

Package leaflet: Information for the user
Panitaz 5 micrograms/h, 10 micrograms/h, 20 micrograms/h Transdermal Patches
Buprenorphine

Important things you need to know about Panitaz

- These patches contain a strong pain killer.
- This medicine contains buprenorphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.
- Ensure that old patches are removed before applying a new one.
- Patches must not be cut.
- Do not expose the patches to a heat source (such as a hot water bottle).
- Do not soak in a hot bath or take a hot shower whilst wearing a patch.
- If you develop a fever tell your doctor immediately.
- Follow the dosage instructions carefully and only change your dose on the same day and at the same time 7 days later.
- If your breathing becomes shallow and weak take the patch off and seek medical help.

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What Panitaz is and what it is used for
- What you need to know before you use Panitaz
- How to use Panitaz
- Possible side effects
- How to store Panitaz
- Contents of the pack and other information

1. What Panitaz is and what it is used for

This medicine has been prescribed for you to relieve moderate, long-lasting pain that requires the use of a strong painkiller. It contains buprenorphine which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to 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 prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. Panitaz patches should not be used to relieve acute pain. Panitaz patches act through the skin. After application, buprenorphine passes through the skin into the blood. Each patch lasts for seven days.

2. What you need to know before you use Panitaz

Do not use Panitaz:

- if you are allergic to buprenorphine or any of the other ingredients of this medicine (listed in section 6)
- if you have **breathing problems**
- if you are **addicted to drugs**
- if you are taking a type of medicine known as a **monoamine oxidase inhibitor** (examples include tranlycypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks
- if you suffer from **myasthenia gravis** (a condition in which the muscles become weak)
- if you have previously suffered from **withdrawal symptoms** such as agitation, anxiety, shaking or sweating **upon stopping taking alcohol**.

Panitaz **must not** be used to treat symptoms associated with **drug withdrawal**.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Panitaz:

- if you are or have ever been **addicted to opioids, alcohol, prescription medicines or illegal drugs**
- if you have previously suffered from withdrawal symptoms such as **agitation, anxiety, shaking or sweating**, when you have stopped taking alcohol or drugs
- if you feel you need to take more Panitaz 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 prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever
- are treated with **antidepressants**. The use of these medicines together with Panitaz can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Panitaz")
- if you suffer from **seizures, fits or convulsions**
- suffer from a breathing related sleep disorder (sleep apnoea)
- if you have a **severe headache or feel sick due to a head injury** or increased pressure in your skull (for instance due to brain disease). This is because the patches may make symptoms worse or hide the extent of a head injury
- if you are feeling **light-headed or faint**
- if you have **severe liver problems**
- if you are a smoker
- if you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses,
- if you have a **high temperature**, as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal.
- if you suffer from constipation.

Using this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber 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 prescriber about your treatment. Addiction can cause withdrawal symptoms when you stop using 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 prescriber 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.

Sleep-related breathing disorders

Panitaz can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakenings due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

This medicine may cause opiate side effects reactions which are usually presented by a mild or moderate skin inflammation, and their typical appearance may include redness, swelling, itching, rash, small blisters, and painful/burning sensation at the application site. Most commonly the cause is skin irritation, and these reactions stop after Panitaz patches are removed. More serious allergic reactions may occur such as blisters with discharge, which may spread outside the application site and may not resolve rapidly after Panitaz removal. Chronic allergic reactions may lead to open wounds, bleeding, ulcers, skin discoloration and infections. If you notice any of the above skin reactions, please contact your doctor.

This medicine may increase your sensitivity to pain particularly at high doses. Tell your doctor if this happens. A reduction in your dose or a change in your medicine may be necessary. If you have recently had an operation, please speak to your doctor before using these patches. Similar to other opioids, Panitaz patches may affect the normal production of hormones in the body, such as cortisol or sex hormones, particularly if you have taken high doses for long period of time.

Children and adolescents

Do not give this medicine to children below 18 years.

Other medicines and Panitaz

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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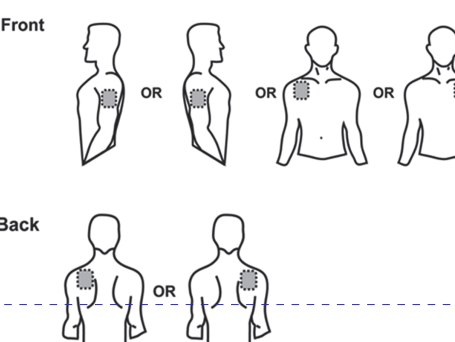


Patients with liver disease

In patients with liver disease, the effects and period of action of the Panitaz patch may be affected and your doctor will therefore check on you more closely.


Before applying the transdermal patch

- Choose an area of non-irritated, intact skin on your upper arm, outer arm, upper chest, upper back or side of the chest (see illustrations below). Ask for assistance if you cannot apply the patch yourself.
- The Panitaz patch should be applied to a relatively hairless or nearly hairless skin site. If no suitable hair free sites are available the hairs should be cut off with a pair of scissors. Do not shave them off.
- Avoid skin which is red, irritated or has any other blemishes, for instance large scars.
- The area of skin you choose must be dry and clean. If necessary, wash it with cold or lukewarm water. Do not use soap, alcohol, oil, lotions or other detergents. 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.



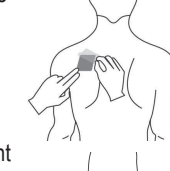
Applying the transdermal patch

Step 1: Each transdermal patch is sealed in a sachet. Just before use, cut the sachet along the sealed edge with scissors. Take out the transdermal patch. Do not use the patch if the sachet seal is broken.



Step 2: The sticky side of the transdermal patch is covered with a transparent protective foil. Carefully peel off **one part** of the foil. Try not to touch the sticky part of the transdermal patch.

Step 3: Stick the transdermal patch on to the area of skin you have chosen and remove the remaining foil.



Step 4: Press the transdermal patch against your skin with the palm of your hand and count slowly to 30. Make sure that the whole transdermal patch is in contact with your skin, especially at the edges.

Wearing the transdermal patch

You should wear the patch for seven days. Provided that you have applied the patch correctly, there is little risk of it coming off. If the edges of the patch begin to peel off, they may be taped down with a suitable skin tape. You may shower, bathe or swim whilst wearing it.

Do not expose the patch to extreme heat (e.g. heating pads, electric blanket, heat lamps, sauna, hot tubs heated water beds, hot water bottle etc) as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal. External heat may also prevent the patch from sticking properly. If you have a high temperature this may alter the effects of Panitaz patches (see "Warnings and precautions" section above).

In the unlikely event that your patch falls off before it needs changing, do not use the same patch again. Stick a new one on straight away (see "Changing the transdermal patch" below).

Changing the patch

- Take the old patch off.
- Fold it in half with the sticky side inwards.
- Open and take out a new patch. Use the empty sachet to dispose of the old patch. Now discard the sachet 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 sight and reach 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.

Duration of treatment

Your doctor will tell you how long you should be treated with the Panitaz patch. Do not stop treatment without consulting a doctor, because your pain may return and you may feel unwell (see also "If you stop using Panitaz" below).

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

If you use more Panitaz than you should

As soon as you discover that you have used more patches than you should, remove all patches and call your doctor or hospital straight away. 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 use Panitaz

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.

What Panitaz patches contain

The active substance is buprenorphine. Each 5 micrograms/h transdermal patch contains 5 mg of buprenorphine in a patch size of 6.25 cm² and releases about 5 micrograms of buprenorphine per hour (over a period of 7 days). Each 10 micrograms/h transdermal patch contains 10 mg of buprenorphine in a patch size of 12.5 cm² and releases about 10 micrograms of buprenorphine per hour (over a period of 7 days). Each 20 micrograms/h transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm² and releases about 20 micrograms of buprenorphine per hour (over a period of 7 days). The other ingredients are polyacrylate, povidone K90, levulinic acid, oleic oleate, PET film, polyester web, blue printing ink.

What Panitaz patches look like and contents of the pack

Transdermal patch. Three sizes are available. Each 5 micrograms/h transdermal patch is beige coloured with rounded corners and is imprinted with "Buprenorphin" and "5 µg/h". Each 10 micrograms/h transdermal patch is beige coloured with rounded corners and is imprinted with "Buprenorphin" and "10 µg/h". Each 20 micrograms/h transdermal patch is beige coloured with rounded corners and is imprinted with "Buprenorphin" and "20 µg/h". One transdermal patch is sealed in one child-resistant sachet. The patches are available in cartons containing 4 transdermal patches. Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer

Dr. Reddy's Laboratories (UK) Ltd, 410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, United Kingdom
This leaflet was last revised in 02/2024

Common (may affect up to 1 in 10 people)

- loss of appetite
- confusion, depression, anxiety, difficulty in sleeping, nervousness, shaking (tremors)
- shortness of breath
- abdominal pain or discomfort, diarrhoea, indigestion, dry mouth
- sweating, rash, skin eruptions
- tiredness, a feeling of unusual weakness, muscle weakness, swelling of hands, ankles or feet

Uncommon (may affect up to 1 in 100 people)

- restlessness, agitation, a feeling of extreme happiness, hallucinations, nightmares, decreased sexual drive, aggression
- changes in taste, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness
- loss of memory, migraine, fainting, problems with concentration or co-ordination
- dry eyes, blurred vision
- a ringing or buzzing sound in the ears, a feeling of dizziness or spinning
- high or low blood pressure, chest pain, fast or irregular heart beat
- cough, hiccups, wheezing
- wind
- weight loss
- dry skin
- spasms, aches and pains
- difficulty in beginning the flow of urine
- fever
- an increase in accidental injuries (e.g. falls)
- withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping using Panitaz patches (see section "Drug withdrawal")

If you need to have blood tests remind your doctor that you are using Panitaz patches. This is important because Panitaz patches may change the way your liver works and this could affect the results of some blood tests.

Rare (may affect up to 1 in 1,000 people)

- angina (chest pain associated with heart disease)
- mental disorder
- difficulties with balance
- swelling of the eyelids or face, a reduction in size of the pupils in the eye
- difficulty in breathing, worsening of asthma, over breathing
- a feeling of faintness, especially on standing up
- difficulty in swallowing
- local allergic reaction with marked signs of swelling (in such cases treatment should be stopped)
- swelling and irritation inside the nose
- decreased erection, sexual dysfunction
- a flu like illness
- flushing of the skin
- dehydration

Very rare (may affect up to 1 in 10,000 people)

- muscle twitching
- mood swings
- ear pain
- blisters

Not known (frequency cannot be estimated from the available data)

- Problems with breathing during sleep (sleep apnoea syndrome), see section 2 "Warnings and precautions."
- seizures, fits or convulsions
- inflammation of the bowel wall. Symptoms may include fever, vomiting and stomach pain or discomfort
- an increased sensitivity to pain
- colicky abdominal pain or discomfort
- feeling detached from oneself
- withdrawal symptoms in babies born to mothers who have been given Panitaz in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties, sweating and not putting on weight
- A need to take increasingly higher doses of this medicine to obtain the same level of pain relief (tolerance), dermatitis contact (skin rash with inflammation which may include burning sensation), skin discoloration
- Dependence and addiction (see section "How do I know if I am addicted?")

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 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 Panitaz

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and sachet after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not use the patch if the sachet seal is broken.

Used patches must be folded over on themselves with the adhesive layer inwards, and discarded safely out of sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

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Previous Material Number: 16181-90016-07

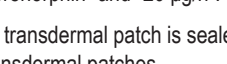
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DR No.: DR001303

DRUGS Code: N/A
Material Code: N/A
Third Party Material Code: N/A
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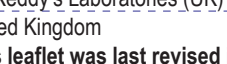
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Technical Information

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Artwork **Dr.Reddy's**

Version No: v1.4

Submission

Brand: DR Reddy's
Country: UK
Product Name: Buprenorphine (Panitaz)
Strength: 5, 10, 20 mg
Form: Transdermal patches
Component: Leaflet
Pack Size: 4 Patches
Date Created: 05 OCT 2021
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Project: CC1000123578

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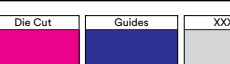
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DR No.: DR001303

DRUGS Code: N/A
Material Code: N/A
Third Party Material Code: N/A
Barcode Type: N/A
Barcode Number: N/A
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Pharmaceutical No.: xxxx


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