Package leaflet: Information for the patient

Sofonac 5 mg/2.5 mg prolonged-release tablets

oxycodone hydrochloride/naloxone 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 Sofonac is and what it is used for
2. What you need to know before you take Sofonac
3. How to take Sofonac
4. Possible side effects
5. How to store Sofonac
6. Contents of the pack and other information

1. What Sofonac is and what it is used for

Pain relief
You have been prescribed Sofonac for the treatment of severe pain, which can be adequately managed only with opioid analgesics.

How Sofonac works in pain relief
Sofonac contains oxycodone hydrochloride and naloxone hydrochloride as active substances. Oxycodone is responsible for the painkilling effect of Sofonac. It is a strong analgesic ("painkiller") that belongs to a group of medicines called opioids.

Naloxone is intended to bring relief from constipation. Constipation is a typical side effect of treatment with strong painkillers (opioid painkillers).

2. What you need to know before you take Sofonac

Do not take Sofonac if you
- are allergic to oxycodone, naloxone or any of the other ingredients of this medicine (listed in section 6).
- have breathing problems, such as breathing more slowly or weakly than expected (respiratory depression).
- suffer from a severe lung disease associated with narrowing of the airways (chronic obstructive pulmonary disease or COPD).
- suffer from a condition known as cor pulmonale. In this condition, the right side of the heart becomes enlarged, due to increased pressure inside blood vessels in the lung etc. (e.g. as a result of COPD – see above).
- suffer from severe bronchial asthma.
- have a type of bowel obstruction (paralytic ileus) not caused by opioids.
- have moderate to severe liver dysfunction.

Warnings and precautions
Talk to your doctor or pharmacist before taking Sofonac
- in the case of elderly or debilitated (weak) patients,
- if you have a type of bowel obstruction (paralytic ileus) caused by opioids,
- if you have kidney problems,
- if you have mild liver problems,
- if you have severe lung problems (i.e. reduced breathing capacity),
- if you suffer from a condition characterised by frequent breathing stops during the night which may make you feel very sleepy during the daytime (sleep apnoea),
- if you have myxoedema (a thyroid disorder, with dryness, coldness and swelling ["puffiness"] of the skin, affecting the face and limbs),
- if your thyroid gland is not producing enough hormones (underactive thyroid or hypothyroidism),
- if you have poor adrenal gland function (your adrenal gland is not working properly) for example Addinson's disease,
- if you have a mental illness accompanied by a (partial) loss of reality (psychosis), due to alcohol or intoxication with other substances (substance-induced psychosis),
- if you suffer from gallstone problems,
- if your prostate gland is abnormally enlarged (prostate hypertrophy),
- if your pancreas is inflamed (pancreatitis),
- if you have low blood pressure (hypotension),
- if you have high blood pressure (hypertension),
- if you have heart problems,
- if you have a head injury (due to the risk of increased brain pressure),
- if you suffer from epilepsy or are prone to fits,
- if you are also taking or have taken in the last two weeks a type of medicine known as MAO inhibitor (used to treat depression or Parkinson's disease), e.g. medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid,
- if sleepiness or episodes of suddenly falling asleep occur.

Sleep-related breathing disorders
Sofonac can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tolerance, dependence and addiction

This medicine contains oxycodone, which is an opioid. It can cause dependence and/or addiction.

This medicine contains oxycodone which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Sofonac may lead to dependence, abuse and addiction which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Sofonac:
- if you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction"),
- if you are a smoker,

- if you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Sofonac, it could be a sign that you have become dependent or addicted.
– You need to take the medicine for longer than advised by your doctor
– You need to take more than the recommended dose
– You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
– You have made repeated, unsuccessful attempts to quit or control the use of the medicine
– When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Sofonac).

Tell your doctor if any of the above has ever applied to you in the past. Also, please contact your doctor if you develop any of them while you are taking Sofonac.

Sofonac is not recommended for use in patients with advanced digestive or pelvic cancers where bowel obstruction may be a problem.

If you experience severe diarrhoea at the start of treatment (within the first 3 to 5 days) this may be due to the effect of naloxone. It may be a sign that your bowel movements are returning to normal. If diarrhoea persists after 3 to 5 days, or it gives you cause for concern, please contact your doctor.

If you have been using high doses of another opioid, withdrawal symptoms (such as restlessness, bouts of sweating and muscle pain) may occur when you initially switch to Sofonac. If you experience withdrawal symptoms, you may need to be specially monitored by your doctor.

Do not use Sofonac for acute post-operative pain because of the increased risk of dependency and developing serious breathing problems.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are taking Sofonac. Your doctor may adjust your dose.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

If you have been taking Sofonac for a long time, you may become tolerant. This means you may need a higher dose to achieve the desired effect. Long-term use of this medicine may also lead to physical dependence. Medicines containing oxycodone should be avoided in patients with a present or past abuse of alcohol, drugs or medicines. Withdrawal symptoms may occur if treatment is stopped too suddenly. If you no longer need treatment, you should reduce your daily dose gradually, in consultation with your doctor.

You may notice remnants of the prolonged-release tablet in your stools. Do not be alarmed, as the active substances will have already been released in the stomach and gut, and absorbed into your body.

<u>Incorrect use of Sofonac</u>

Sofonac must never be abused, particularly if you have a drug addiction. If you are addicted to drugs such as heroin, morphine or methadone, severe withdrawal symptoms are likely if you abuse Sofonac because it contains the active substance naloxone. Pre-existing withdrawal symptoms may be made worse.

You must never misuse Sofonac tablets by dissolving and injecting or inhaling them (e.g. into a blood vessel). They contain talc, which can cause destruction of local tissue (necrosis) and changes in lung tissue (lung granuloma). Misuse can also have other serious consequences which may be fatal.

You must swallow these tablets whole so as not to affect the slow release of oxycodone from the tablets. Do not divide, break, chew or crush them. Taking divided, broken, chewed or crushed tablets may result in your body absorbing a potentially fatal dose of oxycodone (see section 3 "If you take more Sofonac than you should").

The use of Sofonac may produce positive results in doping controls.
The use of Sofonac as a doping agent may become a health hazard.

Children and adolescents
This medicine should not be given to children or adolescents under 18 years of age as the safety and efficacy have not been shown.

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

The risk of side effects is increased if you take Sofonac at the same time as medicines which affect the way the brain works. For example, you may feel very sleepy, or breathing problems (slow and shallow breathing) may get worse.

Examples of medicines that affect the way the brain works include:
- other strong painkillers (opioids)
- sleep medicines and tranquilisers (sedatives, hypnotics)
- antidepressants (such as paroxetine or fluoxetine)
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics)
- other medicines which act on the nervous system (phenothiazines, neuroleptics)

The risk of side effects increases, if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Concomitant use of Sofonac and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However if your doctor does prescribe Sofonac together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tell your doctor if you are taking:
- medicines that decrease the blood's clotting ability (coumarin derivatives), this clotting time may be speeded up or slowed down
- antibiotics of the macrolide type (e.g. clarithromycin, erythromycin, telithromycin)
- antifungal medicines of the azole type (e.g. ketoconazole, voriconazole, itraconazole, posaconazole)
- ritonavir or other protease inhibitors (used to treat HIV, such as indinavir, nelfinavir, saquinavir)
- cimetidine (used to treat stomach ulcers, indigestion or heartburn)

- rifampicin (used to treat tuberculosis)
- carbamazepine (used to treat seizures, fits or convulsions and certain pain conditions)
- phenytoin (used to treat seizures, fits or convulsions)
- St. John's Wort
- quinidine (used to treat an irregular heartbeat)
- medicines to treat depression
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics)
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics)
- muscle relaxants
- medicines to treat Parkinson's disease

Sofonac with food, drink and alcohol
Drinking alcohol whilst taking Sofonac 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. It is recommended not to drink alcohol while you are taking Sofonac.

You should avoid drinking grapefruit juice while you are taking Sofonac.

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
Use of Sofonac should be avoided to the extent possible during pregnancy. If used over prolonged periods during pregnancy, oxycodone may lead to withdrawal symptoms in newborn infants. If oxycodone is given during childbirth, respiratory depression (slow and shallow breathing) may occur in the newborn infant.

Breast-feeding
Breast-feeding should be discontinued during treatment with Sofonac. Oxycodone passes into breast milk. It is not known whether naloxone also passes into breast milk. Therefore, a risk for the suckling infant cannot be excluded, in particular following intake of multiple doses of Sofonac.

Driving and using machines
This medicine can affect your ability to drive or operate machines as it may make you sleepy or dizzy. This is most likely at the start of your treatment, after a dose increase or after switching from a different medicine. These side effects should disappear once you are on a stable dose.

This medicine has been associated with sleepiness and episodes of suddenly falling asleep. If you experience these side effects, you must not drive or operate machines. You should tell your doctor if this occurs.

- 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.

Sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Sofonac

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Sofonac, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop taking Sofonac).

Unless otherwise prescribed by your doctor, the recommended dose is:

To treat pain

Adults
The usual starting dose is 10 mg oxycodone hydrochloride/5 mg naloxone hydrochloride every 12 hours.

Your doctor will decide how much you should take every day and how to divide your total daily dose into morning and evening doses. Your doctor will also decide on any necessary dose adjustments during treatment depending on your level of pain and individual sensitivity. You should be given the lowest dose needed for pain relief. If you have already been treated with opioids, your treatment with Sofonac may be started at a higher dose.

The maximum daily dose is 160 mg oxycodone hydrochloride and 80 mg naloxone hydrochloride. If you need a higher dose, your doctor may give you additional oxycodone without naloxone. However, the maximum daily dose of oxycodone hydrochloride should not exceed 400 mg. The beneficial effect of naloxone on bowel movements may be affected if additional oxycodone is given without additional naloxone.

If you experience pain between doses, you may need to take an additional fast-acting painkiller. Sofonac is not suitable for this. Please talk to your doctor.

If you feel that Sofonac is too strong or too weak, please talk to your doctor or pharmacist.

Elderly patients
In general, no dose adjustment is necessary for elderly patients with normal kidney and/or liver function.

Liver or kidney impairment
If you have kidney or mild liver problems, your doctor will prescribe Sofonac with special caution. You must not take Sofonac if you have moderate or severe liver problems (see also section 2. “Do not take Sofonac” and “Warnings and precautions”).

Method of administration
Oral use.
Swallow the tablets whole with a glass of water.
Do not divide, break, chew or crush the tablets.

You can take the tablets with or without food. Take them every 12 hours according to a fixed time schedule. For instance, if you take a tablet at 8 o’clock in the morning, you should take your next tablet at 8 o’clock in the evening.

Opening instructions for the blister:
This medicine is in child-resistant packaging. The tablets have to be pressed firmly out of the blister.

Duration of use

You should not take Sofonac for any longer than you need to. If you have been taking Sofonac for a long time your doctor should regularly check that you still need it.

If you take more Sofonac than you should
If you have taken more than the prescribed dose, you must inform your doctor immediately.

An overdose may result in:
- a reduction in size of pupils in the eye,
- breathing more slowly or weakly than expected (respiratory depression),
- drowsiness or loss of unconsciousness,
- low muscle tone (hypotonia),
- reduced pulse rate,
- a fall in blood pressure,
- a brain disorder (known as toxic leukoencephalopathy).

In severe cases, loss of consciousness (coma), fluid on the lungs and circulatory collapse may occur, which may be fatal.

You should avoid situations which require you to be alert, e.g. driving.

If you forget to take Sofonac
If you forget to take Sofonac or if you take a lower dose than the one prescribed, you may not feel any effect.
If you forget to take your dose, please follow the instructions below:
- If your next usual dose is due in 8 hours or more: Take the forgotten dose immediately and continue with your normal dosing schedule.
- If your next usual dose is due in less than 8 hours: Take the forgotten dose, then wait another 8 hours before taking your next dose. Try to get back in your normal dosing schedule (e.g. 8 o'clock in the morning and 8 o'clock in the evening).

Do not take more than one dose within any 8 hour period.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Sofonac
Do not stop taking Sofonac without first speaking with your doctor.

If you do not require any further treatment, your doctor will advise you how to reduce the daily dose gradually. In this way, you will avoid withdrawal symptoms, such as restlessness, bouts of sweating and muscle pain.

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.

Important side effects or signs to look out for, and what to do if you are affected:
Stop taking Sofonac and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms:
- A more slow or shallow breathing (respiratory depression). This is the most serious side effect with Sofonac and it mostly occurs in elderly and weak patients.
- Opioids can also cause a severe drop in blood pressure in susceptible patients.
- Swelling of the face, tongue or throat; difficulty swallowing; hives; breathing difficulties and drop in blood pressure (anaphylactic reaction).

The following side effects have been seen in patients being treated for pain

Common (may affect up to 1 in 10 people)

- abdominal pain, indigestion, constipation, diarrhoea, wind
- dry mouth
- vomit (be sick), feel sick
- decreased appetite up to loss of appetite
- a feeling of dizziness or "spinning", vertigo
- headache
- hot flushes, sweating
- general weakness, tiredness or exhaustion
- itchy skin, skin reactions/rash
- difficulty in sleeping, drowsiness

Uncommon (may affect up to 1 in 100 people)

- abdominal bloating
- abnormal thoughts
- anxiety, confusion, depression, nervousness, difficulties to concentrate
- chest tightness, especially if you already have coronary heart disease, chest pain
- drop in blood pressure, rise in blood pressure
- withdrawal symptoms such as agitation
- fainting
- palpitations
- biliary colic
- generally feeling unwell
- pain
- swelling of hands, ankles or feet
- impaired speaking
- shaking
- difficulties breathing
- restlessness
- chills
- hepatic enzymes increased
- runny nose
- cough
- hypersensitivity/allergic reactions
- weight loss
- injuries from accidents
- increased urge to urinate
- muscle cramps, muscle twitches, muscle pain
- vision impairment
- epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures)
- reduced sex drive
- lack of energy
- altered taste
- thirst

Rare (may affect up to 1 in 1,000 people)

- increase in pulse rate
- dental changes
- weight gain
- yawning

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

- euphoric mood

- sedation
- erectile dysfunction
- nightmares
- hallucinations
- shallow breathing
- difficulties in passing urine
- tingling in hands or feet
- belching
- aggression
- problems with breathing during sleep (sleep apnoea syndrome), for more information see section 2 Warnings and precautions.

The active substance oxycodone, if not combined with naloxone, is known to have the following differing side effects:
Breathing problems, such as breathing more slowly or weakly than expected (respiratory depression), reduction in size of the pupils in the eye, muscle cramps and decreased cough reflex.

Common (may affect up to 1 in 10 people)
- altered mood and personality changes (e.g. depression, feeling of extreme happiness)
- decreased activity, increased activity
- difficulties in passing urine
- hiccups

Uncommon (may affect up to 1 in 100 people)
- impaired concentration, agitation
- migraine
- increased muscle tension, involuntary muscle contractions
- drug tolerance
- ileus
- dry skin, flushing of skin
- reduced sensitivity to pain or touch
- abnormal coordination
- vocal changes (dysphonia)
- water retention
- difficulties in hearing
- mouth ulcers, sore gums
- difficulties in swallowing
- perception disturbances (e.g. hallucination, derealisation)
- dehydration
- a decrease in sex hormone levels which may affect sperm production in men or the menstrual cycle in females

Rare (may affect up to 1 in 1,000 people)
- itching rash (urticaria)
- herpes simplex
- increased appetite
- black (tarry) stools
- gingival bleeding

Not known (frequency cannot be estimated from the available data)
- sleep apnoea (breathing pauses during sleep)
- acute generalized allergic reactions (anaphylactic reactions)
- absence of menstrual periods
- problems with bile flow
- tooth decay

- an increase in sensitivity to pain
- long term use of Sofonac during pregnancy may cause life-threatening withdrawal symptoms in the new-born. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sofonac

Keep this medicine out of the sight and reach of children. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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.

Do not store above 25°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 Sofonac contains

The active substances are oxycodone hydrochloride and naloxone hydrochloride.

Each tablet contains 5 mg of oxycodone hydrochloride (equivalent to 4.5 mg oxycodone) and 2.5 mg of naloxone hydrochloride (as 2.73 mg naloxone hydrochloride dihydrate, equivalent to 2.25 mg naloxone).

The other ingredients are:
Tablet core:
Polyvinyl acetate, Povidone K30, Sodium lauryl sulphate, Silica, colloidal anhydrous, Cellulose, microcrystalline, Magnesium stearate

Tablet coating:
Polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc.

What Sofonac looks like and contents of the pack

White, round, biconvex tablet with a diameter of 4.7 mm and a height of 2.9 - 3.9 mm.

Child-resistant blisters of 28 tablets
Bottles with child-resistant closure of 28 tablets.

Marketing Authorisation Holder and Manufacturer

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