Package leaflet: Information for the user

***Sevredol*® 10 mg, 20 mg and 50 mg film-coated tablets**
Morphine sulfate

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

What is in this leaflet:

1. What *Sevredol* tablets are and what they are used for

These tablets have been prescribed for you by your doctor to relieve severe pain. They contain the active ingredient morphine which belongs to a group of medicines called strong analgesics or 'painkillers'.

2. What you need to know before you take *Sevredol* tablets

Do not take *Sevredol* tablets if:
- you are allergic (hypersensitive) to morphine or any of the other ingredients of the tablets (see section 6 'Further Information');
- you have breathing problems, such as obstructive airways disease, respiratory depression or severe asthma. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- you have a head injury that causes a severe headache or makes you feel sick. This is because the tablets may make these symptoms worse or hide the extent of the head injury;
- you have a condition where the small bowel (part of your gut) does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen;
- you have recent onset liver disease;
- you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
- the patient is under three years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking ***Sevredol*** tablets if you:
- have breathing problems, such as impaired lung function or severe bronchial asthma. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness and coughing;
- have an under-active thyroid gland (hypothyroidism), kidney or long-term liver problems as you may need a lower dose;
- have a severe headache or feel sick as this may indicate that the pressure in your skull is increased;

- suffer from, or have ever suffered from epilepsy, seizures, fits or convulsions;
- have low blood pressure;
- have a severe heart problem after long-term lung disease (severe cor pulmonale);
- have inflammation of the pancreas (which causes severe pain in the abdomen and back) or problems with your gall bladder;
- have an inflammatory bowel disorder;
- you suffer from constipation;
- have prostate problems;
- have increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or a change in strong analgesic ("painkiller"), (see section 2);
- experience weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenal glands producing too little of the hormone 'cortisol', and you may need to take a hormone supplement;
- have loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production;
- have previously been dependent on drugs or alcohol. Also tell your doctor if you feel that you are becoming dependent on this medicine while you are using it. You may have started to think a lot about when you can take the next dose, even if you do not need it for the pain;
- have withdrawal (abstinence) symptoms or dependence. The most common abstinence symptoms are mentioned in section 3. If this occurs, your doctor may change the type of medicine or the times between doses.

This medicine may cause breathing problems or worsen already existing problems while sleeping. These problems may include pauses in breathing during sleep, being awoken by shortness of breath, difficulty staying asleep or excessive daytime drowsiness. If you or someone else observes these symptoms contact your doctor. Your doctor may want to lower your dose.

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

You may experience hormonal changes while taking these tablets. Your doctor may want to monitor these changes.

Other medicines and *Sevredol* tablets:
If you are taking or have recently taken any other medicines, or might take any other medicines please tell you doctor or pharmacist. If you take these tablets with some other medicines, the effect of the tablets or the other medicine may be changed.

Concomitant use of ***Sevredol*** and sedative medicines, such as benzodiazepines or related drugs, 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 ***Sevredol*** 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 recommendations closely. It could be helpful to inform friends and relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Sevredol tablets must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks (see section 2 'Do not take…').

Tell your doctor or pharmacist if you are taking any of the medicines mentioned below:
- medicines to help you sleep (for example tranquillisers, hypnotics or sedatives);
- medicines to treat psychiatric or mental disorders (such as phenothiazines);
- muscle relaxants;

- medicines to treat high blood pressure;
- cimetidine to treat stomach ulcers, indigestion or heartburn;
- other strong analgesics or painkillers (such as buprenorphine, nalbuphine or pentazocine);
- rifampicin to treat tuberculosis;
- ritonavir to treat HIV;
- gabapentin to treat epilepsy or neuropathic pain (pain due to nerve problems).
- some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine.

Also tell your doctor if you have recently been given an anaesthetic.

***Sevredol* tablets with alcohol**
Drinking alcohol whilst taking ***Sevredol*** may make you sleepy. If you are affected, you should avoid drinking alcohol.

Pregnancy, breastfeeding 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 this medicine is given to you.
Prolonged use of morphine during pregnancy may cause withdrawal symptoms in newborns, which should be treated by a doctor. Withdrawal (abstinence) symptoms in babies born to mothers who have used ***Sevredol*** tablets in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

Driving and using machines
Sevredol tablets may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking ***Sevredol*** tablets, or when changing to a higher dose. If you are affected, you should not drive or use machinery.

***Sevredol* tablets contain lactose and Sunset Yellow (E110)**
These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.
The 20 mg strength tablets contain sunset yellow (E110) which may cause allergic reactions.

3. How to take *Sevredol* tablets

Always take ***Sevredol*** tablets exactly as your doctor has told you. The label on your medicine will tell you how many tablets to take and how often.

Swallow your tablets whole with a glass of water.

You must only take the tablets by mouth. The tablets should never be crushed and injected as this may lead to serious side effects, which may be fatal.

Adults
The usual starting dose is one tablet every 4 hours. Your doctor will decide how many tablets you should take.

Children
Only the 10 mg and 20 mg strength tablets are suitable for children. Children should not be given the 50 mg tablets.

Children 3 to 5 years of age
The usual dose is 5 mg every four hours.

Children 6 to 12 years of age
The usual dose is 5 – 10 mg every four hours.

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

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

If you take more *Sevredol* tablets than you should
Call your doctor or hospital straight away as you may need emergency treatment in hospital. People who have taken an overdose may feel very sleepy, sick, dizzy or get pneumonia from inhaling vomit or foreign matter (symptoms include breathlessness, cough and fever). People who have taken an overdose may also have breathing difficulties leading to unconsciousness, or even death. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show to the doctor.

If you forget to take *Sevredol* tablets
If you miss a dose you should take it 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 a forgotten tablet.

If you stop taking *Sevredol* tablets
Do not stop treatment with these tablets unless agreed with your doctor. If you want to stop the treatment with these tablets, ask your doctor how to slowly decrease the dose so you avoid abstinence symptoms. Abstinence (withdrawal) symptoms may include body aches, tremors, diarrhoea, stomach pain, nausea, flu-like symptoms, fast heartbeat and large pupils. Psychological symptoms include an intense feeling of unsatisfaction, anxiety and irritability.

If you have any further questions on the use of ***Sevredol*** tablets, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines**, *Sevredol*** tablets can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are uncommon. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The most serious side effect, although uncommon, is a condition where you breathe more slowly or weakly than expected (respiratory depression).

As with all strong painkillers, there is a risk that you may become addicted or reliant on ***Sevredol*** tablets.

Very common side effects (may affect more than 1 in 10 people)
- Constipation (your doctor can prescribe a laxative to overcome this problem).
- Feeling sick.

Common side effects (may affect up to 1 in 10 people)
- Drowsiness (this is most likely when you first start taking your tablets or when your dose is increased, but it should wear off after a few days).
- Dry mouth, loss of appetite, abdominal pain or discomfort.
- Vomiting (being sick). (This should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem).
- Headache, dizziness, confusion, difficulty in sleeping.
- A feeling of unusual weakness.
- Generally feeling unwell, tiredness.
- Involuntary muscle contractions.

- Rash or itchy skin.
- Sweating.

Uncommon side effects (may affect up to 1 in 100 people)
- Difficulty in breathing (possibly due to fluid on the lungs) or wheezing.
- A condition where the bowel does not work properly (ileus).
- Changes in taste, indigestion.
- Vertigo (a feeling of dizziness or 'spinning'), fainting, seizures, fits or convulsions.
- Agitation, mood changes, hallucinations, a feeling of extreme happiness.
- Unusual muscle stiffness.
- Tingling or numbness.
- Difficulty in passing urine.
- Low blood pressure, facial flushing (redness of the face).
- Palpitations.
- Swelling of the hands, ankles or feet.
- Hives.
- A worsening in liver function tests (seen in a blood test).
- Blurred vision.
- Muscle spasms.

Frequency unknown (cannot be estimated from the available data)
- Problems with breathing during sleep (sleep apnoea syndrome)
- Unpleasant or uncomfortable mood, abnormal thoughts.
- An increased sensitivity to pain.
- Reduction in size of the pupils in the eye.
- A fast or slow heart beat.
- High blood pressure.
- Decreased cough reflex.
- Colicky abdominal pain or discomfort, an increase in the severity of symptoms associated with inflammation of the pancreas (severe pain in the abdomen and back).
- Impotence, decreased sexual drive, absence of menstrual periods.
- A need to take increasingly higher doses to obtain the same level of pain relief (tolerance).
- Withdrawal symptoms or dependence (See section 3 "If you stop taking ***Sevredol*** tablets").
- Withdrawal symptoms in babies born to mothers who have used ***Sevredol*** tablets in pregnancy (see "Pregnancy and breastfeeding" in section 2).

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 *Sevredol* tablets

Keep out of the sight and reach of children.

Do not use any tablets after the expiry date which is stated on the blister and carton. EXP 08 2020 means that you should not take the tablets after the last day of that month i.e. August 2020.

Do not store your tablets above 30ºC.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What *Sevredol* tablets contain
The active ingredient is morphine sulfate. Each tablet contains 10 mg, 20 mg or 50 mg of morphine sulfate.

The other ingredients are:
- Lactose
- Pregelatinised maize starch
- Povidone
- Magnesium stearate
- Talc
- Macrogol
- Hypromellose (E464) (10 mg and 50 mg tablets only)
- Titanium dioxide (E171)
- Polyvinyl alcohol (E1203) (20 mg tablet only)

The tablets also contain the following colourants:
10 mg – Brilliant blue (E133)
20 mg - Erythrosine (E127) and sunset yellow (E110)
50 mg – Quinoline yellow (E104), indigo carmine (E132) and iron oxide (E172)

What *Sevredol* tablets look like and the contents of the pack
Sevredol tablets have a score line on one side. 'IR' and the strength (e.g. 10, 20 etc) are on either side of the score line. The tablets are coloured as follows: 10 mg - blue, 20 mg - pink, 50 mg – pale green.

In each box there are 56 tablets.

Marketing Authorisation Holder:
Mundipharma Pharmaceuticals Limited, United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Manufacturer:
Mundipharma DC B.V., Leusderend 16, 3832 RC Leusden, Netherlands.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line on:

0044 1733 37 53 70

You will need to give details of the product name and reference number.
These are as follows:

Product name: Sevredol tablets
Reference number: 1688/9/1

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