Package leaflet: Information for the patient

Rebrikel 5 micrograms/hour transdermal patches
Rebrikel 10 micrograms/hour transdermal patches
Rebrikel 15 micrograms/hour transdermal patches
Rebrikel 20 micrograms/hour transdermal patches

buprenorphine

This medicine contains buprenorphine which is an opioid, which can cause addiction.
You can get withdrawal symptoms if you stop using it suddenly.

These patches contain a strong pain killer
- 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 patch 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:

1. What Rebrikel patches are and what they are used for
2. What you need to know before you use Rebrikel patches
3. How to use Rebrikel patches
4. Possible side effects
5. How to store Rebrikel patches
6. Content of the pack and other information

1. WHAT REBRIKEL PATCHES ARE AND WHAT THEY ARE USED FOR

This medicine has been prescribed for you for the relief of moderate, long-lasting pain that requires the use of a strong painkiller. It contains the active ingredient 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 using it suddenly. Your prescriber should have explained how long you will use it for, when it is appropriate to stop, and how to do this safely.

Rebrikel patches should not be used to relieve acute pain.

Rebrikel 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 REBRIKEL PATCHES

Do not use Rebrikel patches if you:
- are allergic to buprenorphine or any of the other ingredients of this medicine (listed in section 6);
- have breathing problems;
- are addicted to drugs;
- are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
- suffer from myasthenia gravis (a condition in which the muscles become weak);
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol;
- are taking naltrexone or nalmefene for the treatment of alcohol or opioid dependence.

Rebrikel patches must not be used to treat symptoms associated with drug withdrawal.

Warning and precautions
Talk to your doctor, pharmacist or nurse before using Rebrikel patches if you:
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs;
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs;
- feel you need to use more Rebrikel patches 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 Rebrikel patches can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Rebrikel patches");
- suffer from seizures, fits or convulsions;
- suffer from breathing related sleep disorder (sleep apnoea);
- 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;
- are feeling light-headed or faint;
- have severe liver problems;
- are a smoker;
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illness;
- have a high temperature, as this may lead to larger quantities of the active ingredient being absorbed into the blood than normal;
- suffer from constipation.

Tolerance, dependence, and addiction
This medicine contains buprenorphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Rebrikel patches can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Your prescriber should have explained how long you will be using this medicine for, when it is appropriate to stop, and how to do this safely.
Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.
The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to Rebrikel patches if:
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- 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.

<u>If you notice any of the following signs whilst taking Rebrikel patches, it could be a sign that you have become</u> dependent or addicted:
- You need to take the medicine for longer than advised by your doctor.
- You need to take more than the recommended dose.
- You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'.
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (see section 3, 'If you stop taking Rebrikel patches').

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 using 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. Using 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
Buprenorphine 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 awakening 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 application site 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 the Rebrikel patches are removed. Chronic allergic reactions may lead to open wounds, bleeding, ulcers, skin discolouration 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 medication may be necessary.

Do not use if you have pain which lasts only for a short period or pain after having an operation because of the increased risk of dependence and developing serious breathing problems.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are currently treated with Rebrikel patches to discuss your pain management.

Similar to other opioids, Rebrikel patches may affect the normal production of hormones in the body, such as cortisol or sex hormones, particularly if you have used high doses for a long time.

Children and adolescents
Do not give this medicine to children below 18 years.

Other medicines and Rebrikel patches

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

Rebrikel patches may sometimes cause very serious reactions. Do not take any other medicines whilst using Rebrikel patches without first talking to your doctor, especially:

- Anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepin, or trimipramine. These medicines may interact with Rebrikel patches 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.
- Rebrikel patches must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or if you have taken this type of medicine in the last two weeks.
- If you take some medicines such as phenobarbital or phenytoin (medicines commonly used to treat seizures, fits or convulsions), carbamazepine (a medicine to treat seizures, fits or convulsions and certain pain conditions), or rifampicin (a medicine to treat tuberculosis) the effects of Rebrikel patches may be reduced.
- Rebrikel patches 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 pain, depression, anxiety, psychiatric or mental disorders, medicines to help you sleep, medicines to treat high blood pressure such as clonidine, other opioids (which may be found in painkillers or certain cough mixtures e.g. morphine, dextropropoxyphene, codeine, dextromethorphan, noscapine), antihistamines (medicines used to treat allergies) which make you drowsy, or anaesthetics such as halothane.
- Concomitant use of Rebrikel patches and sedative medicines such as benzodiazepines or related drugs may increase the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Rebrikel patches together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- Medicines used to treat travel sickness or nausea (antiemetics).
- Medicines to treat psychiatric disorders (antipsychotics or neuroleptics).
- Muscle relaxants.
- Medicines to treat Parkinson's disease.
- Naltrexone and nalmefene (for the treatment of addictive disorders) may stop buprenorphine from working. They must not be used with buprenorphine to avoid a sudden onset of long-lasting and severe withdrawal symptoms.

Using Rebrikel patches with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

Do not use Rebrikel patches if you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, unless otherwise instructed by your doctor having carefully considered the benefits and risk to both mother and child.

If you use Rebrikel patches during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not use Rebrikel patches while you are breast-feeding as buprenorphine passes into breast milk and will affect your baby. Ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Rebrikel patches may affect your reactions to such an extent that you may not react adequately or quickly enough in the event of unexpected or sudden occurrences. This applies particularly:
- at the beginning of treatment;
- if you are taking medicines to treat anxiety or help you sleep;
- if your dose is increased.

If you are affected (e.g. feel dizzy, drowsy or have blurred vision), you should not drive or operate machinery whilst using Rebrikel patches, or for 24 hours after removing the patch.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while using this medicine until you know how it affects you.
- It is an offence to drive while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').
- This defence applies when:
  - The medicine has been prescribed to treat a medical or dental problem; and
  - You have used it according to the instructions given by the prescriber and in the information provided with the medicine.
- Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while using this medicine.

Details regarding the driving offence concerning driving after drugs have been taken/used in the UK may be found here: https://www.gov.uk/drug-driving-law

3. HOW TO USE REBRIKEL PATCHES

Always use Rebrikel patches exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Different strengths of Rebrikel patches are available. Your doctor will decide which strength of Rebrikel patch will suit you best. When people first start using Rebrikel patches, they often experience some nausea and vomiting (see section 4). This usually passes after the first week of treatment. It's a good idea to book a follow-up appointment with your doctor a week or two after you first start using Rebrikel patches to ensure that you are using the correct dose and to manage any side effects. During treatment, your doctor may change the patch you use to a smaller or larger one if necessary or tell you to use a combination of up to two patches. Do not cut or divide the patch or use a higher dose than recommended.
You should not apply more than two patches at the same time, up to a maximum total dose of 40 micrograms/hour.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Rebrikel patches, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also, 'If you stop taking Rebrikel patches').

Adults and elderly patients

Unless your doctor has told you differently, attach one Rebrikel patch (as described in detail below) and change it every seventh day, preferably at the same time of day. Your doctor may wish to adjust the dose after 3-7 days until the correct level of pain control has been found. If your doctor has advised you to take other painkillers in addition to the patch, strictly follow the doctor's instructions, otherwise you will not fully benefit from treatment with the Rebrikel patch. The patch should be worn for 3 full days before increasing the dose, this is when the maximum effect of a given dose is established.

Patients under 18 years of age

Rebrikel patches should not be used in patients below the age of 18 years.

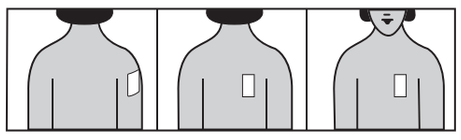
Patients with kidney disease/dialysis patients

In patients with kidney disease, no change in dose is necessary.

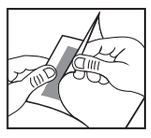
Patients with liver disease

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

Before applying the Rebrikel 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.

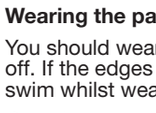


- The Rebrikel patch should be applied to a relatively hairless or nearly hairless skin site. If no suitable hair free sites are available the hairs should be cut off with a pair of scissors. Do not shave them off.
- Avoid skin which is red, irritated or has any other blemishes, for instance large scars.
- 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 patch

Step 1: Each patch is sealed in a pouch. Just before use, cut the pouch along the sealed edge with scissors. Be careful not to damage the transdermal patch with the scissors. Take out the patch. Do not use the patch if the pouch seal is broken.
Step 2: The sticky side of the patch is covered with a silvery protective foil. Carefully peel off **half** the foil. Try not to touch the sticky part of the patch.



Step 3: Stick the patch on to the area of skin you have chosen and remove the remaining foil.
Step 4: Press the patch against your skin with the palm of your hand and count slowly to 30. Make sure that the whole patch is in contact with your skin, especially at the edges.

Wearing the 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 Rebrikel patches (see "Take special care" 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 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 pouch to dispose of the old patch. Now 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 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.

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Duration of treatment

Your doctor will tell you how long you should be treated with the Rebrikel 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 Rebrikel patches" below).

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

If you use more Rebrikel patches 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 apply the Rebrikel patch

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 Rebrikel patches

Do not suddenly stop using this medicine. If you want to stop using this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop using this medicine.

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

The pain relieving effect of Rebrikel patch 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

Like all medicines, Rebrikel patches can cause side effects, although not everybody gets them.

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

This medicine 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.

Drug Withdrawal
When you stop using Rebrikel patches, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst using Rebrikel patches, it could be a sign that you have become addicted.
- You need to use the medicine for longer than advised by the prescriber.
- You feel you need to use more than the recommended dose.
- You are using the medicine for reasons other than prescribed.
- When you stop using the medicine you feel unwell, and you feel better once using the medicine again.

If you notice any of these signs, it is important you talk to your prescriber.

In patients treated with Rebrikel patches, the following other side effects have been reported:

Very common (may affect more than 1 in 10 people)
- Headache, dizziness, drowsiness.
- Constipation, feeling or actually being sick.
- Itchy skin.
- Rash, redness, itching, inflammation or swelling of the skin at application site.

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 heartbeat.
- 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 Rebrikel patches (see section 'Drug withdrawal').

If you need to have blood tests remind your doctor that you are using Rebrikel patches. This is important because Rebrikel 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 (severe 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 Rebrikel patches in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties, sweating and not putting on weight.
- A need to use 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 discolouration.
- Dependence and addiction (see section "How do I know if I am addicted?").
- Joint pain.

Reporting of side effects
If you get any side effects, talk to your doctor or 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 REBRIKEL PATCHES

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

Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.

Rebrikel 5 µg/h, 10 µg/h and 15 µg/h transdermal patch:
Do not store above 25°C.
Rebrikel 20 µg/h transdermal patch:
Do not store above 30°C.

Do not use the patch if the pouch 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 use Rebrikel patches 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. After the expiry date, take any unused patches to a pharmacy.

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

What Rebrikel patches contain

The active ingredient is buprenorphine.

Rebrikel 5 micrograms/hour transdermal patch
Each transdermal patch contains 5 mg of buprenorphine in a patch size of 6.25 cm^2 and releases about 5 micrograms of buprenorphine per hour (over a period of 7 days).

Rebrikel 10 micrograms/hour transdermal patch
Each transdermal patch contains 10 mg of buprenorphine in a patch size of 12.5 cm^2 and releases about 10 micrograms of buprenorphine per hour (over a period of 7 days).

Rebrikel 15 micrograms/hour transdermal patch
Each transdermal patch contains 15 mg of buprenorphine in a patch size of 18.75 cm^2 and releases about 15 micrograms of buprenorphine per hour (over a period of 7 days).

Rebrikel 20 micrograms/hour transdermal patch
Each transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm^2 and releases about 20 micrograms of buprenorphine per hour (over a period of 7 days).

The other ingredients are:
Adhesive matrix (containing buprenorphine): povidone K90, levulinic acid, oleyl oleate, Poly[acrylic acid-co-butylacrylate-co-(2-ethylhexyl)acrylate-co-vinylacetate] (5:15:75:5)
Adhesive matrix (without buprenorphine): Poly[(2-ethylhexyl)acrylate-co-glycidylmethacrylate-co-(2-hydroxyethyl)acrylate-co-vinylacetate] (68:0,15:5:27),
Separating foil between adhesive matrices with and without buprenorphine: Polyethylene terephthalate film,
Backing foil: polyester,
Release liner: Polyethylene terephthalate film, siliconised
Blue printing ink

What Rebrikel patches look like and contents of the pack

Transdermal patch
5 micrograms/hour: square, beige coloured patch with rounded corners marked Buprenorphin 5 µg/h
10 micrograms/hour: rectangular, beige coloured patch with rounded corners marked Buprenorphin 10 µg/h
15 micrograms/hour: rectangular, beige coloured patch with rounded corners marked Buprenorphin 15 µg/h
20 micrograms/hour: square, beige coloured patch with rounded corners marked Buprenorphin 20 µg/h

Rebrikel patches are available in cartons containing 1, 2, 3, 4, 5, 8, 10 or 12 pouches each containing a single patch.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Zentiva Pharma UK Limited,
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