

# SEVREDOL<sup>®</sup> tablets

Morphine sulfate pentahydrate (mor-fean sul-fate pent-ta-hi-drate)

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about SEVREDOL tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What SEVREDOL tablets are taken for

SEVREDOL tablets contain morphine sulfate pentahydrate. Morphine belongs to a group of medicines called opioid analgesics.

SEVREDOL tablets are used to treat chronic severe cancer pain.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

As with all strong painkillers, your body may become used to you taking SEVREDOL tablets. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking SEVREDOL tablets suddenly, so it is important to take it exactly as directed by your doctor.

This medicine is only available with a doctor's prescription.

### Before you take it

#### **When you must not take it**

**Do not take SEVREDOL tablets if you:**

- have any breathing problems such as acute asthma, respiratory depression (breathing slows or weakens) or other obstructive airways disease
- are severely drowsy or have a reduced level of consciousness
- suffer from irregular heartbeats or changes in the way the heart beats
- have heart disease due to long-term lung disease
- have just consumed a large amount of alcohol, regularly consume large amounts of alcohol or have confusion and shaking due to alcohol withdrawal
- suffer from convulsions, fits or seizures
- have a head injury, brain tumour, increased pressure in your head or spine
- have sudden, severe abdominal pain
- have a condition where your stomach empties more slowly than it should or your small bowel does not work properly
- have an obstruction of the bowel or a condition where it could occur

- have severe kidney or liver disease or a disease of the brain caused by liver disease
- are about to have an operation or have had one within the last 24 hours including surgery on your spine for pain relief
- take a medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.

**Do not take SEVREDOL tablets if you are allergic to morphine, opioid painkillers, or any of the ingredients listed at the end of this leaflet.**

One of the ingredients in the 20 mg tablet, sunset yellow, may cause allergic reactions. This medicine also contains lactose so consider this if you are lactose intolerant.

**Do not take this medicine after the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work very well.

**Do not take it if the packaging is torn or shows signs of tampering.**

**Do not take this medicine if you are pregnant or intend to become pregnant whilst taking this medicine.**

Like most medicines of this kind, SEVREDOL tablets are not recommended to be taken during pregnancy. Your doctor will discuss the risks of using it if you are pregnant.

**Do not give this medicine to a child aged three years of age or younger.**

Safety and effectiveness in children younger than three years of age have not been established.

## ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- low blood pressure
- increased prostate size or difficulty passing urine
- problems or recent surgery of your gall bladder or bile duct
- inflammation of the pancreas
- underactive adrenal glands
- underactive thyroid gland
- inflammatory bowel disease or recent abdominal surgery
- galactose intolerance, lactase deficiency or have problems with glucose-galactose absorption
- an addiction or history of abuse of alcohol or drugs.

**This medicine is not recommended to be taken during labour.**

Morphine given to the mother during labour may cause breathing problems in the newborn.

**Tell your doctor if you are breastfeeding or planning to breastfeed.**

Morphine can pass into the breast milk and can affect the baby. Your doctor can discuss with you the risks involved.

**If you have not told your doctor about any of the above, tell them before you start taking SEVREDOL tablets.**

## ***Taking other medicines***

**Tell your doctor or pharmacist if you are taking any other medicines or dietary supplements, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines, alcohol and SEVREDOL tablets may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders

- medicines to treat depression belonging to a group called 'monoamine oxidase inhibitors' must be stopped 14 days before SEVREDOL tablets are taken
- medicines to help you sleep
- medicines to put you to sleep during an operation or procedure
- medicines to relax your muscles
- medicines to prevent or relieve the symptoms of allergy such as antihistamines
- propranolol or other medicines to lower blood pressure
- gabapentin or barbiturates, medicines to treat seizures
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- medicines used to relieve heartburn or treat stomach ulcers such as cimetidine or antacids (take antacids at least two hours before or after taking SEVREDOL tablets)
- medicines to treat Parkinson's disease
- medicines to stop nausea and vomiting e.g. metoclopramide or prochlorperazine
- rifampicin, a medicine to treat tuberculosis
- other pain relievers including other opioids
- alcohol
- medicines to treat HIV infection and AIDS e.g. ritonavir or zidovudine.

These medicines, dietary supplements or alcohol may be affected by SEVREDOL tablets, may affect how well SEVREDOL tablets work or may increase side effects. You may need to use different amounts of your medicines, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

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## **How to take SEVREDOL tablets**

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### ***How much to take***

**Your doctor will tell you exactly how much to take.**

**Follow the instructions your doctor or pharmacist gives you exactly.**

### ***How to take it***

**Swallow SEVREDOL tablets with a glass of water.**

**You must only take SEVREDOL tablets by mouth.**

SEVREDOL tablets are only designed to work properly if taken by mouth. Taking this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

### ***When to take it***

**Take SEVREDOL tablets every four hours or as directed by your doctor to control the pain.**

If you begin to experience pain and you are taking your SEVREDOL tablets as prescribed, contact your doctor as your dosage may have to be reviewed.

**You can take SEVREDOL tablets before or after a meal.**

### ***How long to take it***

**Continue taking your medicine for as long as your doctor tells you.**

If you stop taking this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea, stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness.

### ***If you forget to take it***

If you forget to take your dose, contact your doctor or pharmacist for advice.

**Do not take a double dose to make up for the dose that you missed.**

This will increase the chance of you getting unwanted side effects.

**If you have trouble remembering when to take your medicine, ask your pharmacist for hints.**

For example, take your medicine at the same times each day.

### ***If you take too much (overdose)***

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too many SEVREDOL tablets.**

**Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

**Keep telephone numbers for these places handy.**

You should also follow the above steps if someone other than you has accidentally taken the tablets that were prescribed for you.

If someone takes an overdose they may experience difficulties in breathing, become drowsy and tired, lack muscle tone, have cold or clammy skin, have constricted pupils, have very low blood pressure or slow heart rate, and possibly may even become unconscious or die.

When seeking medical attention, take this leaflet and any remaining tablets with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

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## **While you are taking it**

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### ***Things you must do***

Take SEVREDOL tablets exactly as your doctor has prescribed.

**Before you start on a new medicine, remind your doctor and pharmacist that you are taking SEVREDOL tablets.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**

**If you are about to have any blood tests, tell your doctor that you are being given this medicine.**

It may interfere with the results of some tests.

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**Keep all of your doctor's appointments so that your progress can be checked.**

Tell your doctor if your pain is getting worse. Also tell your doctor if you are having any problems or difficulties while you are being treated with SEVREDOL tablets.

Tolerance to morphine may develop which means that the effect of the medicine may decrease. If this happens, speak to your doctor.

**Keep enough SEVREDOL tablets with you to last over weekends and holidays.**

### ***Things you must not do***

**Do not drink alcohol while you are taking SEVREDOL tablets.**

Drinking alcohol whilst taking SEVREDOL tablets may make you feel more sleepy and increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Do not take SEVREDOL tablets to treat any other complaint unless your doctor tells you to.

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine, exceed the dose recommended or change the dosage without checking with your doctor.**

Over time your body may become used to morphine. If you stop taking it suddenly, your pain may worsen and you may experience unwanted side effects such as withdrawal symptoms. This is called physical dependence.

If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

### ***Things to be careful of***

**Tell your doctor if you find that you cannot concentrate or that you feel more sleepy than normal when you start taking this medicine or when the dose is increased.**

This feeling should wear off after a few days.

**Do not drive or operate machinery until you know how SEVREDOL tablets affect you.**

SEVREDOL tablets may cause drowsiness, dizziness, hallucinations, confusion, vision problems or may affect alertness. If you are affected, you should not drive or operate machinery. Discuss these effects with your doctor.

**Be careful if you are elderly, unwell or taking other medicines.**

Some people may experience side effects such as drowsiness, dizziness and unsteadiness, which may increase the risk of a fall.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly will help your body get used to the change in position and blood pressure. If this

problem continues or gets worse, talk to your doctor.

**Tell your doctor if you suffer from nausea or vomiting when taking SEVREDOL tablets.**

If you vomit after taking your dose, your pain may come back as you may not have absorbed your medicine. If this happens speak to your doctor. Your doctor may prescribe some medicine to help stop vomiting.

**Tell your doctor if taking SEVREDOL tablets causes constipation.**

Your doctor can advise you about your diet, the proper use of laxatives or alternative treatments and suitable exercise you can do to help manage this.

**There is potential for abuse of morphine and the development of addiction to morphine. It is important that you discuss this issue with your doctor.**

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## Side Effects

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All medicines may have some unwanted side effects. Sometimes they are serious but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

**Do not be alarmed by this list of possible side effects.**

Not everybody experiences them.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SEVREDOL tablets.**

This medicine helps most people with severe pain, but it may have unwanted side effects in a few people. Other side effects not listed here may also occur in some people.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- mild abdominal problems such as feeling sick (nausea), loss of appetite or constipation
- dry mouth or changes in taste
- sweating
- facial flushing
- trouble sleeping
- trouble with your balance
- new problems with your eyesight
- skin rash or itching
- absence of menstrual periods, sexual problems or other hormonal changes
- muscle twitching or muscle stiffness
- swelling, including but not only of legs or ankles.

**Tell your doctor as soon as possible if you notice any of the following and they worry you:**

- stomach discomfort or cramps, vomiting, indigestion or abdominal pain
- abnormal thinking or changes in mood
- drowsiness, feeling faint or fainting or dizziness especially when standing up
- slow or noticeable heartbeats
- headache, confusion or hallucinations
- unusual weakness or loss of strength
- fatigue, generally feeling unwell
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently.

The above list includes serious side effects that may require medical attention.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- your breathing slows or weakens

- you have an allergic reaction: shortness of breath, wheezing, shallow or difficult breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- seizures, fits or convulsions
- fast or irregular heartbeats.

**The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.**

**When seeking medical attention, take this leaflet and any remaining tablets with you to show the doctor.**

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## After taking it

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### Storage

**Keep your tablets in the blister pack until it is time to take them.**

If you take the tablets out of the blister pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C.**

**Do not store it or any other medicine in the bathroom, near a sink or on a window sill.**

**Do not leave it in the car.**

Heat and damp can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

**If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist how to dispose of medicines no longer required.**

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## Product Description

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### **What it looks like**

SEVREDOL® tablets are film coated capsule shaped tablets and are biconvex in shape. They are available in two strengths:

10 mg tablets are blue, scored tablets marked with "IR" and "10" on one side

20 mg tablets are pink, scored tablets marked with "IR" and "20" on one side.

SEVREDOL® tablets are available in packs of 20 tablets.

### **Ingredients**

Active ingredients:

- 10 mg tablets contain 10 mg morphine sulfate pentahydrate
- 20 mg tablets contain 20 mg morphine sulfate pentahydrate.

Inactive ingredients:

- lactose
- pregelatinised maize starch
- povidone
- magnesium stearate
- purified talc.

SEVREDOL® tablets are coated with the ingredients listed below:

- titanium dioxide
- hypromellose (10 mg only)
- macrogol 400 (10 mg only)
- macrogol 3350 (20 mg only)
- polyvinyl alcohol (20 mg only)
- purified talc (20 mg only).

In addition, the tablets also contain the colourants listed below:

10 mg tablet: E133 (brilliant blue)

20 mg tablet: E127 (erythrosine) and E110 (sunset yellow).

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes apart from sunset yellow.

### **Supplier**

SEVREDOL® tablets are supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

88 Phillip Street

SYDNEY NSW 2000

Phone: 1800 188 009

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Australian Register Numbers for SEVREDOL® tablets:

10 mg: AUST R 47543

20 mg: AUST R 214089

Orbis RA-0176