard®

Do not take Abtard® if:
- you are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (see section 4).
- you have liver problems, such as cirrhosis, acute or chronic liver failure, or ascites or severe, severe internal bleeding, or severe jaundice.
- you have a history of or are at risk of addiction.
- you have a history or risk of liver disease.
- you have experienced severe problems with alcohol or drug abuse, or you are an alcoholic withdrawals.
- you have pain due to liver cirrhosis.
- you have high blood pressure.
- you have an inflammatory bowel disease.
- you have had a colostomy or ileostomy.
- you have recently had abdominal surgery.

Tell your doctor or pharmacist if any of these apply to you or if any of these conditions applied to you in the past. Abtard® has a primary dependence potential, often used for a long time, tolerance and the effects offolk use require regular therapy with other opioids.

Abtard® is not recommended for use before an operation or in the 24 hours after an operation. If you have any questions on this medicine, ask your doctor or pharmacist.

3. How to take Abtard®

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

DOSAGE AND ADMINISTRATION

Adults and adolescents (12 years of age and older)
The recommended initial dose is 1 or 2 mg oxycodone. The dose should be increased at intervals of 4 to 6 hours to the smallest amount of drug adequate to relieve pain.

Further examination of the daily dose, the division into the single doses and the dose adjustments during the further course of therapy are performed by the treating physician and depend on the previous dosage.

Some patients who have already taken oxycodone can start treatment with higher dosages taking into account their experience with opioid therapy.

Bifrontal tablets can be split. Some patients who require treatment according to a fixed schedule need adapting, during periods in which they are used to be controlled by time-release tablets. Abtard® is designed for the treatment of the time-release tablets.

For the treatment of non-cancer pain a daily dose of 5 to 15 mg oxycodone is recommended. For cancer patients, doses up to 100 mg oxycodone hydrochloride may be increased up to 400 mg in individual cases. The treatment needs to be controlled regularly with regard to pain relief and other effects in order to achieve the best possible pain therapy provision as well as to be able to deal with the occurrence of side effects in good time and to decide whether treatment should be continued.

Kidney impairment or low body weight
If you have impaired kidney or liver function of any type or have a low body weight your doctor may prescribe a lower starting dose.

Method of administration
Swallow the prolonged-release tablets whole with a sufficient amount of liquid; do not chew or swallow the tablets whole or with a small amount of fluid. The tablets should be taken with a large glass of water.