Package leaflet: Information for the user

Oxycodone Hydrochloride Teva 5 mg Capsules, hard
Oxycodone Hydrochloride Teva 10 mg Capsules, hard
Oxycodone Hydrochloride Teva 20 mg Capsules, hard
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 Oxycodone Hydrochloride Teva is and what it is used for

Oxycodone Hydrochloride Teva is a centrally acting, strong painkiller from the group of opioids.
Oxycodone Hydrochloride Teva is used to treat severe pain, which can only be adequately managed with opioid analgesics.

2. What you need to know before you take Oxycodone Hydrochloride Teva

Do NOT take Oxycodone Hydrochloride Teva if you:
- are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- suffer from severely depressed breathing (respiratory depression) with too little oxygen in the blood (hypoxia) and/or too much carbon dioxide (hypercapnia) in the blood
- suffer from severe chronic obstructive lung disease, cor pulmonale (cardiac changes due to chronic overload of lung circulation) or acute, severe bronchial asthma
- suffer from intestinal paralysis (paralytic ileus)
- have an acute abdomen or suffer from a delayed gastric emptying.

Warnings and precautions
Talk to your doctor or pharmacist before taking Oxycodone Hydrochloride Teva
- if you are older or debilitated
- if your lung, liver or kidney function is severely impaired
- if you suffer from myxoedema (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 (prostatic hypertrophy)
- if you suffer from alcoholism or are undergoing alcohol withdrawal and problems occur (e.g. delirium tremens)
- if you suffer from intoxication psychosis (e.g. alcohol)
- if you suffer from known opioid-dependence
- if you suffer from inflammation of the pancreas (pancreatitis)
- in conditions with increased brain pressure such as head injury
- if you suffer from disturbances of circulatory regulation
- if you suffer from diseases of the biliary tract, 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 have recently undergone a bowel-surgery or abdominal surgery
- if you suffer from an inflammatory bowel disorder.

Please talk to your doctor if any of these apply to you or if any of these conditions applied to you in the past.

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

Physical dependence and withdrawal symptoms
Oxycodone Hydrochloride Teva 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 Oxycodone Hydrochloride Teva may lead to physical dependence and a withdrawal syndrome may occur if you suddenly stop taking this medicine. When you no longer require therapy with Oxycodone Hydrochloride Teva, it may be advisable to reduce 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. Please discuss this with your doctor.

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

Surgery
If you are going to have an operation, please tell the doctor at the hospital that you are taking these tablets.

Children and adolescents
Oxycodone Hydrochloride Teva is NOT recommended for use in children under 12 years of age as the safety and efficacy have not been established.

Elderly patients

In elderly patients without impairment of kidney and/or liver function a dose adjustment is usually not necessary.

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

- Medicines that dampen the activity of the central nervous system, e.g.
  - sleeping pills or tranquillizers (sedatives, hypnotics)
  - other medicines that act on the nervous system (phenothiazines, neuroleptics)
  - medicines used to treat depression
  - muscle relaxants
  - medicines used to treat allergies or vomiting (antihistamines, antiemetics)
  - other opioids or alcohol can enhance the side effects of Oxycodone Hydrochloride Teva, in particular depressed breathing (respiratory depression).
- Medicines with an anticholinergic effect, e.g.
  - other medicines that act against parasympathetic and cholinergic nerve fibers on the central nervous system (psychotropic medicines)
  - medicines used to treat allergies (antihistamines) or vomiting (antiemetics)
  - medicines used to treat Parkinson´s disease can enhance certain side effects of oxycodone (e.g. constipation, dry mouth or urinary disturbances).
- Macrolide antibiotics, some antifungal and antiviral medicines can increase the effect of oxycodone and so the dose may need to be adjusted if you are taking these medicines.
- Cimetidine (a medicine used to treat heartburn) and quinidine (a medicine used to treat heart disease) can inhibit the metabolism of oxycodone.
- Some antiepileptic medicines and also the herbal remedy ‘St John Wort’ can decrease the effect of oxycodone
- Monoamine oxidase inhibitors (a medicine used to treat depression) can enhance the side effects of oxycodone (e.g. excitation, decrease or increase in blood pressure).
- Medicines used to prevent blood clotting (anticoagulants of the coumarin type) may cause an increase or decrease of blood clotting if used together with Oxycodone Hydrochloride Teva.

Oxycodone Hydrochloride Teva with food, drink and alcohol
Oxycodone Hydrochloride Teva may be taken with or without food with a sufficient amount of liquid.

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

Alcohol
Drinking alcohol whilst taking Oxycodone Hydrochloride Teva may make you feel sleepier or increase the risk of serious side effects such as **shallow breathing with a risk of stopping breathing, and loss of consciousness**. It is recommended that you **do NOT** drink alcohol while you are taking Oxycodone Hydrochloride Teva.

Please refer to section 4 “Possible side effects” for information on counteractive measures which may be used to ease certain side effects.

Pregnancy, breast-feeding and fertility
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.

The use of Oxycodone Hydrochloride Teva should be avoided to the extent possible during pregnancy and breast-feeding.

Pregnancy
There are limited data from the use of oxycodone in pregnant women. Use of oxycodone during pregnancy may cause withdrawal symptoms in the newborn. Infants born to mothers who have received oxycodone during the last 3-4 weeks before labour may experience severe breathing difficulties. Oxycodone Hydrochloride Teva should only be used during pregnancy if the benefit outweighs the possible risks for the baby.

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

Driving and using machines
Oxycodone impairs alertness and reactivity to such an extent that the ability to drive and operate machinery is affected or ceases altogether. To look at the possible side effects affecting the motor skills and concentration see section 4 “Possible side effects”. With stable therapy, a general ban on driving a vehicle may not be necessary. The treating physician must assess the individual situation. **Please discuss with your doctor whether or under what conditions you can drive vehicle**.

3. How to take Oxycodone Teva

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 over 12 years
The usual starting dose is one 5 mg capsule every 6 hours.
However, your doctor will prescribe the appropriate dose and frequency of administration required to treat your pain.

If you find that you are still in pain whilst taking these capsules discuss this with your doctor.

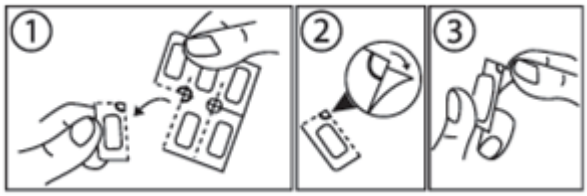
Method of use
Oxycodone Hydrochloride Teva capsules should be swallowed whole with a sufficient amount of liquid and may be taken with or without food.

Oxycodone Hydrochloride Teva should NOT be taken with alcoholic beverages (see section 2, “Oxycodone Hydrochloride Teva with food, drink and alcohol”).

You must only take the capsules orally. The capsule contents should never be injected as this may lead to serious side effects, which may be fatal.

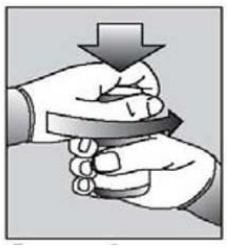
[For peel-off blister packs only:]

Instructions for use of peel-off blisters:
Do not push the capsule directly out of the pocket
Separate one blister cell from the strip at the perforations (see 1)
Carefully peel off the backing to open the pocket (see 2 and 3)



[For child resistant HDPE containers only]

Instruction for use of child resistant plastic containers:
Push down and turn to open.



Adults with kidney or liver impairment
The usual starting dose is half the recommended dose for adults.
Your doctor will prescribe the appropriate dose based on your clinical situation and by using a more suitable formulation if available.

Use in children
Oxycodone Hydrochloride Teva is NOT recommended for children under 12 years of age.

If you take more Oxycodone Hydrochloride Teva than you should
If you have taken more Oxycodone Hydrochloride Teva than prescribed you should **inform your doctor or your local poison control center IMMEDIATELY**. The following symptoms may occur: constricted pupils, depressed breathing, muscle weakness and drop in blood pressure. In severe cases circulatory collapse, mental and motor inactivity, unconsciousness, slowing of the heart rate and accumulation of water in the lungs may occur; abuse of high doses of strong opioids such as oxycodone can be fatal. Do NOT expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Oxycodone Hydrochloride Teva
If you miss a dose you should take the next dose as soon as you remember and then carry on as before. Do NOT take two doses within 4 hours. Do NOT take a double dose to make up for forgotten capsules.

If you stop taking Oxycodone Hydrochloride Teva
Do NOT stop treatment without informing your doctor.

When you no longer require therapy with Oxycodone Hydrochloride Teva, it may be advisable to reduce 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.

Stop taking Oxycodone Hydrochloride Teva and contact a doctor or go to the nearest emergency department immediately if you experience any of the following symptoms:

- Depressed breathing which is most likely to occur in elderly or debilitated patients. This can also cause severe drops in blood pressure.
- Severe hypersensitivity reactions (anaphylactic reactions) which may cause nettle rash, swelling of the face, lips, mouth, tongue or throat or difficulty in breathing.

Oxycodone Hydrochloride Teva 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)
- dizziness
- headache
- constipation
- feeling sick
- vomiting
- itching.

Common (may affect up to 1 in 10 people):
- loss of appetite
- several psychological side effects such as
  - changes in mood (e.g. generalised fear, depression)
  - changes in activity (mostly sedation, sometimes accompanied by tiredness, occasionally increase with nervousness and sleep disorders)
  - changes in performance (thought process disorder, confusion)
- trembling (tremor)

- wheezing, shortness of breath, hiccups
- dry mouth, stomach pain, diarrhoea, indigestion (dyspepsia)
- rash, increased sweating
- increased urge to urinate
- feeling weak (asthenia).

Uncommon (may affect up to 1 in 100 people):
- allergic reactions
- abnormal production of antidiuretic hormone
- lack of water in the body (dehydration)
- change in perception such as depersonalisation and seeing, hearing or feeling things that are not there (hallucinations), decreased sexual drive, restlessness, extreme emotional behaviour, a feeling of extreme happiness, drug dependence (see section 2)
- increased or decreased muscle tone, coordination disturbances, involuntary muscle contractions, fits; in particular in patients suffering from epilepsy or with a tendency to fits, increased tightness and difficulty in stretching muscles, speech disorders, fainting, tingling or pins and needles (paraesthesia), reduced sense of touch (hypaesthesia), migraine, change in taste, loss of memory
- changes in tear secretion , constriction of the pupil, visual impairment
- abnormally acute sense of hearing (hyperacousis), feeling of dizziness or spinning (vertigo)
- accelerated heart rate, being aware of the heart beat
- widening of the blood vessels (vasodilatation)
- difficulty in breathing, cough, sore throat, runny nose, voice changes
- difficulty swallowing, mouth ulcers, inflammation of the gums,
- inflamed mouth (stomatitis), wind, belching, intestinal obstruction (ileus)
- increased liver enzymes
- dry skin
- difficulty in passing urine
- impotence
- pain (e.g. chest pain), chills, excessive fluid in the tissues (oedema), feeling unwell, physical dependence with withdrawal symptoms, drug tolerance requiring increased dosage to maintain effect, thirst
- injuries due to accidents.

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

Very rare (may affect up to 1 in 10,000 people):
- scaly rash (exfoliative dermatitis).

Unknown frequency (cannot be estimated from the available data)
- aggression
- increased sensitivity to pain which cannot be improved by increasing the dose
- tooth decay
- pain on the right side of the abdomen, biliary colic
- absence of menstrual periods (amenorrhoea).

Counteractive measures:
If you observe any of the above listed side effects contact your doctor who usually will take appropriate measures. The side effect constipation may be prevented by a fiber enriched diet and increased intake of fluids. If you are suffering from sickness or vomiting contact your doctor who will 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 this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxycodone Hydrochloride Teva

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 label or carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Oxycodone Hydrochloride Teva contains
• The active substance is oxycodone hydrochloride.
• Oxycodone Hydrochloride Teva 5 mg capsules:
Each capsule contains 5.0 mg oxycodone hydrochloride corresponding to 4.48 mg oxycodone.
• Oxycodone Hydrochloride Teva 10 mg capsules:
Each capsule contains 10.0 mg oxycodone hydrochloride corresponding to 8.96 mg oxycodone.
• Oxycodone Hydrochloride Teva 20 mg capsules:
Each capsule contains 20.0 mg oxycodone hydrochloride corresponding to 17.93 mg oxycodone.
• The other ingredients are: Capsule content: microcrystalline cellulose, magnesium stearate. Capsule shell: Gelatine, sodium laurilsulfate, titanium dioxide (E171), iron

oxide yellow (E172), iron oxide red (E172), indigotine (E132). Printing ink: shellac, propylene glycol, ammonia solution, iron oxide black (E172), potassium hydroxide.

What Oxycodone Hydrochloride Teva looks like and contents of the pack
Oxycodone Hydrochloride Teva 5 mg:
Hard capsules, 14.4 mm in length, with a dark pink body marked with '5' and a brown cap marked with 'OXY'.

Oxycodone Hydrochloride Teva 10 mg:
Hard capsules, 14.4 mm in length, with a white body marked with '10' and a brown cap marked with 'OXY'.

Oxycodone Hydrochloride Teva 20 mg:
Hard capsules, 14.4 mm in length, with a light pink body marked with '20' and a brown cap marked with 'OXY'.

Peel-off blister packs (PVC/PVdC/Alu).
Pack sizes:
5 mg
14, 20, 28, 30, 50, 56, and 100 capsules
10 mg
20, 28, 30, 50, 56, and 100 capsules
20 mg
20, 28, 30, 50, 56, and 100 capsules

Push-through blister packs (PVC/PVdC/Alu).
Pack sizes:
5 mg
14, 20, 28, 30, 50, 56, and 100 capsules
10 mg
20, 28, 30, 50, 56, and 100 capsules
20 mg
20, 28, 30, 50, 56, and 100 capsules

Child resistant plastic containers.
Pack sizes: 98, 100 and 250 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturer:
Actavis ehf.

Reykjavikurvegur 78
220 Hafnarfjörður
Iceland

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

Merckle GmbH
Ludwig-Merckle-Straße 3,
Blaubeuren 89143
Germany

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

Bulgaria	Oxycodone TEVA
Denmark	Oxycodone Teva
Finland	Oxycodone ratiopharm XX mg kapseli, kova
Germany	Oxycodon-HCl-ratiopharm akut XX mg Hartkapseln
Ireland	Oxycodone Hydrochloride Teva
Netherlands	Oxycodon HCl Teva XX mg, capsules, hard
Sweden	Oxycodone Teva

This leaflet was last revised in January 2015.

Detailed information on this medicine is available on the web site of the Health Products Regulatory Authority, http://www.hpra.ie/