**17 August 2026**

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S6**

**TENYL 25 µg/h** (transdermal therapeutic system)

**TENYL 50 µg/h** (transdermal therapeutic system)

**TENYL 75 µg/h** (transdermal therapeutic system)

**TENYL 100 µg/h** (transdermal therapeutic system)

Fentanyl

**Read all of this leaflet carefully before you start using TENYL**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- **TENYL** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What **TENYL** is and what it is used for
2. What you need to know before you use **TENYL**
3. How to use **TENYL**
4. Possible side effects
5. How to store **TENYL**
6. Contents of the pack and other information

## 1. What TENYL is and what it is used for

**TENYL** is an opioid analgesic (medicines used for relief of pain), used for the treatment and relief of intractable chronic pain, and is not recommended for treatment of mild or intermittent pain that can be managed with less potent analgesics.

## 2. What you need to know before you use TENYL

### Do not use TENYL

- If you are hypersensitive (allergic) to fentanyl or any of the other ingredients of **TENYL** (listed in section 6).
- If you suffer from asthma or any other acute (sudden) or chronic (long-term) respiratory problems.
- If you have diarrhoea (frequent or loose watery stools) caused by poisoning or antibiotic therapy.
- If you suffer from inflammatory bowel disease.

Do not use **TENYL** if you are pregnant or breastfeeding.

Do not use **TENYL** if you are under 12 years old as safety in children has not been established.

### Warnings and precautions

Take special care with **TENYL** if you:

- Have a fever, as temperature increases may increase the absorption of fentanyl from transdermal patches.
- Have myasthenia gravis (muscle disorder causing weakness) as the effects of muscular rigidity on respiration may be particularly pronounced.
- Are susceptible to the intracranial (inside the skull) effects of $CO_2$ retention such as those with evidence of intracranial pressure, impaired consciousness or coma. Opioids may obscure the clinical course of patients with head injury, thus **TENYL** should be used with caution in such patients.
- Have slow irregular heartbeat as **TENYL** may produce bradycardia (abnormally slow pulse rate) and should therefore be used with caution in such patients.
- Have impaired renal (of the kidney) or hepatic (related to liver) functions as **TENYL** undergoes hepatic metabolism (physical and chemical processes necessary to maintain life) and limited renal excretion and should be used with caution in such patients.
- Are elderly as you may be more susceptible to the effects of **TENYL**.
- Experience any dizziness, drowsiness, light-headedness or false sense of well-being occurs.
- Receive **TENYL** treatment you may have impaired ability to drive or operate machinery. Patients should be warned of this possibility and are advised not to drive or operate machinery if they are

affected.

- Store this medicine in a safe and secure place, where other people cannot access it (see section 5).

**Long-term use and tolerance**

This medicine contains fentanyl which is an opioid medicine. Repeated use of opioid painkillers can result in the medicine being less effective (you become accustomed to it, known as drug tolerance). You may also become more sensitive to pain while using TENYL. This is known as hyperalgesia.

Increasing the dose of your patches may help to further reduce your pain for a while, but it may also be harmful. If you notice that your medicine becomes less effective, talk to your doctor. Your doctor will decide whether it is better for you to increase the dose or to gradually decrease your use of TENYL.

**Dependence and addiction**

Repeated use of TENYL 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 use or how often you need to use it. You might feel that you need to carry on using your medicine, even when it doesn't help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on TENYL 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 illness.

If you notice any of the following signs whilst using TENYL, it could be a sign that you have become dependent or addicted.

- You need to use the medicine for longer than advised by your doctor
- You need to use more than the recommended dose

- 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 using 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.

**Other medicines and TENYL:**

If you are taking medicines on a regular basis, including complementary or traditional medicines, the use of **TENYL** may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

- Alcohol or other central nervous system depressants (slowing down of the central nervous system activity) may result in increased depressant effects, hypoventilation (abnormal shallow breathing), hypotension (low blood pressure) and profound sedation and coma may occur.
- CYP3A4 inducers (such as carbamazepine, phenytoin or rifampin) may cause increased clearance of **TENYL**, resulting in decreased opioid effects.
- CYP3A4 inhibitors (such as ketoconazole, erythromycin or ritonavir) may cause decreased clearance of **TENYL**, resulting in increased or prolonged opioid effects of **TENYL**.

**TENYL** will be ineffective if administered to a patient receiving naltrexone, which blocks the therapeutic effects of opioid analgesics.

**Pregnancy and Breastfeeding:**

**TENYL** is **contra-indicated** (when it should not be used) during pregnancy and breastfeeding.

**Driving and using machines**

Receive TENYL treatment you may have impaired ability to drive or operate machinery. Patients should be warned of this possibility and are advised not to drive or operate machinery if they are affected.

## 3. HOW TO USE TENYL:

Always use **TENYL** only as prescribed by your doctor. Do not exceed the recommended dose. Do not share medicines prescribed for you or your child with others. Please check with your doctor or pharmacist if you are unsure.

Before starting treatment and regularly during treatment, your doctor will also discuss with you what you may expect from using TENYL, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also section 2, withdrawal symptoms when stopping TENYL).

**TENYL** should be kept in the protective packaging until used. It should be applied to a dry, flat, non-irritated and non-irradiated skin surface of the upper arm or torso. If necessary, hair at the application site may be clipped (not shaved) prior to application. The application site should be cleansed with clear water and not with soaps, oils, lotions, alcohol or other agents that might irritate the skin or change its characteristics. The patch should be pressed firmly in place with the palm of the hand for about 30 seconds, making sure that contact is complete especially around the edges.
The skin should be completely dry before applying the patch. The patches should be applied immediately upon removal from the sealed package. The **TENYL** patch can be worn continuously for 72 hours. If treatment is being continued, a new patch should be applied to a new site after the previous patch has been removed.

**The usual dosage is:**

***Initial dose***

*For patients who have not previously used opioid analgesics:* The lowest **TENYL** dose 25 µg/h should be used.

*For patients who have previously used opioid analgesics:* Initially, a quantity of **TENYL** equivalent to the patient's current 24-hour analgesic requirement.

*For patients who are receiving opioid analgesics (medicines used for relief of pain) other than morphine, the patient's 24-hour opioid requirement should be determined then converted to the equianalgesic oral*

*morphine dose.*

**If you use more TENYL than you should (an overdose):**

The following signs and symptoms may be indicative of an overdosage with this product:

- Cold, clammy skin; confusion; convulsions (seizure, fit); severe dizziness; drowsiness; nervousness; restlessness; weakness; low blood pressure; pinpoint pupils; slow heartbeat; slow or troubled breathing and unconsciousness.
- Signs of overdose include trouble breathing or shallow breathing, tiredness, extreme sleepiness, being unable to think clearly, walk or talk normally and feeling faint, dizzy or confused. An overdose may also result in a brain disorder known as toxic leukoencephalopathy. An overdose may also result in a brain disorder known as toxic leukoencephalopathy.

General measures would be to remove the patch and monitor the patient, keeping in mind that **TENYL** absorption continues and plasma concentrations decline slowly after the patch has been removed.

Prolonged monitoring may be required.

The most serious effect of overdosage is respiratory depression (abnormally slow or shallow breathing).

Specific treatment would be physical or verbal stimulation. The specific opioid antagonist (medicine working against), naloxone may be used if necessary. Respiratory depression following an overdose may outlast the duration of action of the opioid antagonist. Administration of naloxone via intravenous infusion (administered directly into a vein) should be according to the needs of the individual patient.

If a clinical situation warrants, a patent (open) airway should be established and maintained. Oxygen should be administered and respiration assisted or controlled as appropriate. Adequate body temperature and fluid intake should be maintained.

For bradycardia (abnormally slow pulse rate), atropine can be used.

For hypotension (low blood pressure), use of intravenous (into the vein) fluids and/or vasopressors (drugs that stimulate contraction of blood vessels) and using other supportive measures as needed.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

**If you forget to use TENYL:**

Do not use a double dose to make up for forgotten individual doses.

**4. POSSIBLE SIDE EFFECTS:**

**TENYL** can have side effects.

Not all side effects reported for **TENYL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **TENYL**, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Common/Frequent side effects:

- Hallucinations (false perceptions), nervousness, anxiety and paranoid reaction (generalised fear of persecution) and depersonalization (alteration in selfperception);
- Headache, confusion, dizziness, abnormal coordination, abnormal thinking, abnormal gait, abnormal dreams, agitation, amnesia, central nervous system depression slowing down of the central nervous system activity) and stupor (partial unconsciousness);
- Amblyopia (impairment of vision);
- Arrhythmia (irregular heartbeat) and bradycardia (abnormally slow pulse rate);
- Hypoventilation (abnormal shallow breathing), apnoea (cessation of breathing), haemoptysis (expectoration of blood), respiratory disorder and asthma;
- Nausea, vomiting, constipation, abdominal pain, diarrhoea (frequent or loose watery stools), flatulence (excess amount of air/gas in the stomach), indigestion and abdominal distension;
- Sweating, erythema (red skin rash), itching and exfoliative dermatitis (shedding of scaly dead skin);
- Urinary retention, bladder pain and urinary frequency;
- Papules (small solid elevation of skin) and chest pain.

Uncommon/Less frequent side effects:

- Anorexia (lack of appetite);

- Euphoria (unrealistic feeling of well being), depression, hostility and acute toxic delirium (sudden harmful delirious effects), drug tolerance and you can become dependent on TENYL;
- Somnolence (sleepiness), aphasia (loss of ability to speak or write), tremor (shake), paraesthesia (numbness), syncope (fainting) and vertigo (dizziness);
- Hypotension (low blood pressure) and hypertension (high blood pressure);
- Dyspnoea (shortness of breath), pharyngitis (inflammation of mouth and throat), hiccups and stertorous breathing (harsh, noisy breathing);
- Dry mouth and dyspepsia (impairment of digestion);
- Pruritus (itching) and rash;
- Asthenia (lack of energy), hypertonia (high salt content in body fluid) and hypotonia (low salt content in body fluid);
- Oliguria (reduced urine production);
- Oedema (swelling due to retained fluid) and pustules (pimples/white heads).
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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist for advice. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **TENYL**.

**5. How to store TENYL**

- Store in a cool (at or below 25 °C) dry place.
- Keep medication in sealed pouch until ready to apply.
- Keep all medicines out of the reach and sight of children.
- Dispose of used or unneeded patches by folding in half with adhesive layer inside the fold, before appropriately discarding.

- Do not use after the expiry date on the label/carton.
- 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.

**6. Contents of the pack and other information**

**What TENYL contains:**

**TENYL** contains the active substance fentanyl in each of the transdermal therapeutic systems:

**TENYL 25 µg/h:** 4,8 mg fentanyl that delivers 25 µg Fentanyl / hr

**TENYL 50 µg/h:** 9,6 mg fentanyl that delivers 50 µg Fentanyl / hr

**TENYL 75 µg/h:** 14,4 mg fentanyl that delivers 75 µg Fentanyl / hr

**TENYL 100 µg/h:** 19,2 mg fentanyl that delivers 100 µg Fentanyl / hr

Each transdermal therapeutic system is made with:

The other ingredients are: Acrylic polymer, polyester / ethyl vinyl acetate laminated film and siliconised polyester film. The product also contains lauryl alcohol as an inactive carrier.

**What TENYL looks like and contents of the pack**

**TENYL** patches have a transparent backing film of a rectangular shape, entirely covered by a transparent uncoloured and opaque adhesive matrix that contains the active ingredient and covered by a transparent backing film that is easily detachable.

**TENYL** patches are packed in cartons containing 5, 10, 15 or 20 individually packed closure systems. The closure system is a silver foil polyester /aluminium /mono-orientated polypropylene pouch, which is thermo sealed at its four sides.

**TENYL** is available in four strengths:

**TENYL 25 µg/h**

**TENYL 50 µg/h**

**TENYL 75 µg/h**

**TENYL 100 µg/h**

**17 August 2026**

**Holder of Certificate of Registration**

MC Pharma (Pty) Ltd.

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