Package leaflet: Information for the patient

Bupramyl 5 micrograms/hour, 10 micrograms/hour and 20 micrograms/hour transdermal patches

buprenorphine

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.
- 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.

What is in this leaflet

1. What Bupramyl is and what it is used for

Bupramyl contains the active ingredient buprenorphine which belongs to a group of medicines called strong analgesics or 'painkillers'. It has been prescribed for you by your doctor to relieve moderate, long-lasting pain that requires the use of a strong painkiller.

Bupramyl should not be used to relieve acute pain.

2. What you need to know before you use Bupramyl

Do not use Bupramyl:
- 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 tranylcypromine, 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.

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

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Bupramyl:
- if you suffer from seizures, fits or convulsions
- 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 have ever been addicted to drugs or alcohol
- 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 have depression or other conditions that are treated with antidepressants. The use of these medicines together with Bupramyl can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Bupramyl").

If you have recently had an operation, please speak to your doctor before using these patches.

Athletes should be aware that this medicine may cause a positive reaction to sports doping control tests.

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 Bupramyl 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. 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 Bupramyl 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.

If you notice any of the following signs whilst taking Bupramyl, it could be a sign that you have become 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 Bupramyl).

Sleep-related breathing disorders
Bupramyl 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 paused 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.

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

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

- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- Bupramyl 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.
- Bupramy may sometimes cause very serious reactions when taken with medicines to treat depression such as, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepin, or trimipramine. These medicines may interact with Bupramy 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.
- 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 Bupramyl may be reduced.
- Bupramyl 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), medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics) which make you drowsy, or anaesthetics such as halothane.
- Concomitant use of Bupramyl and sedative medicines such as benzodiazepines or related drugs increases 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 Bupramyl together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics);
- muscle relaxants;
- medicines to treat Parkinson's disease.

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.

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

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy
There is not sufficient experience regarding the use of buprenorphine in pregnant women. Therefore you should not use Bupramyl if you are pregnant or if you could become pregnant during treatment.

Breast-feeding
Buprenorphine, the active substance contained in the transdermal patch, may inhibit milk formation and passes into the breast milk. Therefore, you should not use Bupramyl if you are breast-feeding.

Driving and using machines
Bupramyl 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 Bupramyl, 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 taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
    - the medicine has been prescribed to treat a medical or dental problem and
    - you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
    - it was not affecting your ability to drive safely.

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

3. How to use Bupramyl

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Bupramyl, 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 Bupramyl).

Different strengths of Bupramyl are available. Your doctor will decide which strength of Bupramyl will suit you best.

During treatment, your doctor may change the patch you use to a smaller or larger one if necessary. 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.

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

Adults and elderly patients
Unless your doctor has told you differently, attach one Bupramyl 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 Bupramyl. 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 with kidney disease/dialysis patients
In patients with kidney disease, no change in dose is necessary.

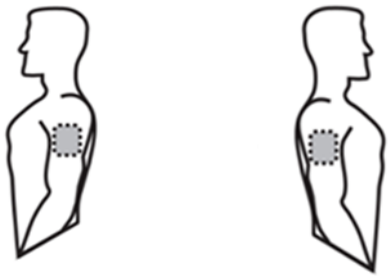
Patients with liver disease
In patients with liver disease, the effects and period of action of Bupramyl may be affected and your

doctor will therefore check on you more closely.

Patients under 18 years of age
Bupramyl should not be used in patients below the age of 18 years.

Method of administration
Bupramyl is for transdermal use.
Bupramyl acts through the skin. After application, buprenorphine passes through the skin into the blood.

Before applying the transdermal patch

<table>
<tr>
<td>- 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 besides). Ask for assistance if you cannot apply the patch yourself.</td>
<td>
Upper Arm
or

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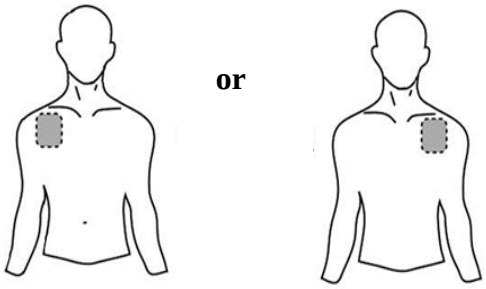
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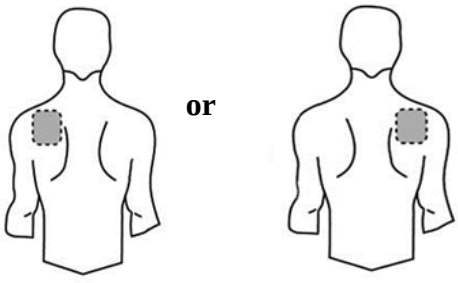
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- Bupramyl should be applied to a relatively hairless or nearly hairless skin site. If no suitable hair free sites are available the hairs should be cut off with a pair of scissors. Do not shave them off.

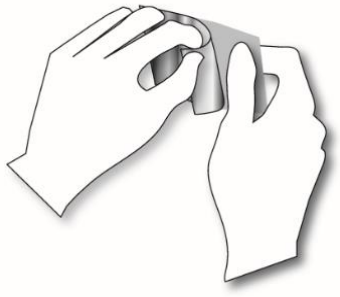
- Avoid skin which is red, irritated or has any other blemishes, for instance large scars.

- 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.

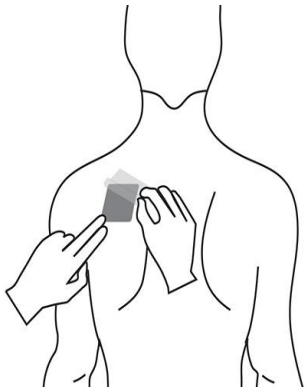
Applying the transdermal patch

- 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.

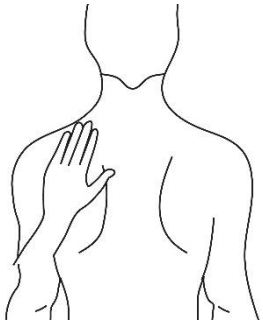
- Step 2: The sticky side of the transdermal patch is covered with a transparent protective foil. Carefully peel off **one part of** the foil. Try not to touch the sticky part of the transdermal patch.



- 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 Bupramyl (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 transdermal patch

- Take the old transdermal 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.
- Stick a new transdermal 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 Bupramyl. Do not stop treatment without consulting a doctor, because your pain may return and you may feel unwell (see also 'If you stop using Bupramyl' below).

If you use more Bupramyl 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 Bupramyl
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 Bupramyl
If you stop using Bupramyl 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.

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 Bupramyl is very low. However, if you feel agitated, anxious, nervous or shaky, if you are overactive, have difficulty sleeping or digestive problems, tell your doctor.

The pain relieving effect of Bupramyl 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

There is a risk that you may become addicted or reliant on Bupramyl.

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

Remove the transdermal patch and contact a doctor immediately if you experience any of the following side effects:

Uncommon (may affect up to 1 in 100 people):
- sudden wheeziness, difficulties in swallowing or breathing, swelling of the face or lips, rash or itching especially those covering your whole body. These can be symptoms of a serious allergic reaction (hypersensitivity, anaphylaxis).
- inability of heart to pump blood or lack of blood flow (circulatory collapse)
- unable to pass urine (urinary retention).

Rare (may affect up to 1 in 1,000 people):
- chest pain associated with heart disease (angina)
- severe breathing difficulties (respiratory depression, respiratory failure)
- persistent constipation with swollen stomach and vomiting (ileus).

Other possible side effects:

Very common (may affect more than 1 in 10 people):
- headache, dizziness, drowsiness or sleepiness
- constipation, feeling sick (nausea), vomiting
- itchy skin, redness of the skin
- rash, redness, itching, inflammation or swelling of the skin at the 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 (exanthema)
- tiredness, a feeling of unusual weakness, muscle weakness, swelling of hands, ankles or feet (oedema).

Uncommon (may affect up to 1 in 100 people):
- sleep disorder, restlessness, agitation, a feeling of extreme happiness, mood swings, hallucinations, nightmares, decreased sexual drive, aggression
- changes in taste, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness in the hands or feet (pins and needles)
- loss of memory, migraine, fainting, problems with concentration or co-ordination
- dry eyes, blurred vision
- ringing or buzzing sound in the ears (tinnitus), a feeling of dizziness or spinning (vertigo)
- high or low blood pressure, chest pain, fast or irregular heart beat
- cough, hiccups, wheezing
- wind

- weight loss
- dry skin
- muscle spasms, muscle aches and pains (myalgia)
- difficulty passing urine or loss of control passing urine
- feeling tired (fatigue)
- fever, chills
- local allergic reaction with marked signs of swelling (in such cases treatment should be stopped)
- flushing of the skin
- increase in accidental injuries (e.g. falls)
- withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping using this medicine
- change in liver function tests (shown by blood tests).

Rare (may affect up to 1 in 1,000 people):
- mental health problem
- difficulties with balance
- eyesight problems (visual disturbance), swelling of the eyelids or face, a reduction in size of the pupils in the eye
- worsening of asthma, abnormally fast and deep breathing
- feeling of faintness, especially on standing up
- difficulty in swallowing
- itchy, runny nose (rhinitis)
- decreased erection, sexual dysfunction
- flu-like symptoms
- feeling thirsty and dark-coloured urine (dehydration).

Very rare (may affect up to 1 in 10,000 people):
- drug dependence
- muscle twitching
- ear pain
- skin pimples or blisters.

Not known (frequency cannot be estimated from the available data)
- seizures, fits or convulsions
- inflammation of the bowel wall (diverticulitis) with symptoms that may include fever, vomiting and stomach pain or discomfort
- recurring pain in the upper abdomen (biliary colic)
- feeling detached from oneself
- withdrawal symptoms in babies born to mothers who have been given buprenorphine in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties, sweating and not putting on weight.
- Dermatitis contact (skin rash with inflammation which may include burning sensation)
- Skin discolouration

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Bupramyl

- 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.

[5 micrograms/hour] & [10 micrograms/hour]
- Do not store above 25°C.

[20 micrograms/hour]
- This medicine does not require any special storage conditions.

- 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.

- 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.

- 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 Bupramyl patches contain
The active substance is buprenorphine.

- 5 micrograms/hour: Each transdermal patch contains 5 mg of buprenorphine in a patch size of 6.25 cm2 and releases 5 micrograms of buprenorphine per hour (over a period of 7 days).
- 10 micrograms/hour: Each transdermal patch contains 10 mg of buprenorphine in a patch size of 12.5 cm2 and releases 10 micrograms of buprenorphine per hour (over a period of 7 days).
- 20 micrograms/hour: Each transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm2 and releases 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 Bupramyl look like and contents of the pack
Transdermal patch
Three sizes are available.
- 5 micrograms/hour: Rectangular beige coloured patch with rounded edges and imprinted with ‘Buprenorphin’ and ‘5 µg/h’ in blue colour.
- 10 micrograms/hour: Rectangular beige coloured patch with rounded edges and imprinted with ‘Buprenorphin’ and ‘10 µg/h’ in blue colour.
- 20 micrograms/hour: Rectangular beige coloured patch with rounded edges and imprinted with ‘Buprenorphin’ and ‘20 µg/h’ in blue colour.

One transdermal patch is sealed in one child-resistant sachet. The patches are available in cartons containing 2, 4, 8 or 12 transdermal patches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer
Gerard Laboratories, Unit 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Tesa Labtec GmbH, Heykenaukamp 10, 21147 Hamburg, Germany

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