Package leaflet: Information for the patient

Abtard 5 mg prolonged-release tablets
Abtard 10 mg prolonged-release tablets
Abtard 15 mg prolonged-release tablets
Abtard 20 mg prolonged-release tablets
Abtard 30 mg prolonged-release tablets
Abtard 40 mg prolonged-release tablets
Abtard 60 mg prolonged-release tablets
Abtard 80 mg prolonged-release tablets

Oxycodone hydrochloride

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Abtard is and what it is used for

Abtard contains the active ingredient oxycodone hydrochloride which belongs to a group of medicines called opioids. These are strong painkillers.

Abtard is used to relieve severe pain, which can only be controlled by opioid analgesics in adults and adolescents 12 years of age 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 (listed in section 6).
- if you have severe problems breathing, low amounts of oxygen in your blood (hypoxia) or too much carbon dioxide in your blood.
- if you suffer from severe chronic obstructive lung disease, cor pulmonale (cardiac changes due to chronic overload of lung circulation) or acute, severe bronchial asthma.
- if you suffer from intestinal paralysis.
- if you have an acute abdomen or suffer from a delayed gastric emptying.

Warnings and precautions
Talk to your doctor or pharmacist before taking Abtard
- if you are older or debilitated,
- if you have lung, liver or kidney problems,

- if you suffer from certain illnesses of the thyroid gland, impaired function of the thyroid gland,
- if you suffer from adrenal insufficiency (Addison's disease),
- if you suffer from enlargement of the prostate,
- if you suffer from alcoholism or are undergoing alcohol withdrawal
- if you suffer from known opioid-dependence,
- if you suffer from inflammation of the pancreas,
- in conditions with increased brain pressure such as head injury,
- if you suffer from disturbances of circulatory regulation,
- if you suffer from colic of the bile duct and ureter,
- if you suffer from low blood pressure or reduced blood volume,
- if you suffer from epilepsy or have a seizure tendency,
- if you take MAO inhibitors (for the treatment of depression),
- if you suffer from an inflammatory bowel disorder,
- if you have recently had abdominal surgery.

Please talk to your doctor 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. When used for a long time, tolerance to the effects may develop and progressively higher doses may be required to maintain pain control.

Chronic use of Abtard may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation. When a patient no longer requires therapy with oxycodone hydrochloride, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

When used as directed in patients suffering from chronic pain the risk of developing physical or psychological dependence is markedly reduced and needs to be weighed against the potential benefit. Please discuss this with your doctor.

Increased sensitivity to pain that does not respond to dose increases can rarely develop. If this happens, your doctor will reduce your dose or switch you to an alternative opioid painkiller.

Abtard is not recommended for use before an operation or in the 24 hours after an operation.

Abtard should be used with particular care in patients with a history of or present alcohol and drug abuse.

You should not drink alcohol while you are taking Abtard. Drinking alcohol whilst taking Abtard may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness.

Children and adolescents
Oxycodone has not been investigated in children under 12 years. Safety and efficacy have not been established and therefore use in children under 12 years of age is not recommended.

Elderly patients
If kidney or liver function is not impaired, a dose adjustment is usually not necessary for elderly patients.

Other medicines and Abtard
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines may influence the effect or side effects of Abtard

- sleeping pills or tranquillizers (sedatives, hypnotics)
- anti-depressants
- anaesthetics
- muscle relaxants
- other opioids or alcohol can enhance the side effects of oxycodone, in particular depressed breathing (respiratory depression).

- other medicines that act against parasympathetic and cholinergic nerve fibres on the central nervous system
- medicines used to treat allergies (antihistamines)
- medicines used to treat vomiting (antiemetics)
- medicines used to treat Parkinson's disease can enhance certain side effects of oxycodone (e.g. constipation, dry mouth or urinary disturbances)
- anticoagulants of the coumarin type (medicines used to reduce blood clotting)
- monoamine oxidase inhibitors (MAOIs) such as moclobemide, phenelzine, isoniazid, tranylcypromine or selegiline as these can enhance some side effects of oxycodone (e.g. excitation, decrease or increase in blood pressure).

The following medicines may possibly increase the blood levels of oxycodone and your doctor may need to re-consider the dose of Abtard;
- Medicines used to treat infections (e.g. clarithromycin, erythromycin and telithromycin) or to treat fungal infections (e.g. ketoconazole, voriconazole, itraconazole, and posaconazole).
- Medicines such as rifampicin (used to treat tuberculosis).
- Medicines used to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir and saquinavir).
- Cimetidine (to treat heart burn).
- Medicines such as paroxetine and fluoxetine (antidepressants) and St John's Wort (herbal medicine).
- Quinidine (used in the treatment of heart diseases).
- Carbamazepine, phenytoin (used to treat epilepsy).

Grapefruit juice may also increase the blood levels of oxycodone.

Abtard with food, drink and alcohol
You should not drink alcohol while you are taking Abtard. Drinking alcohol whilst taking Abtard may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness.

Grapefruit juice can inhibit the metabolism of oxycodone which will increase its effect. Therefore you should avoid drinking grapefruit juice while taking Abtard.

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 are limited data from the use of oxycodone in pregnant women. Oxycodone passes through the placenta into the blood circulation of the baby.
Use of oxycodone during pregnancy may cause withdrawal symptoms in newborns. Infants born to mothers who have received oxycodone during the last 3-4 weeks before labour should be monitored for respiratory depression. Use of oxycodone during childbirth can cause severe breathing difficulties in the newborn.
Abtard should only be used during pregnancy if the benefit outweighs the possible risks to the baby.

Breast-feeding
Oxycodone may pass into breast milk and may cause breathing difficulties in the newborn. Abtard should therefore not be used during breast-feeding.

Driving and using machines
Oxycodone may affect your ability to drive and use machines.
With stable therapy, a general ban on driving a vehicle may be not necessary. The treating physician must assess the individual situation. Please discuss with your doctor whether or under what conditions you can drive a vehicle.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.

- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
    - The medicine has been prescribed to treat a medical or dental problem and
    - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
    - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Abtard contains lactose
This medicinal product contains lactose. 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 Abtard

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

Adults and adolescents (12 years of age and older)
The recommended initial dose is 5 or 10 mg oxycodone hydrochloride, in 12 hourly intervals. However, your doctor will prescribe the dose required to treat pain.

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

Patients who have already taken opioids can start treatment with higher dosages taking into account their experience with opioid treatment.

Some patients who receive Abtard according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Abtard is not intended for the treatment of breakthrough pain.

For the treatment of non cancer pain a daily dose of 40 mg of oxycodone hydrochloride (20 mg given twice a day) is generally sufficient, but higher dosages may be necessary. Patients with cancer pain usually require dosages from 80 to 120 mg of oxycodone hydrochloride which 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 pain therapy possible as well as to be able to treat any occurring side effects in good time and to decide whether treatment should be continued.

Kidney/liver impairment or low body weight
If you have impaired kidney and/or liver function or if you have a low body weight your doctor may prescribe a lower starting dose.

Method and duration of administration
Swallow the prolonged-release tablets whole with a sufficient amount of liquid (½ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).

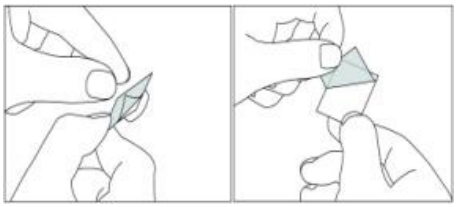
The tablets must not be broken, crushed or chewed as this leads to rapid oxycodone release due to the damage of the prolonged release properties. The administration of broken, chewed or crushed Abtard leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section "If you take more Abtard than you should"). Abtard are for oral use only. In case of abusive injection (injection in a vein) the tablet excipients may lead to destruction (necrosis) of the local tissue, change of lung tissue (granulomas of the lung) or other serious, potentially fatal events.

[For child resistant blister packs only:]

Instructions for use of child resistant blisters:
1. Do not push the tablet directly out of the pocket

2. Separate one blister cell from the strip at the perforations

3. Carefully peel off the backing to open the pocket



Your doctor will adjust the dosage depending on the pain intensity and how you respond to the treatment. Take the number of prolonged-release tablets determined by your doctor twice daily.

If you take more Abtard than you should
If you have taken more Abtard as prescribed you should inform your doctor or your local poison control centre immediately. The following symptoms may occur: constricted pupils, depressed breathing, skeletal muscle flaccidity and drop in blood pressure. In severe cases circulatory collapse, mental and motor inactivity, unconsciousness, slowing of the heart rate, accumulation of water in the lungs, low blood pressure and death may occur; abuse of high doses of strong opioids such as oxycodone can be fatal. In no case you should expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Abtard
If you use a smaller dose of Abtard than directed or you miss the intake of the tablets, pain relief will consequently be insufficient or cease altogether.
You can make up for a forgotten tablet if the next regular intake is not due for at least another 8 hours. You can then continue to take the tablets as directed.
You should also take the prolonged-release tablets if the time to the regular next intake is shorter, but postpone the next intake by 8 hours. In principle, you should not take Abtard more than once every 8 hours. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Abtard
Do not stop treatment without informing your doctor.
When a patient no longer requires therapy with Abtard, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

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

4. Possible side effects

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

Significant side effects or signs to consider and measures to be taken when these side effects or signs occur:

If you experience any of the following side effects, stop taking Abtard and contact your doctor immediately.

Depressed breathing is the most significant risk induced by opioids and is most likely to occur in elderly or debilitated patients. As a consequence, in predisposed patients opioids can cause severe drops in blood pressure.

Apart from this oxycodone can cause constricted pupils, bronchial spasms and spasms in smooth muscles and suppress the cough reflex.

Other possible side effects
Very common (may affect more than 1 in 10 people):
- sedation (tiredness to drowsiness) – this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days.
- dizziness
- headache
- constipation
- feeling sick (nausea)
- being sick (vomiting)
- itching.

Common (may affect up to 1 in 10 people):
- feeling weak (asthenia)
- several psychological side effects such as
    - changes in mood (e.g. anxiety, depression)
    - changes in activity (nervousness and insomnia)
    - changes in performance (abnormal thinking, confusion, amnesia, isolated cases of speech disorders)
- involuntary trembling or shaking
- depressed breathing
- difficulty in breathing or wheezing
- dry mouth, rarely accompanied by thirst; gastrointestinal disorders such as stomach pain; diarrhoea; upset stomach; loss of appetite
- skin disorders such as rash, rarely increased sensitivity to light (photosensitivity), in isolated cases itchy or scaly rash, excessive sweating
- urinary disorders (frequent urination).

Uncommon (may affect up to 1 in 100 people):
- allergic reactions
- dehydration
- agitation
- change in perception such as emotional instability, depersonalisation, a feeling of extreme happiness, hallucinations, change in taste, visual disturbances, abnormally acute sense of hearing, feeling of dizziness or spinning, decreased sex drive; drug dependence (see section 2)
- abnormal production of intidiuretic hormone
- loss of memory, fits, increased tightness and difficulty in stretching muscles, both increased and decreased muscle tone; tics; reduced sense of touch; coordination disturbances; speech disorders; fainting; tingling or pins and needles
- feeling unwell, accelerated pulse, being aware of the heart beat
- widening of the blood vessels
- increased coughing; pharyngitis; runny nose; voice changes; difficulty breathing
- oral ulcers; inflammation of the gums, inflamed mouth; difficulty swallowing, wind, flatulence, intestinal obstruction
- increased liver enzymes
- dry skin
- difficulty in passing urine
- disturbances of sexual function, impotence

- injuries due to accidents
- pain (e.g. chest pain); excessive fluid in the tissues (oedema); chills; thirst; migraine; physical dependence with withdrawal symptoms
- changes in tear secretion, constriction of the pupil, visual impairment.

Rare (may affect up to 1 in 1,000 people):
- lymph node disease
- lowering of blood pressure, dizziness when standing up from a sitting or lying position
- muscle spasms (involuntary contraction of the muscle)
- gum bleeding; increased appetite; tarry stool; tooth staining
- herpes simplex (disorder of the skin and mucosa)
- itchy skin rash (hives)
- blood in urine
- changes in body weight (loss or rise); cellulitis.

Not known (frequency cannot be estimated from the available data):
- severe hypersensitivity reactions (anaphylactic reactions)
- aggression
- increased sensitivity to pain which cannot be improved by increasing the dose
- tooth decay
- pain on the right side of the abdomen, itchiness and jaundice caused by inflammation of the gall bladder.
- absence of menstrual bleeding

Counteractive measures
If you observe any of the above listed side effects your doctor will usually take appropriate measures.

The side effect constipation may be prevented by fibre enriched diet and increased intake of fluids.
If you are suffering from sickness or vomiting your doctor may prescribe you an appropriate medicine.

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Abtard

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 blister, carton and container after "EXP". The expiry date refers to the last day of that month.

Blister packs: Do not store above 25°C.
HDPE container: This medicinal product does not require any special storage conditions.

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 Abtard contains
- The active substance is oxycodone hydrochloride. Each prolonged-release tablet contains 5 10 15 20 30 40 60 80 mg oxycodone hydrochloride.
- The other ingredients are:
Tablet core: Lactose monohydrate, hypromellose, povidone, stearic acid, magnesium stearate, colloidal anhydrous silica.

Tablet coating:
5 mg tablets: Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, blue Indigo Carmine Aluminium Lake (E132), yellow iron oxide (E172).
10 mg tablets: Titanium dioxide (E171), hypromellose, macrogol, polysorbate 80
15 mg tablets: Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, yellow iron oxide (E172), black iron oxide (E172).
20 mg tablets: Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, red iron oxide (E172).
30 mg tablets: Polyvinyl alcohol, macrogol, talc, red iron oxide (E172), black iron oxide (E172), blue Indigo Carmine Aluminium Lake (E132)
40 mg tablets: Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, yellow iron oxide (E172).
60 mg tablets: Polyvinyl alcohol, macrogol, talc, red iron oxide (E172), carmine (E120), black iron oxide (E172).
80 mg tablets: Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, blue Indigo Carmine Aluminium Lake (E132), yellow iron oxide (E172).

What Abtard looks like and contents of the pack
Abtard 5 mg prolonged-release tablets are blue, round, biconvex tablets, 7 mm in diameter, with 'OX 5' debossed on one side.

Abtard 10 mg prolonged-release tablets are white, round, biconvex tablets, 9 mm in diameter, with 'OX 10' debossed on one side.

Abtard 15 mg prolonged-release tablets are grey, round, biconvex tablets, 9 mm in diameter, with 'OX 15' debossed on one side.

Abtard 20 mg prolonged-release tablets are pink, round, biconvex tablets, 7 mm in diameter, with 'OX 20' debossed on one side.

Abtard 30 mg prolonged-release tablets are brown, round, biconvex tablets, 9 mm in diameter, with 'OX 30' debossed on one side.

Abtard 40 mg prolonged-release tablets are yellow, round, biconvex tablets, 7 mm in diameter, with 'OX 40' debossed on one side.

Abtard 60 mg prolonged-release tablets are red, round, biconvex tablets, 9 mm in diameter, with 'OX 60' debossed on one side.

Abtard 80 mg prolonged-release tablets are green, round, biconvex tablets, 9 mm in diameter, with 'OX 80' debossed on one side.

Abtard are available in blister packs (PVC/Aluminium) of:
5 mg: 1, 20, 28, 30, 50, 56, 60 and 100 prolonged-release tablets
10 mg, 20 mg, 40 mg, 80 mg: 1, 20, 28, 30, 50, 56, 60, 98 and 100 prolonged-release tablets
15 mg: 1, 20, 30, 56, 98 and 100 prolonged-release tablets
30 mg, 60 mg: 1, 20, 30, 50, 56, 98 and 100 prolonged-release tablets

Abtard are available in child resistant blister packs (PVC/PVdC/Al/PET/paper) of:
5 mg: 1, 20, 28, 30, 50, 56, 60 and 100 prolonged-release tablets
10 mg, 20 mg, 40 mg, 80 mg: 1, 20, 28, 30, 50, 56, 60, 98 and 100 prolonged-release tablets
15 mg: 1, 20, 30, 56, 98 and 100 prolonged-release tablets
30 mg, 60 mg: 1, 20, 30, 50, 56, 98 and 100 prolonged-release tablets

Abtard are also availible in white, round, HDPE tablet containers with LDPE caps containing 98 or 100 prolonged-release tablets.

And white, round, child-resistant, HDPE tablet containers with LDPE caps containing 98 or 100 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
- Marketing Authorisation Holder
DB Ashbourne Limited
The Rectory, Braybrooke Road,
Arthingworth, Market Harborough
LE16 8JT, United Kingdom

- **Manufacturer**
Actavis hf.,
Reykjavíkurvegi 78,
IS-220 Hafnarfjörður
Iceland

Balkanpharma-Dupnitsa AD
3 Samokovsko Shosse Str., Dupnitza 2600,
Bulgaria

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden:	Oxytia Depot
United Kingdom:	ABTARD 5mg Prolonged-release Tablets
	ABTARD 10mg Prolonged-release Tablets
	ABTARD 15mg Prolonged-release Tablets
	ABTARD 20mg Prolonged-release Tablets
	ABTARD 30mg Prolonged-release Tablets
	ABTARD 40mg Prolonged-release Tablets
	ABTARD 60mg Prolonged-release Tablets
	ABTARD 80mg Prolonged-release Tablets

This leaflet was last revised inMarch 2015.

Detailed information on this medicine is available on the web sites of DB Ashbourne Limited and the Medicines and Healthcare Products Regulatory Agency (MHRA).