

## Package leaflet: Information for the user

### **Sevredol® 10 mg, 20 mg and 50 mg tablets**

Morphine sulfate

**This medicine contains morphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

**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.

#### **In this leaflet:**

1. What **Sevredol** tablets are and what they are used for
2. What you need to know before you take **Sevredol** tablets
3. How to take **Sevredol** tablets
4. Possible side effects
5. How to store **Sevredol** tablets
6. Contents of the pack and other information

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

This medicine has been prescribed for you for the relief of severe pain. It contains morphine, which belongs to a class of medicines called opioids, which are 'pain relievers'. The medicine has been prescribed for you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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

##### **Do not take *Sevredol* tablets if:**

- you are allergic to morphine or any of the other ingredients of the tablets (see section 6);
- 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

Tell your doctor or pharmacist before taking these tablets if you experience any of the following symptoms while taking **Sevredol** tablets:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating when you have stopped taking alcohol or drugs;
- feel you need to take more **Sevredol** tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever;
- have breathing problems, such as impaired lung function or severe bronchial asthma. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness and coughing;
- have an under-active thyroid gland (hypothyroidism), kidney or longterm 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;
- experience weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals 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;

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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**

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 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.

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.

*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 benzodiazepines, 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;
- certain types of medicines to stop you feeling or being sick;
- medicines used to prevent or relieve the symptoms of an allergy (antihistamines);
- other strong analgesics or 'painkillers' (such as buprenorphine, nalbuphine or pentazocine);
- rifampicin to treat tuberculosis;
- ritonavir to treat HIV;
- medicines to treat Parkinson's disease;
- 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 a general anaesthetic.

### **Taking *Sevredol* tablets with alcohol**

Drinking alcohol during your treatment with these tablets may make you sleepy. If you are affected, you should avoid drinking alcohol.

### **Pregnancy and breastfeeding**

### **Pregnancy**

Do not take **Sevredol** tablets if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take **Sevredol** tablets during pregnancy your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated. 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.

### **Breast-feeding**

Do not take **Sevredol** tablets while you are breastfeeding as morphine passes into breast milk and will affect your baby.

### **Driving and using machines**

These 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 the tablets, or when changing to a higher dose. If you are affected, you should not drive or use machinery.

This 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 while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').
- This defence applies when:
  - 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 and in the information provided with the medicine.
- Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: <https://www.gov.uk/drug-driving-law>

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

### **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 tablets contain sunset yellow (E110) which may cause allergic reactions.

### **3. How to take Sevredol tablets**

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

Your doctor should have discussed with you how long the course of **Sevredol** tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

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 or if someone accidentally swallows your tablets**

Call your doctor or hospital straight away as you may need emergency treatment in a hospital. People who have taken an overdose may feel very sleepy, sick, dizzy or get pneumonia from inhaling vomit or foreign matter (symptoms may 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 suddenly stop taking this medicine. If you want to stop taking this medicine discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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

#### **4. Possible side effects**

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

This medicine can cause allergic reactions, although serious allergic reactions are uncommon. **Tell your doctor immediately** if you get any sudden wheeziness, difficulties in breathing, dizziness, 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). **Tell your doctor immediately** if this happens to you.

In patients treated with **Sevredol** tablets, the following side effects have been reported:

**Very common** (may affect more than 1 in 10 people)

- Feeling sick.
- Constipation (your doctor can prescribe a laxative to overcome this problem).

**Common** (may affect up to 1 in 10 people)

- 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-vomiting medicine if it continues to be a problem).
- Drowsiness (this is most likely when you start taking your tablets or when your dose is increased but should wear off after a few days).
- Dizziness, headache, confusion, difficulty in sleeping.
- A feeling of unusual weakness.
- Generally feeling unwell, tiredness.
- Involuntary muscle contractions.
- Rash or itchy skin.

**Uncommon** (may affect up to 1 in 100 people)

- Withdrawal symptoms (see section 'Drug Withdrawal')
- Indigestion, changes in taste.
- A condition where the bowel does not work properly (ileus).
- Vertigo, (a feeling of dizziness or 'spinning'), fainting, seizures, fits or convulsions.
- Agitation, mood changes, hallucinations, a feeling of extreme happiness.
- Unusual muscle stiffness.
- Difficulty in breathing (possibly due to fluid on the lungs) or wheezing.
- Tingling or numbness.
- Difficulty in passing urine.
- Low blood pressure, facial flushing (redness of the face).
- Feeling your heart beat (palpitations).
- Swelling of the hands, ankles or feet.
- A raised, itchy rash (hives).
- A worsening in liver function tests (seen in a blood test).
- Blurred vision.
- Muscle spasms.

**Frequency not known** (Frequency 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 heartbeat.
- High blood pressure.

- Decreased cough reflex.
- Colicky abdominal pain or discomfort, an increase in the severity of symptoms associated with inflammation of the pancreas.
- Absence of menstrual periods, decreased sexual drive, impotence.
- Withdrawal symptoms in babies born to mothers who have used **Sevredol** tablets in pregnancy (See section 2 “Pregnancy, breastfeeding and fertility”).
- Dry Mouth
- Sweating
- Dependence and addiction (see section ‘How do I know if I am addicted?’)

#### Drug withdrawal

When you stop taking **Sevredol** tablets you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

#### **How do I know if I am addicted?**

If you notice any of the following signs whilst taking **Sevredol** tablets it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber;
- You feel you need to use more than the recommended dose;
- You are using the medicine for reasons other than prescribed;
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs it is important you talk to your doctor.

#### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 *Sevredol* tablets**

Keep this medicine 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 30°C.

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**

The 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 and Manufacturer**

The tablets are made by Bard Pharmaceuticals Limited for the marketing authorisation holder Napp Pharmaceuticals Limited, both at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

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 (free of charge) on: 0800 198 5000

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

Product name: ***Sevredol*** tablets

Reference number: 16950/0063

**This leaflet was last revised in November 2020.**

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