PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

BUPREMED 5 / 10 / 20 transdermal patch

Buprenorphine

Read all of this leaflet carefully before you start using are given BUPREMED

- 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.
- BUPREMED 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 BUPREMED is and what it is used for

BUPREMED is a strong “painkiller” or analgesic and belongs to the medicine group called opioids.

BUPREMED is used for the relief of chronic (musculoskeletal) pain of the lower back and of the joints, 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 BUPREMED

Do not use BUPREMED

- if you are hypersensitive (allergic) to buprenorphine or any of the other ingredients of **BUPREMED** (listed in section 6).
- if you are experiencing a severe and potentially life-threatening condition that can occur during alcohol withdrawal, called delirium tremens;
- if you are addicted to (dependent) painkillers (opioids) and if you are receiving treatment for painkiller withdrawals (narcotic withdrawals);
- if you have impaired breathing, or have a condition that can cause your breathing to be impaired;
- if you have severe liver disease;
- if you suffer from a condition in which the muscles become weak – called myasthenia gravis;
- if you are taking medicines known as monoamine oxidase inhibitors (MAOIs), or if you have taken this medicine in the last two weeks;
- if you suffer from a head injury, or have increased pressure in your skull, shock or a reduced level of consciousness (of uncertain origin)

Warnings and precautions

Special care should be taken with **BUPREMED**:

- if you have difficulty breathing or have breathing problems;
- if you are or ever have been addicted to alcohol or medicines or if you have serious mental illness (illness of the mind);
- if you are physically dependent on opioids, as the use of **BUPREMED** may lead to a withdrawal syndrome (all dependent on the level of physical dependence and the timing

and dose of **BUPREMED**.

- if this information (as mentioned above) applies to you or formerly applied to you, please speak to your doctor or healthcare provider.

Other medicines and BUPREMED

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

BUPREMED or the other medicines may be changed.

- **BUPREMED** should not be used together with a type of medicine known as a monoamine oxidase inhibitor (medicine to treat depression), or if you have taken this medicine in the last two weeks.
- If you take some medicines such as carbamazepine (medicine to treat convulsions, fits or seizures and certain pain conditions), phenobarbital or phenytoin (medicines used to treat convulsions, fits or seizures) or if you take rifampicin (a medicine to treat tuberculosis), the effects of BUPREMED can be reduced.
- **BUPREMED** must not be used together with medicines to treat anxiety or to help you sleep (known as benzodiazepines). This combination may cause a potentially fatal breathing problem.
- **BUPREMED** may make you feel drowsy, sick or faint or make some people breathe more slowly or weakly. These side effects may be worsened if other medicines, that produces the same effect, are taken at the same time. These include medicines to treat anxiety (benzodiazepines), depression, medicines to help you sleep, psychiatric or mental disorders (phenothiazines) and other opioids found in painkillers and certain cough mixtures. Some of these effects may also be seen when **BUPREMED** are used together with alcohol.
- A decline in liver blood flow caused by some general anaesthics (such as halothane) and other medicines, may result in a lower rate of eliminiation of the active ignreidnt,

buprenorphine, found in **BUPREMED**.

Using BUPREMED with alcohol:

Some side effects may be worsened when drinking alcohol whilst wearing the **BUPREMED**, and your reactions time may also be affected.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, 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 taking this medicine. **BUPREMED** should not be used during pregnancy and breastfeeding.

Driving and using machines

It is not always possible to predict to what extent **BUPREMED** 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 **BUPREMED** affects them.

BUPREMED may affect mental and / or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and / or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines / equipment.

This pertains particularly in the beginning of treatment and in conjunction with other centrally acting substances including alcohol, sedatives, tranquillisers and hypnotics.

In cases where a stable dose is used, a general restriction is not necessary.

If you experience and are affected by side effects such as dizziness drowsiness and or blurred vision during treatment initiation or titration to a higher dose, you should not drive or use machines, for at least 24 hours after the patch has been removed.

3. How to use BUPREMED

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

Always use **BUPREMED** exactly as your doctor or pharmacist has told you. Check with your

doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with **BUPREMED** will last.

Three different strengths of **BUPREMED** are available. Your doctor will decide which strength of **BUPREMED** will suit you best and may change (during your treatment) which patch you use to a smaller or larger patch if necessary.

You should not apply more than two patches at the same time.

Dosage

The lowest dose of **BUPREMED 5 Transdermal Patch,** should be used as the starting dose for all patients.

During treatment with **BUPREMED** you may continue your existing NSAID (anti-inflammatory) or paracetamol regimen as needed.

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

Your doctor may change the dosage of **BUPREMED** based on your need for supplemental analgesia (painkillers) and your pain relief response to **BUPREMED**.

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:

- **BUPREMED** should be applied to non-irritated, intact skin of the upper outer arm, upper chest, the side of the chest and upper back.
- **BUPREMED** 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, such as large scars.
- If the application site must be cleaned, it should be done with clear water only. Soaps, alcohol, oils, lotions, or abrasive 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:

- Step 1: Each patch is sealed in a pouch. Open the pouch just before applying the patch (by tearing the pouch where indicated). Take out the patch. Do not use the patch if the pouch seal is broken.

- Carefully peel of half of 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 the edges.

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

Wearing the patch:

BUPREMED should be worn continuously for 7 days.

If you have applied the patch correctly, there is little risk that the patch will come off. Should the edges of the patch begin to peel off, the edges may be taped down with a 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 **BUPREMED**, please avoid exposing the **BUPREMED** site to direct external heat sources such as heating pads, electric blankets, heat lamps, etc., as this may lead to larger quantities of the active ingredient being absorbed into your blood than normal. The effects of the use of **BUPREMED** in saunas and hot tubs have not been studied.

Changing the patch:

- Take the old patch off and fold it in half with the sticky side inwards.
- Open a new pouch and take out a new patch. Use the empty pouch to dispose the old patch and discard the pouch safely.
- Please remember, even used patches still contain some active ingredient, that may be harmful to children or animals. Make sure that your old patch is out of reach of children and animals.
- Stick a new patch on a different 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.

Duration of treatment:

Your doctor will tell you how long your treatment with **BUPREMED** will last. Do not stop the treatment without consulting with you doctor, because your pain may return and you may feel unwell.

If you feel that the effect of the **BUPREMED** is too weak or too strong, talk to your doctor or pharmacist.

If you use more BUPREMED than you should

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

As soon as you realise (or discover) that you have used more patches than you should, remove all patches and call your doctor or healthcare provider. In the event of over-dosage, consult your doctor or pharmacist.

If neither is available, contact the nearest hospital or poison control centre.

If you have taken an overdose, you may feel very sleepy and sick. Some people may have difficulty breathing or lose consciousness and may need emergency treatment in hospital. When seeking medical attention, make sure that this leaflet and any remaining patches are shown to your doctor.

If you forget to apply BUPREMED

Apply a new patch to your skin as soon as you remember and make a note of the date. Your usual day of changing may now be different.
If you are very late in changing your patch, your pain may return. In this case, contact your doctor.
Do not apply additional patches to make up for the forgotten applications.

If you stop using BUPREMED

If you stop using **BUPREMED** too soon or interrupt your own treatment, your pain may return. If you wish to stop your treatment, please consult with your doctor, as he/she 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 it. The risk of having side effects after stopping **BUPREMED** is very low. Should you feel agitated, drowsy, anxious, nervous or shaky, if you are overactive, have difficulty sleeping or have digestive problems, tell your doctor.

BUPREMED has a pain-relieving effect after some time after the removal of the patch. You should not use other pain killers within 24 hours after the removal of the patch.
If you have any further questions on the use of **BUPREMED**, ask your doctor or pharmacist.

4. Possible side effects

BUPREMED can have side effects.

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

If any of the following happens, stop taking / using **BUPREMED** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Wheeziness;
- difficulties in breathing;
- swelling of the eyelids, face or lips;
- rash or itching (especially those covering your whole body)
- low blood pressure

These are all very serious side effects. If you have them, you may have had a serious reaction to **BUPREMED**. You may need urgent medical attention or hospitalisation.

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

Tell your doctor if you notice any of the following:

Frequent

- Headache, dizziness, drowsiness, abnormal pins and needles sensation, shaking;
- Abdominal pain, constipation, loose stools (diarrhoea), indigestion, dry mouth, feeling or actually being sick;
- Itching and redness, or rash at the application site;
- Weight loss (anorexia);
- Confusion, depression, difficulty in sleeping, nervousness, anxiety;

- Numbness of the hands and feet;
- Flushing of the skin;
- Shortness of breath;
- Sweating, rash, skin eruptions, itching, reddening of the skin (especially the face);
- Tiredness, a feeling of unusual weakness, pain, chest pain, swelling of hands, ankles or feet, redness or rash at the application site;
- Feeling weak;

Less frequent

- Dehydration;
- Restlessness, agitation, feeling detached from oneself, feeling of extreme happiness, aggression, hallucinations, decrease in libido (sexual need), nightmares, sleep disorders, becoming addicted to the medicine;
- Difficulty with balance, concentration and coordination, difficulty speaking, changes in taste, reduced sense of touch, loss of memory, migraine, fainting, shaking, convulsions, increased sensitivity to feeling pain and an extreme response to pain, breathing stops for short periods whilst you are sleeping;
- Dry eyes, swelling of the eyelids, constriction of the pupil (pupil looks very small), blurred vision and visual disturbances;
- Ear pain, ringing or bussing sound in the ears, and a feeling of dizziness or spinning;
- High or low blood pressure, angina (severe chest pain, associated with heart disease), fast irregular heartbeat, blood pressure drops when standing up;
- Worsening of breathing problems associated with asthma, cough, reduced oxygen in the blood, runny nose, wheezing, hiccups;
- Diverticulitis (inflammation of pouches or diverticula's that formed in the wall of the colon), difficulty swallowing, wind, lack of movement in the bowls;
- Gallbladder attach or gallstone attack;

- Dry skin, irritation of the skin, swelling of the face, formation of fluid-containing bumps on the skin, raised, itchy welts on the skin;
- Muscle cramps, muscles spasms, aches and pains;
- Difficulty passing urine, loss of bladder control;
- Decreased erection (difficulty getting and maintaining an erection), sexual dysfunction;
- Weariness, flu-like symptoms, high temperature, shivering, swelling, chest pain, general weakness;
- Withdrawal symptoms (agitation, anxiousness, sweating or shaking upon stopping the use of **BUPREMED**);
- Liver enzyme increase;
- Accidental injuries, such as falling.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **BUPREMED.**

5. How to store BUPREMED

Store all medicines out of reach of children.

- Store at or below 25 °C
- Do not refrigerate/ freeze
- Store in the original package/ container

- Keep the container in the outer carton
- Protect from light / moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the carton

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BUPREMED contains

- The active substance is buprenorphine.

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

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

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

- The other ingredients are levulinic acid, oleyl oleate, povidone (PVP), polyacrylate (dry solids) and polyethylene terphthalate (PET) and 2-propanol.

For the pressure sensitive adhesive (PSA): Copolymer of 2-ethylhexyl acrylate, butyl acrylate, glacial acrylic acid, vinyl acetate (75:15:5:5) (Acrylate polymer I, DT 387-2054)

What BUPREMED looks like and contents of the pack

One transdermal patch packed into a heat sealed child-resistant pouch composed of composite material, paper, PET, PE, aluminium, surlyn.

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

BUPREMED 5 Transdermal Patch: A rectangular patch with rounded edges, a beige coloured backing web imprinted with a blue coloured name and respective strength, **BUPREMED 5** Transdermal Patch, a transparent adhesive matrix laminated with a central placed transparent matrix and a transparent release liner.

BUPREMED 10 Transdermal Patch: A rectangular patch with rounded edges, a beige coloured backing web imprinted with a blue coloured name and respective strength, **BUPREMED 10** Transdermal Patch, a transparent adhesive matrix laminated with a central placed transparent matrix and a transparent release liner.

BUPREMED 20 Transdermal Patch: A rectangular patch with rounded edges, a beige coloured backing web imprinted with a blue coloured name and respective strength, **BUPREMED 20** Transdermal Patch, a transparent adhesive matrix laminated with a central placed transparent matrix and a transparent release liner.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

PI is avaiable on our website