

Norspan[®] Transdermal Patch

Buprenorphine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Norspan[®] patches.

This leaflet answers some common questions about Norspan[®] patches. 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 using Norspan[®] against the benefits they expect it will have for you.

Use Norspan[®] patches as instructed and follow the advice given in this leaflet.

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

Keep this leaflet with your medicine. You may need to read it again.

What Norspan[®] patches are used for

Norspan[®] is used to relieve moderate to severe pain. Each Norspan[®] patch is designed to provide around the clock relief from moderate to severe pain for up to 7 days.

Norspan[®] patches contain a medicine called buprenorphine. It belongs to a group of medicines called opioid analgesics.

Buprenorphine is continuously absorbed through the skin in

contact with the patch and then into the blood stream. It then acts at receptors to block pain messages being sent to the brain.

Opioid analgesics such as Norspan[®] have been used to treat pain for many years. In most cases addiction does not occur. However, over time your body may become used to using Norspan[®] so if you suddenly stop using it you may experience some symptoms of withdrawal. It is important to discuss this issue with your doctor.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Be careful driving or operating machinery until you know how Norspan[®] affects you.

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

Before you use Norspan[®] patches

When you must not use it

Do not use Norspan[®] if you have an allergy to:

- buprenorphine
- any of the ingredients or patch components listed at the end of this leaflet

Do not use this medicine if you have difficult or shallow breathing.

Do not use this medicine if you are taking antidepressants called monoamine oxidase inhibitors

(MAOIs). They should be stopped 14 days before Norspan[®] is used.

Do not use Norspan[®] if you are dependent on opioids. Examples of these are morphine, oxycodone, pethidine, fentanyl and methadone. Using Norspan[®] after using these medicines can cause the onset of withdrawal symptoms because Norspan[®] blocks some receptors.

Do not use this medicine after the expiry date (exp) printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Talk to your doctor if you are not sure whether you should start using this medicine,

Before you start to use 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 of the following medical conditions:

- convulsions, fits or seizures
- head injury
- shock (rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting)
- raised pressure within the head
- breathing or lung problems
- low blood pressure or volume
- bile tract disease (gallstones)
- inflamed pancreas
- inflammatory bowel disease
- increased prostate size
- low activity of the adrenal gland (Addison's disease; taking steroids for a long time >2 weeks)

- kidney or liver disease
- weakened body
- underactive thyroid gland
- a very recent operation
- a high fever
- misuse or abuse of drugs and/or alcohol
- mental illness
- heart condition or heart beat irregularities

Tell your doctor if you are about to undergo any of the following procedures:

- pain relieving surgery
- stomach surgery

Tell your doctor if you have never used an opioid before.

Norspan[®] 5 micrograms/hr should be used as the starting dose if you have never used an opioid before.

Tell your doctor if you have used an opioid before. Using Norspan[®] after using other opioids may lead to withdrawal symptoms (see under side effects)

Ongoing use of this medicine can cause your body to depend on the medicine. If you stop using Norspan[®] suddenly, withdrawal symptoms may occur (See under side effects).

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have severe liver problems. This may cause the medicine to build up in your body.

If you have not told your doctor about any of the above, tell him/her before you start using Norspan[®].

Norspan[®] is not recommended for children under 18 years of age.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other

medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Norspan[®] may interfere with each other. These include:

- Medicines used to treat depression belonging to a group called monoamine oxidase inhibitors (MAOIs). They should be stopped 14 days before Norspan[®] is used.
- Medicines that cause sleepiness or muscle relaxation like sleeping tablets, antidepressants or antipsychotics.
- Other opioid pain relievers
- Alcohol
- Medicines to stop nausea or vomiting
- General anaesthetics
- Medicines used to change the way the heart beats
- Medicines used to thin the blood e.g. warfarin

These medicines or alcohol may increase the side effects of Norspan[®]. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines or use alcohol.

How to use Norspan[®] patches

How much to use

The dose of Norspan[®] may be different for each person. Your doctor will decide the right dose for you.

The amount of Norspan[®] needed to give good pain relief varies. The doctor will take into account your age, weight, level of pain and medical history when choosing your dose.

How to use it

- Norspan[®] is available in three different strengths. Your doctor

will decide which patch, or combination of patches, is suitable to control your pain.

- Each patch is applied onto the skin and lasts for seven days.
- After seven days, remove the patch and apply a new patch to the skin at a different place.

Using it for the first time

- The usual starting dose of Norspan[®] is 5 micrograms/hr, applied once every 7 days. 10 and 20 micrograms/hr patches are available for stronger pain. Your doctor may prescribe a combination of patches, if necessary, to control your pain.
- The first patch may take up to three days to reach maximum effect. This is because buprenorphine is slowly absorbed through the skin and into the blood. Your doctor may prescribe additional medicines to control the pain during this time.

Applying the patch

1. Find a clean skin site on the upper outer arm, upper chest, upper back or the side of the chest. Do not place the patch onto skin that is red, burnt or injured.
2. **Make sure the site is nearly hairless and has no large scars.** Remove the hair by cutting with scissors if you have to, but do not shave the chosen area as this may injure the skin.
3. **The chosen area must be clean.** If necessary, wash the area with water only. Do not use soap, alcohol or a coarse cloth to clean. Do not apply oils or lotions. **The area you have chosen to apply the patch must be dry.** Dry the area completely after washing with water.
4. Remove the patch from the sealed pouch packaging.
5. Remove the release liner then press the patch firmly onto the chosen site with the palm of the hand for about 30 seconds.
6. Make sure the whole patch is in contact with the skin especially

around the edges. If the edges of the patch begin to peel off, they may be taped down with suitable skin tape.

7. Wash your hands with clean water.

The patch should be worn continuously for 7 days. Bathing, showering, or swimming should not affect the patch. However, it is a good idea to keep the patch dry whenever possible. If a patch should fall off, a new one should be applied.

Changing the patch

Change your patch at the same time of the same day each week.

For example, if you start using your patch at 9am Monday morning, change your patch the following Monday morning at 9am.

1. After seven days, remove the patch
2. Fold the used patch in half so that the sticky side sticks to itself.
3. Dispose of the used patch in a safe place, where children cannot reach it.
4. Apply a new patch straight away to a different area of the skin, following the steps under 'Applying the patch'. **A new patch should not be applied to the same skin site for 3 to 4 weeks.**

If you forget to change it

Apply a new patch as soon as you remember, and then go back to using your medicine as you would normally.

Do not apply double the patches to make up for the patch that you missed. This will increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to change your patch, ask your pharmacist for some hints.

If you receive too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 0800 76 47 66) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Norspan®. 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.

Symptoms of an overdose may include difficulties in breathing, drowsiness, nausea, vomiting, fainting, collapsing or very small pupils.

While you are using Norspan® patches

Things you must do

Use Norspan® exactly as your doctor has prescribed.

Visit your doctor regularly for a check-up and always discuss any problems or difficulties while using Norspan® patches.

Tell your doctor if your pain is getting worse, or if you are having frequent breakthrough pain.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Norspan®.

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

If you are going to have surgery, tell the surgeon and anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

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

Things you must not do

Do not drive or operate machinery until you know how Norspan® affects you.

Norspan® may cause drowsiness or dizziness in some people and therefore may affect alertness. Ask your doctor's advice about whether or not it will be safe for you to drive a car or operate any machinery while using Norspan® or anything else that may be dangerous if you are drowsy.

Do not stop using your medicine, lower or increase the dosage without checking with your doctor.

If you stop taking it suddenly, your pain may worsen or you may have unwanted withdrawal effects. If possible, your doctor will gradually reduce the amount you use each day before stopping the medicine completely.

Do not apply more than two patches at any one time.

Do not wear the patch near heat sources such as heating pads, hot water bottles, electric blankets, heat lamps, sauna, hot tubs and heated water beds, etc, and avoid intensive sunbathing.

This may cause more medicine than normal to be absorbed and lead to an increase in side effects.

Do not use Norspan® to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how Norspan® affects you.

You may feel drowsy when you begin to use Norspan® patches. If you drink alcohol the drowsiness may be worse.

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

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

Norspan[®] can cause constipation. You should speak to your doctor about your diet and proper use of laxatives.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Norspan[®].

This medicine helps most people with pain, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

The most common side effects are:

- Constipation, nausea, vomiting, dry mouth
- Drowsiness, dizziness, confusion
- Itching, itching at the patch site, reaction at patch site
- Headache

Other less common side effects include:

- Lack of appetite, diarrhoea, upset stomach
- Anxiety, depression, difficulty in sleeping, nervousness, abnormal sensations
- Widening of the blood vessels
- Swelling
- Shortness of breath
- Redness and rash at site of application, sweating
- Abnormal taste

- Stomach pain, weakness, chest pain, pain

Tell your doctor as soon as possible if you notice any of the following:

- Swelling
- Chest pain

Remove the Norspan[®] patch and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if the following happens:

- Breathing slows or weakens.

Medicines like Norspan[®] can lead to addiction. This is unlikely when Norspan[®] is used correctly.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After using Norspan[®] patches

Storage

Keep your patches in the pack until it is time to use them.

If you take the patch out of the pack they may not keep as well.

Keep your patches in a cool dry place where the temperature stays below 25°C.

Do not store Norspan[®] or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness 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

After removing the used patch, fold it over on itself and dispose of it safely.

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Norspan[®] patches are either rectangular or square with rounded corners. They are beige in colour. Each Norspan patch is printed with the trade name and the strength in blue ink. Each strength is a different size. The higher the strength the larger the size. Norspan[®] is supplied in cartons containing 2 individually packaged patches.

Ingredients

Norspan[®] patches contain buprenorphine as the active ingredient and is available in three different strengths:

NORSPAN 5
Each patch releases buprenorphine 5 micrograms/hr.
Total buprenorphine content: 5mg

NORSPAN 10
Each patch releases buprenorphine 10 micrograms/hr.
Total buprenorphine content: 10mg

NORSPAN 20
Each patch releases buprenorphine 20 micrograms/hr.
Total buprenorphine content: 20mg

The patches also contain:

- levulinic acid
- oleyl oleate
- povidone
- Duro Tak 387-2051
- Duro Tak 387-2054
- polyethylene terephthalate

Identification

Sponsor

Mundipharma NZ Limited
C/o Pharmaco NZ Limited
P O Box 4079
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NEW ZEALAND

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