Package leaflet: Information for the user

Busiete 5 micrograms/hour Transdermal Patch
Busiete 10 micrograms/hour Transdermal Patch
Busiete 20 micrograms/hour Transdermal Patch

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Busiete Transdermal Patch is and what it is used for

Busiete Transdermal Patch contain 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.

Busiete Transdermal Patch should not be used to relieve acute pain.

2. What you need to know before you use Busiete Transdermal Patch

Do not use Busiete Transdermal Patch:
- 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 tranylcypromide, 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.

Busiete Transdermal Patch must not be used to treat symptoms associated with drug withdrawal.

Warnings and precautions
Talk to your doctor or pharmacist before using Busiete Transdermal Patch:
- 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 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.

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

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

- Busiete Transdermal Patch must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromide, phenelzine, isocarboxazid, moclobamide 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 Busiete Transdermal Patch may be reduced.
- Busiete Transdermal Patch 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 which make you drowsy, or anaesthetics such as halothane.
- Busiete Transdermal Patch must be used with caution if you are also taking benzodiazepines (medicines used to treat anxiety or to help you sleep). This combination may cause serious breathing problems.

Busiete Transdermal Patch with alcohol
Alcohol may make some of the side effects worse and you may feel unwell if you drink alcohol whilst wearing Busiete Transdermal Patch. Drinking alcohol whilst using Busiete Transdermal Patch 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 Busiete Transdermal Patch 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 Busiete Transdermal Patch if you are breast-feeding.

Driving and using machines
Busiete Transdermal Patch 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 Busiete Transdermal Patch, or for 24 hours after removing the patch.

3. How to use Busiete Transdermal Patch

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

Different strengths of Busiete Transdermal Patch are available. Your doctor will decide which strength of Busiete Transdermal Patch 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 Busiete Transdermal Patch 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 Busiete Transdermal 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 Busiete Transdermal 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.

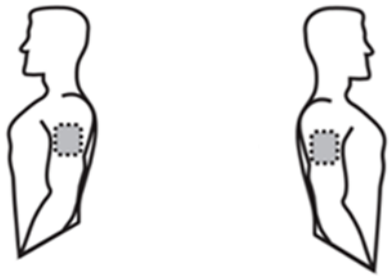
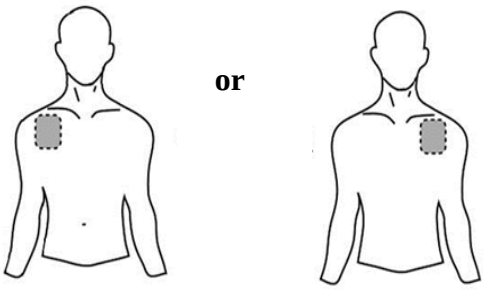
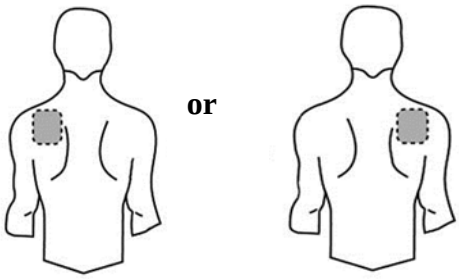
Patients with kidney disease/dialysis patients
In patients with kidney disease, no change in dose is necessary.

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

Patients under 18 years of age
Busiete Transdermal Patch should not be used in patients below the age of 18 years.

Method of administration
Busiete Transdermal Patch is for transdermal use.
Busiete Transdermal Patch act through the skin. After application, buprenorphine passes through the skin into the blood.

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 besides). Ask for assistance if you cannot apply the patch yourself.	**Upper Arm** **or**  **Front**  **or** **Back**  **or**

- Busiete Transdermal 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.

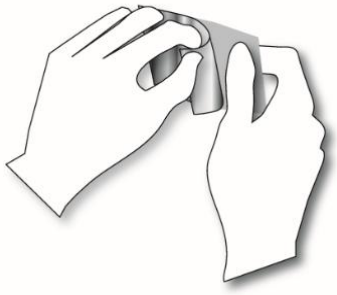
- Avoid skin which is red, irritated or has any other blemishes, for instance large scars.

- 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.

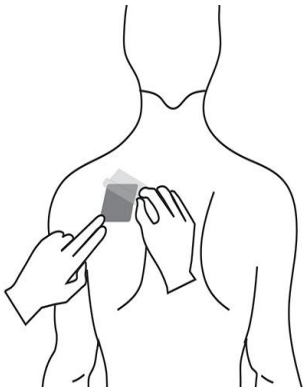
Applying the transdermal patch

- 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.

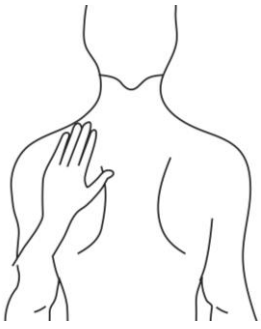
- Step 2: The sticky side of the transdermal patch is covered with a transparent protective foil. Carefully peel off **one part of** the foil. Try not to touch the sticky part of the transdermal patch.



- 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 Busiete Transdermal Patch (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 Busiete Transdermal 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 Busiete Transdermal Patch" below).

If you use more Busiete Transdermal Patch 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 Busiete Transdermal 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 Busiete Transdermal Patch
If you stop using Busiete Transdermal Patch 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 Busiete Transdermal Patch 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 Busiete Transdermal 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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.

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.

There is a risk that you may become addicted or reliant on Busiete Transdermal Patch.

In patients treated with Busiete Transdermal Patch, 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, redness.
- 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.
- Tiredness, a feeling of unusual weakness, muscle weakness, oedema (e. g. swelling of hands, ankles or feet).

Uncommon (may affect up to 1 in 100 people):
- Hypersensitivity
- Sleep disorder, restlessness, agitation, a feeling of extreme happiness, affect liability, hallucinations, nightmares, decreased sexual drive.
- Changes in taste, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness.
- Sedation.
- 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, circulatory collapse, chest pain, fast or irregular heart beat.
- Cough, hiccups, wheezing.
- Wind.
- Weight loss.
- Dry skin, urticaria, dermatitis contact.
- Spasms, aches and pains.
- Difficulty in beginning the flow of urine.
- Inability to fully empty the bladder.
- Weariness, oedema.
- Fever, chills.
- Local allergic reaction with marked signs of swelling (in such cases treatment should be stopped).

- Flushing of the skin.
- An increase in accidental injuries (e.g. falls).
- Withdrawal symptoms such as agitation, anxiousness, sweating or shaking upon stopping using Busiete Transdermal Patch.

If you need to have blood tests remind your doctor that you are using Busiete Transdermal Patch. This is important because Busiete Transdermal Patch 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.
- Visual disturbance, 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, ileus.
- Swelling and irritation inside the nose.
- Decreased erection, sexual dysfunction.
- A flu like illness.
- Dehydration.

Very rare (may affect up to 1 in 10,000 people):
- Mood swings, drug dependence.
- Muscle twitching.
- Ear pain.
- Blisters.

Not known (frequency cannot be estimated from the available data)
- Seizures, fits or convulsions.
- Inflammation of the bowel wall. Symptoms may include fever, vomiting and stomach pain or discomfort.
- Colicky abdominal pain or discomfort.
- Feeling detached from oneself.

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:
Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie
Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Busiete Transdermal Patch

- 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/h] & [10 micrograms/h]:
- Do not store above 25°C.

[20 micrograms/h]:

- This medicine does not require any special storage conditions.

- 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 Busiete Transdermal Patches contain

- The active substance is buprenorphine.

[5 micrograms/h:]
Each transdermal patch contains 5 mg of buprenorphine in a patch size of 6.25 cm^2 and releases 5 micrograms of buprenorphine per hour (over a period of 7 days).
[10 micrograms/h:]
Each transdermal patch contains 10 mg of buprenorphine in a patch size of 12.5 cm^2 and releases 10 micrograms of buprenorphine per hour (over a period of 7 days).
[20 micrograms/h:]
Each transdermal patch contains 20 mg of buprenorphine in a patch size of 25 cm^2 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 Busiete Transdermal Patch looks like and contents of the pack

Transdermal patch
Three sizes are available.
[5 micrograms/h:]
Rectangular beige coloured patch with rounded edges and imprinted with “Buprenorphin” and “5 µg/h” in blue colour.
[10 micrograms/h:]
Rectangular beige coloured patch with rounded edges and imprinted with “Buprenorphin” and “10 µg/h” in blue colour.
[20 micrograms/h:]
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 1, 2, 3, 4, 5, 8, 10 or 12 transdermal patches.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

Manufacturer
tesa Labtec GmbH
Heykenaukamp 10
21147 Hamburg
Germany
21147

Merckle GmbH
Ludwig-Merckle-Straße 3
89143 Blaubeuren
Germany
89143

Teva Opoerations Poland Sp.z.o.o
ul. Mogilska 80
31-546 Krakow
Poland
31-546

Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands
2031 GA

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Buprenorphin ratiopharm 5 Mikrogramm/h; 10 Mikrogramm/h; 20 Mikrogramm/h transdermales Pflaster
Belgium	Buprenorphine Teva Wekelijks 5 10 20 microgram/u pleister voor transdermaal gebruik Buprenorphine Teva Hebdomadaire 5 10 20 microgrammes/h dispositif transdermique Buprenorphine Teva Wöchentlich 5 10 20 Mikrogramm/St transdermales Pflaster
Croatia	Mitoren 5 mikrograma/h; 10 mikrograma/h; 20 mikrograma/h transdermalni flaster
Denmark	Buprenorphine Teva
Finland	Buprenorphine ratiopharm 5 mikrog/ tunti; 10 mikrog/ tunti; 20 mikrog/ tunti depotlaastari
Germany	Buprenoratiopharm 7 Tage 5 Mikrogramm/Stunde; 10 Mikrogramm/Stunde; 20 Mikrogramm/Stunde Transdermales Pflaster
Iceland	Buprenorphine ratiopharm 5 míkrógrömm/klst.; 10 míkrógrömm/klst.; 20 míkrógrömm/klst. forðaplástur
Ireland	Busiete 5 microgram/hr; 10 microgram/hr; 20 microgram/hr Transdermal Patch
Netherlands	Buprenorfine Teva 5 microgram/uur; 10 microgram/uur; 20 microgram/uur pleister voor transdermaal gebruik
Malta	Busiete 5 microgram/hr; 10 microgram/hr; 20 microgram/hr Transdermal Patch
Poland	Buprenorfina Teva
Spain	Buprenorfina Teva 5 microgramos/hora; 10 microgramos/hora; 20

	microgramos/hora parches transdérmicos
Sweden	Buprenorphine Teva 5 mikrogram/timme; 10 mikrogram/timme; 20 mikrogram/timme depotplåster
United Kingdom	Busiete 5 micrograms/h; 10 micrograms/h; 20 micrograms/h Transdermal patch

This leaflet was last revised in July 2017.