PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S6**

SOVENOR® 5 (transdermal patches)

SOVENOR® 10 (transdermal patches)

SOVENOR® 20 (transdermal patches)

Active substance(s)

Buprenorphine

Read all of this leaflet carefully before you start using SOVENOR®.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SOVENOR® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SOVENOR® is and what it is used for
2. What you need to know before you use SOVENOR®
3. How to use SOVENOR®
4. Possible side effects
5. How to store SOVENOR®
6. Contents of the pack and other information

1. What SOVENOR® is and what it is used for

SOVENOR® is a painkiller and belongs to the group of medicines called opioids.

SOVENOR® is used for the relief of chronic musculoskeletal pain of the joints and lower back, when that pain is of a severity sufficient to require an opioid to obtain adequate relief of pain.

2. What you need to know before you use SOVENOR®

Do not use SOVENOR® if you:

- are allergic (hypersensitive) to the active ingredient, buprenorphine, or any of the other ingredients of SOVENOR®, including previous history of application site reactions suggestive of contact dermatitis;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking, or sweating, upon stopping to take alcohol or medicines;
- have severe liver disease;
- suffer from myasthenia gravis (a condition in which the muscles become weak);
- have a head injury or increased pressure in your skull, shock or a reduced level of consciousness of uncertain origin.

Warnings and precautions

Take special care with SOVENOR® if you:

- have breathing problems;
- have depression or other conditions that are treated with antidepressants. The use of these medicines together with SOVENOR® can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and SOVENOR®”);
- are taking a type of medicine known as a monoamine oxidase inhibitor (MAO-I) (a medicine class used to treat depression) or if you have taken this type of medicine in the last two weeks;
- have constipation;

- have a history of seizures;
- have a high fever, as the absorption rate of buprenorphine, the active ingredient in SOVENOR®, may be increased;
- are, or ever have been, addicted to drug substances, alcohol or have or had serious illness of the mind;
- are using SOVENOR® regularly, particularly for a long time, as this can lead to addiction;
- feel you need to use more SOVENOR® to get the same level of pain relief as this may mean you are becoming tolerant;
- are physically dependant on opioids, as the use of SOVENOR® may lead to a withdrawal syndrome, depending on the level of physical dependence, and the timing and dose of SOVENOR®;
- need to have blood tests, remind your doctor that you are using SOVENOR®. This is important because SOVENOR® may change the way your liver works, and this could affect the results of some blood tests;
- you become more sensitive to pain when using SOVENOR®.

If this information applies to you or formerly applied to you, please speak to your doctor.

Children and adolescents under 18 years of age

SOVENOR® has not been tested in children and adolescents under 18 years of age. Therefore, safety and efficacy are not established and SOVENOR® is not recommended in children and adolescents under 18 years of age.

Other medicines and SOVENOR®

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines). If you use SOVENOR® with some other medicines, the effect of either of the medicine may be changed.

- Anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepin, or trimipramine. These medicines may interact with SOVENOR® and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C. Contact your doctor when experiencing such symptoms.
- SOVENOR® should be used with caution together with a type of medicine known as a monoamine oxidase inhibitor (MAO-I) (medicines to treat depression) or if you have taken this type of medicine in the last two weeks.
- If you take medicines such as phenobarbitone or phenytoin (medicines commonly used to treat convulsions, fits or seizures), or if you take carbamazepine (a medicine to treat convulsions, fits or seizures and certain pain conditions), or if you take rifampicin (a medicine to treat tuberculosis) the effects of SOVENOR® may be reduced.
- SOVENOR® must not be used together with benzodiazepines (medicines used to treat anxiety or to help you sleep). This combination may cause serious breathing problems which may be fatal.
- SOVENOR® may make some people feel drowsy, sick or faint, or make them breathe more slowly or weakly. These side effects may be made worse if other medicines that produce the same effects are taken at the same time. These include certain medicines to treat depression, anxiety, psychiatric or mental disorders, medicines to help you sleep and other opioids (which may be found in painkillers or certain cough mixtures). These effects may also be seen when SOVENOR® is used with alcohol.
- Reductions in liver blood flow caused by some general anaesthetics (e.g. halothane) and other medicines may result in a lower rate of liver elimination of the active ingredient buprenorphine, contained in SOVENOR®.

SOVENOR® with food and drink

Alcohol may make some of the side effects worse and you may feel unwell if you drink alcohol whilst using SOVENOR®. Drinking alcohol whilst using SOVENOR® may also affect your reaction time.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

SOVENOR® should not be used during pregnancy or breastfeeding.

Driving and using machines

You may feel sleepy when first using SOVENOR®, or when changing to a higher dose. If you are affected, you should not drive or use machinery.

It is not always possible to predict to what extent SOVENOR® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SOVENOR® affects them.

3. How to use SOVENOR®

Do not share medicines prescribed for you with any other person.

Always use SOVENOR® exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long you should be treated with the SOVENOR®. Do not stop treatment without consulting a doctor, because your pain may return, and you may feel unwell. If you feel that the effect of the SOVENOR® is too weak or too strong, talk to your doctor or pharmacist.

Three different strengths of SOVENOR® are available. Your doctor will decide which strength of SOVENOR® will suit you best. During treatment, your doctor may change the patch you use to a smaller or larger one if necessary. **You should not apply more than two patches at the same time.**

Dosage

The lowest SOVENOR® dose available, SOVENOR® 5 (5 µg/h) should be used as the starting dose in all patients.

During treatment with SOVENOR®, you may continue your existing NSAID (nonsteroidal anti-inflammatory drug) or paracetamol pain treatment regimen as needed.

The dose of SOVENOR® should not be increased at less than 3-day intervals when steady state levels are attained.

Your doctor may change the dosage of SOVENOR® based on your need for supplemental analgesia and your pain relief response to SOVENOR®.

To increase the dose, a larger patch should replace the patch that is currently being worn, or a combination of patches should be applied in different places to achieve the desired dose.

Before applying the patch

- SOVENOR® should be applied to non-irritated, intact skin of the upper outer arm, upper chest, upper back, or the side of the chest.
- SOVENOR® should be applied to a relatively hairless or nearly hairless skin site. If none are available, the hair at the site should be clipped, not shaven.
- Avoid skin which is red, irritated or has any other blemishes, for instance large scars.
- If the application site must be cleaned, it should be done with clear water only. Soaps, alcohol, oils, lotions, or rubbing devices should not be used. The skin must be dry before

the transdermal patch is applied. After a hot bath or shower, wait until your skin is completely dry and cool.

- Do not apply lotion, cream or ointment to the chosen area. This might prevent your patch from sticking properly.

Applying the patch

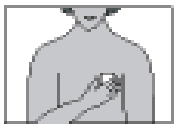
- Just before applying the patch, cut the pouch along the dotted line with scissors. Be careful not to damage the transdermal patch with the scissors. Take out the patch. Carefully peel off **half** the foil. Try not to touch the sticky part of the patch.



- Attach the patch to the upper arm, upper chest, upper back, or sides of the chest and remove the remaining foil.



- Press the patch with the hand for approximately 30 seconds and make sure that the whole patch is in contact with your skin, especially at the edges.



The patch should not be used if the seal is broken.

Wearing the patch

SOVENOR® should be worn continuously for 7 days. If you applied the patch correctly, there is little risk of it coming off. If the edges of the patch begin to peel off, the edges may be taped down with suitable skin tape. If a transdermal patch falls off, a new one should be applied. Bathing, showering, or swimming should not affect the system.

While wearing SOVENOR®, please avoid exposing the SOVENOR® site to direct external heat sources such as heating pads, electric blankets, heat lamps, hot water bottles etc., as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal. The effects of the use of SOVENOR® in hot tubs and saunas have not been studied.

Changing the patch

- Take the old patch off and fold it in half with the sticky side inwards.
- Open the pouch and take out a new patch. Use the empty pouch to dispose of the old patch and discard the pouch safely.
- Even used patches contain some active ingredient that may harm children or animals, so make sure your used patches are always kept out of the reach and sight of them.
- Stick a new patch on a different appropriate skin site (as described above). You should not apply a new patch to the same site for 3-4 weeks.
- Remember to change your patch at the same time of day. It is important that you make a note of the time of day.

If you use more SOVENOR® than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither are available, contact the nearest hospital or poison control centre.

As soon as you discover that you have used more patches than you should, remove all patches.

People who have taken an overdose may feel very sleepy and sick. They may also have breathing difficulties or lose consciousness and may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining patches with you to show to the doctor.

If you forget to apply the SOVENOR®

Stick a new patch on as soon as you remember. Also make a note of the date, as your usual day of changing may now be different. If you are very late changing your patch, your pain may return. In this case, please contact your doctor. Do not apply additional patches to make up for the forgotten application.

If you stop using SOVENOR®

If you stop using SOVENOR® too soon, or you interrupt your treatment, your pain may return. If you wish to stop treatment, please consult your doctor, who will tell you what can be done and whether you can be treated with other medicines.

Some people may have side effects when they have used strong painkillers for a long time and stop using them. The risk of having effects after stopping SOVENOR® is very low. However, if you feel agitated, anxious, nervous or shaky, if you are overactive, have difficulty sleeping or digestion problems, tell your doctor.

The pain-relieving effect of SOVENOR® is maintained for some time after removal of the patch. You should not start another opioid analgesic (strong painkiller) within 24 hours after removal of the patch.

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

4. Possible side effects

SOVENOR® can have side effects.

Not all side effects reported for SOVENOR® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOVENOR®, please consult your health care professional for advice.

Serious side effects that may be associated with SOVENOR® are similar to those seen with other strong painkillers and include difficulty in breathing and low blood pressure.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Remove the patch and 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.

As with all strong painkillers, there is a risk that you may become addicted or reliant on SOVENOR®.

The following side effects have been reported during the use of SOVENOR®:

Frequent side effects

- Headache, dizziness, drowsiness, shaking;
- Constipation, dry mouth, feeling or being sick;
- Itching and redness or rash at the application site;
- Weight loss (anorexia);
- Confusion, depression, difficulty in sleeping, nervousness, anxiety;
- Shortness of breath;
- Abdominal pain or discomfort, diarrhoea, indigestion, heartburn;
- Sweating, rash;
- Tiredness, a feeling of unusual weakness, swelling of hands, ankles, or feet, water retention in the body (oedema) or rash.

Less frequent side effects

- Severe allergic reactions (anaphylaxis) which can include swelling of throat and tongue and difficulty breathing;
- Dehydration;
- Agitation, a feeling of extreme happiness, mood swings, aggression;
- Changes in taste, difficulty in speaking, reduced sensitivity to pain or touch, loss of

memory, migraine, fainting, numbness of the hands or feet;

- Dry eyes, blurred vision;
- A ringing or buzzing sound in the ears, a feeling of dizziness or spinning;
- High or low blood pressure, sudden drop in blood pressure when standing up, angina (severe chest pain associated with heart disease), fast irregular heartbeat;
- Flushing of the skin;
- Worsening of breathing problems associated with asthma, being unable to breathe, cough, over breathing, hiccups, reduced oxygen in the blood, runny nose, wheezing;
- Wind;
- Weight loss;
- Dry skin, swelling of the face, skin eruptions;
- Muscle cramps, aches and pains;
- Difficulty in passing urine;
- Flu like illness, high temperature, shivering, chest pain, water retention;
- An increase in accidental injuries (e.g. falls);
- Hallucinations, nightmares, decreased sexual drive, mental disorder;
- Difficulties with concentration or balance;
- Blocked intestines (ileus), difficulty in swallowing;
- Local allergic reaction with signs of swelling (in such cases treatment should be stopped);
- Sexual dysfunction;
- Withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping to use SOVENOR®;
- Reduction in size of the pupils in the eye;
- Convulsions;
- Swelling or inflammation of the pancreas (pancreatitis);
- Changes in enzymes in the liver.

The frequency of the following side effects is unknown

- Feeling detached from oneself;
- Diverticulitis (inflammation of the intestine);
- Pain caused by gallstones;
- Development of a condition where your breathing stops for short periods whilst you are asleep (sleep apnoea).

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SOVENOR®.

Alternatively report to: ZADrugSafety@mundipharma.co.za.

5. How to store SOVENOR®

Store all medicines out of reach of children.

Store at or below 25 °C in original package.

Do not use SOVENOR® after the expiry date which is stated on the carton and on the pouch. The expiry date refers to the last day of that month.

Dispose of the patch after use. When changing the patch, take off the patch and fold in the adhesive side of the patch. Open a new pouch and take out a new patch. Use the empty pouch to dispose of the old patch and discard the pouch safely.

Do not use if the seal of the pouch is broken.

Return all unused medicines to your pharmacist. Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOVENOR® contains

The active substance is buprenorphine.

Each SOVENOR® 5 Patch contains 5 mg buprenorphine in a medicine-containing matrix that releases a nominal 5 µg of buprenorphine per hour over 7 days.

Each SOVENOR® 10 Patch contains 10 mg buprenorphine in a medicine-containing matrix that releases a nominal 10 µg of buprenorphine per hour over 7 days.

Each SOVENOR® 20 Patch contains 20 mg buprenorphine in a medicine-containing matrix that releases a nominal 20 µg of buprenorphine per hour over 7 days.

The other ingredients are: Levulinic acid, oleyl oleate, polyacrylate (dry solids), polyethylene terephthalate (PET) and povidone (PVP).

What SOVENOR® looks like and contents of the pack

SOVENOR® 5: A square, transdermal patch with rounded corners on a rigid aluminium removable protective layer with a beige coloured backing layer. In the centre is posted a buprenorphine-containing adhesive matrix, printed with “SOVENOR® 5 mg, 5 microgram per hour”.

SOVENOR® 10: A rectangular, transdermal patch with rounded corners on a rigid aluminium removable protective layer with a beige coloured backing layer. In the centre is posted a buprenorphine-containing adhesive matrix, printed with “SOVENOR® 10 mg, 10 microgram per hour”.

SOVENOR® 20: A square, transdermal patch with rounded corners on a rigid aluminium removable protective layer with a beige coloured backing layer. In the centre is posted a buprenorphine-containing adhesive matrix, printed with “SOVENOR® 20 mg, 20 microgram per hour”.

One transdermal patch packed into a heat sealed protective pouch composed of composite material: either paper, LDPE film, aluminium and ethylene copolymer (Composite 1); or paper, PET, polyethylene, aluminium and ethylene copolymer (Composite 2).

Two or four individually sealed pouches are packed into one outer carton.

Holder of Certificate of Registration

Mundipharma (Pty) Ltd

Block D, Grosvenor Square

Park Lane

Century City

Cape Town

7441

South Africa

This leaflet was last revised in

18 July 2025

Registration numbers

South Africa: S6

SOVENOR® 5 Patch: 41/2.7/0589

SOVENOR® 10 Patch: 41/2.7/0590

SOVENOR® 20 Patch: 41/2.7/0591

Namibia: NS4

SOVENOR® 5 Patch: 12/2.7/0253

SOVENOR® 10 Patch: 12/2.7/0254

SOVENOR® 20 Patch: 12/2.7/0255

Botswana: S1B

SOVENOR® 5 Patch: BOT1402610B

SOVENOR® 10 Patch: BOT1402611B

SOVENOR® 20 Patch: BOT1402612B

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

® = SOVENOR® is a registered trademark