Applicant: MC Pharma (Pty) Ltd
Product name: TENYL
Dosage form: Transdermal therapeutic system
Strength: Each 15 cm2, contains: 4,8 mg fentanyl, delivered at 25 µg/h. 9,6 mg fentanyl, delivered at 50 µg/h. 14,4 mg fentanyl, delivered at 75 µg/h. 19,2 mg fentanyl, delivered at 100 µg/h

17 August 2026

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S6

1. NAME OF THE MEDICINE

TENYL

Strength

TENYL 25 microgram per hour

TENYL 50 microgram per hour

TENYL 75 microgram per hour

TENYL 100 microgram per hour

Pharmaceutical form

Transdermal Therapeutic System

2. QUALITATIVE AND QUANTITATIVE

Each 15 cm^2 transdermal therapeutic system contains 4,8 mg fentanyl, delivered at 25 microgram per hour.

Each 30 cm^2 transdermal therapeutic system contains 9,6 mg fentanyl delivered at 50 microgram per hour.

Each 45 cm^2 transdermal therapeutic system contains 14,4 mg fentanyl delivered at 75 microgram per hour.

Each 60 cm^2 transdermal therapeutic system contains 19,2 mg fentanyl delivered at 100 microgram per hour.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Transdermal patches.

The transdermal 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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TENYL is indicated in the management of chronic intractable pain that requires opioid analgesia which cannot be managed by lesser means such as paracetamol-opioid combinations, non-steroidal analgesics or as required dosing with short acting opioids.

4.2 Posology and method of administration

Posology

Dosage must be individualised and assessed regularly. The rate at which tolerance develops varies widely among individuals.

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 transdermal 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 **TENYL** patch should be applied immediately upon removal from the sealed package.

Patches that are cut, divided or damaged in any way should not be used.

When ready to apply the patch, remove it from the sealed protective pouch.

Special populations

Elderly population:

Elderly patients should be observed carefully for signs of fentanyl toxicity and the dose of **TENYL** should be reduced if necessary *(*refer to section 4.4*)*.

Renal and Hepatic impairment:

TENYL undergoes hepatic metabolism and limited renal excretion and should be used with caution in patients with impaired renal or hepatic functions *(*refer to section 4.4*)*.

Method of administration

1. To remove the patch from the protective pouch, locate the pre-cut notch (indicated by an arrow on the back of the pouch label) along the edge of the seal.



2. Fold the pouch at the notch, then carefully tear or cut the pouch close to the sealed edge in order not to damage the patch inside. Further open the pouch along both sides, folding the pouch open like a book. Remove the patch from the inside.



3. Remove the protective liner before applying the patch as described below.



4. The protective liner for the matrix patch is slit (s-shaped cut). Fold the patch in the middle and remove each half of the liner separately. Avoid touching the adhesive side of the patch.



5. **TENYL** should be applied immediately upon removal of the protective liner. Apply the patch to the skin by applying light pressure with the palm of the hand for about 30 seconds. Make certain that the edges of the patches are adhering properly.



6. Please wash hands with clean water.



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. Several days should elapse before a new patch is applied to the same area of the skin.

Initial dose:

For patients who are not opioid-tolerant: The lowest **TENYL** dose 25 µg/h should be used.

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

For patients who are receiving opioid analgesics other than morphine, the patient's 24-hour opioid requirements should be determined then converted to the equianalgesic oral morphine dose.

EQUIANALGESIC POTENCY CONVERSION

The following quantities are equivalent to 30 mg of chronically administered oral morphine or 60 mg of intermittently administered oral morphine:

Drug name	**Intramuscular (mg)**	**Oral (mg)**
Buprenorphine	0,3	-
Butorphanol	2	-
Codeine	130	200
Dezocine	10	-
Heroin	5	60
Hydromorphone	1,5	7,5
Levorphanol	2	4
Meperidine	75	300
Methadone	10	20
Nalbuphine	10	-
Oxycodone	-	30
Oxymorphone	1	10 (rectally)
Pentazocine	60	180

Note: This table should not be used to convert from fentanyl to other analgesic therapies. Use of the above table can overestimate the dosage of the new agent.

*Use the table below to derive from the calculated 24-hour morphine dose, the corresponding **TENYL** dose.*

Recommended TENYL dose based upon daily oral morphine dose	
TENYL (mcg/hr)	**Oral morphine (mg/24 hr)**
25	45 to 134
50	135 to 224
75	225 to 314
100	315 to 404
125	405 to 494
150	495 to 584
175	585 to 674
200	675 to 764
225	765 to 854
250	855 to 944
275	945 to 1 034
300	1 035 to 1 124
These ratios are conservative. The need for an increase in dose should be anticipated.	

Evaluation of the maximum analgesic effect of **TENYL** cannot be made before the system is worn for 24 hours. The delay is due to the gradual increase in serum fentanyl concentration. Previous analgesic therapy should be phased out until **TENYL** reaches analgesic efficacy.

Dose titration and maintenance therapy: 50 % of patients are likely to require a dose increase after the initial application of **TENYL** as the conversation ratio from morphine is conservative. Dose titration should normally be performed in increments of 25 µg/h (oral morphine 90 mg/day) during the second or third day of application. Six days may be required to reach equilibrium after each increase in dose; therefore the higher dose should be worn for 72-hour applications before further increases are made. More than one **TENYL** system may be applied at a time for

doses greater than 100 µg/h.

Treatment duration and goals: Before initiating treatment with **TENYL**, a treatment strategy including treatment duration and treatment goals, and a plan for end of the treatment, should be agreed together with the patient, in accordance with pain management guidelines. During treatment, there should be frequent contact between the physician and the patient to evaluate the need for continued treatment, consider discontinuation and to adjust dosages if needed. In absence of adequate pain control, the possibility of hyperalgesia, tolerance and progression of underlying disease should be considered (see section 4.4).

Discontinuation of TENYL: In general, the discontinuation of opioid analgesia should be gradual in order to prevent withdrawal symptoms. Replacement with other analgesics should also be gradual, starting at low dose and increasing slowly.

Disposal of the patch: Used patches should be folded firmly in half, adhesive side inwards so that the patch adheres to itself, and then discard safely, and out of the reach of children.

Wash hands, with clean water only, after applying or removing patch.

4.3 Contraindications

- Hypersensitivity to fentanyl or to the adhesives in the transdermal system.
- Use in children: Safety and efficacy in children has not been established.
- Safety in pregnancy and lactation has not been established. **TENYL** is distributed in breast milk and should be avoided during breastfeeding (see section 4.6).
- Diarrhoea associated with pseudomembranous colitis or caused by poisoning.
- Respiratory depression or disease.
- Asthma.
- Inflammatory bowel disease.

4.4 Special warnings and precautions for use

TENYL SHOULD BE PRESCRIBED AND MONITORED, ONLY BY PERSONS KNOWLEDGEABLE IN THE CONTINUOUS ADMINISTRATION OF POTENT OPIOID ANALGESICS, IN THE CARE OF PATIENTS REQUIRING SUCH TREATMENT AND IN THE DETECTION AND MANAGEMENT OF HYPOVENTILATION INCLUDING THE USE OF OPIOID ANTAGONISTS.

TENYL IS NOT APPROPRIATE FOR ACUTE OR POSTOPERATIVE PAIN AS SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD RESULT AND THERE IS NO OPPORTUNITY FOR DOSE TITRATION DURING SHORT-TERM USE.

IF **TENYL** IS REMOVED BECAUSE OF SIDE EFFECTS, MONITORING SHOULD CONTINUE FOR AT LEAST 12 TO 24 HOURS AS SERUM CONCENTRATIONS DECREASE SLOWLY AND ARE REDUCED BY 50 %, 17 HOURS LATER (RANGE: 13 to 22 HOURS).

Long-term treatment effects and tolerance

In all patients, tolerance to the analgesic effects, hyperalgesia, physical dependence, and psychological dependence may develop upon repeated administration of opioids, whereas incomplete tolerance is developed for some side effects like opioid induced constipation. Particularly in patients with chronic non cancer pain, it has been reported that they may not experience a meaningful amelioration in pain intensity from continuous opioid treatment in the long term. During treatment, there should be frequent contact between the doctor and the patient to evaluate the need for continued treatment. When it is decided that there is no benefit for continuation, gradual down titration should be applied to address withdrawal symptoms.

Do not abruptly discontinue **TENYL** in a patient physically dependent on opioids. Drug withdrawal syndrome may occur upon abrupt cessation of therapy or dose reduction.

There have been reports that rapid tapering of **TENYL** in a patient physically dependent on opioids may lead to serious withdrawal symptoms and uncontrolled pain. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimise symptoms of withdrawal. Tapering from a high dose may take weeks to months. The opioid drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate.

Opioid use disorder (abuse and dependence)

Repeated use of **TENYL** can lead to Opioid Use Disorder (OUD). A higher dose and longer duration of opioid treatment can increase the risk of developing OUD. Abuse or intentional misuse of **TENYL** may result in overdose and/or death. The risk of developing OUD is increased in patients with a personal or a family history (parents or

siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).

Before initiating treatment with **TENYL** and during the treatment, treatment goals and a discontinuation plan should be agreed with the patient. Before and during treatment the patient should also be informed about the risks and signs of OUD. If these signs occur, patients should be advised to contact their doctor.

Patients treated with opioid medicine should be monitored for signs of OUD, such as drug-seeking behaviour (e.g. too early requests for refills), particularly with patients at increased risk. This includes the review of concomitant opioids and psycho-active medicines (like benzodiazepines). For patients with signs and symptoms of OUD, consultation with an addiction specialist should be considered. If opioid discontinuation is to occur.

Special precautions:

Absorption of fentanyl from **TENYL** transdermal patches may increase as the temperature rises and patients should therefore avoid exposure to external heat. Therefore patients with a fever should be monitored for opioid side effects and the dose of **TENYL** should be adjusted if necessary.

Caution is advised in patients with myasthenia gravis as the effects of muscular rigidity on respiration may be particularly pronounced.

TENYL and other central nervous system active agents may exacerbate respiratory depression. **TENYL** may have more severe adverse effects in patients with any pulmonary disease. In such patients, opioids may decrease respiratory drive and increase airway resistance.

Regular consultations with healthcare professionals during therapy should take place as tolerance and physical and psychological dependence may develop upon repeated administration of opioids.

TENYL should not be used in patients who are susceptible to the intracranial 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. **TENYL** may produce bradycardia and should therefore be used with caution in patients with bradyarrythmias.

TENYL undergoes hepatic metabolism and limited renal excretion and should be used with caution in patients with impaired renal or hepatic functions.

Elderly patients should be observed carefully for signs of fentanyl toxicity and the dose of **TENYL** should be reduced if necessary.

Safety has not been established during pregnancy therefore **TENYL** should not be used in women of childbearing potential.

Fentanyl is distributed in breast milk, therefore **TENYL** is not recommended for use in nursing women.

TENYL should be used with caution in patients who have a history of drug or alcohol abuse.

Because of the risks, including fatal outcome, associated with accidental ingestion, misuse, and abuse, patients and their carers must be advised to keep **TENYL** in a safe and secure place, not accessible by others.

4.5 Interaction with other medicines and other forms of interaction

- Alcohol, CNS depression-producing medications, including other opioids, sedatives, hypnotics, general anaesthetics, phenothiazines, tranquilisers, skeletal muscle relaxants and sedating antihistamines with the concurrent or sequential use of **TENYL** may result in increased depressant effects, hypoventilation, hypotension and profound sedation and coma may occur.
- Concurrent use of CYP3A4 inducers (carbamazepine, phenytoin, rifampin) with **TENYL** may cause increased clearance of fentanyl, resulting in decreased opioid effects.
- Concurrent use of CYP3A4 inhibitors (azole antifungal agents e.g.: ketoconazole, macrolide antibiotics e.g.: erythromycin, protease inhibitors e.g.: ritonavir) with **TENYL** may cause decreased clearance of fentanyl, resulting in increased or prolonged opioid effects.
- **TENYL** will be ineffective if administered to a patient receiving naltrexone, which blocks the therapeutic effects of opioid analgesics.

4.6 Fertility, pregnancy, and lactation

TENYL is contraindicated during pregnancy and lactation (see section 4.3).

Pregnancy: Adequate and well-controlled studies have not been conducted in humans.

Lactation: **TENYL** is distributed in breast milk and should be avoided during breast-feeding.

4.7 Effects of ability to drive and use machines

Patients who receive **TENYL** treatment 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.

4.8 Undesirable effects

a) Summary of the safety profile

Tolerance

Tolerance can develop on repeated use.

Drug dependence

Repeated use of **TENYL** can lead to drug dependence, even at therapeutic doses. The risk of drug dependence may vary depending on a patient's individual risk factors, dosage, and duration of opioid treatment (see section 4.4).

Opioid withdrawal symptoms

Opioid withdrawal symptoms (such as nausea, vomiting, diarrhea, anxiety, and shivering) are possible in some patients after conversion from their previous opioid analgesic to **TENYL** or if therapy is stopped suddenly (see sections 4.2 and 4.4).

Neonatal withdrawal syndrome

There have been very rare reports of newborn infants experiencing neonatal withdrawal syndrome when mothers chronically used **TENYL** during pregnancy (see section 4.6).

Serotonin syndrome

Cases of serotonin syndrome have been reported when fentanyl was administered concomitantly with highly serotonergic medicine (see sections 4.4 and 4.5).

b) Tabulated list of adverse reactions

MedDRA System Organ Class	**Adverse reaction**	**Frequency**
Metabolism and nutrition disorders	Anorexia	Frequency Unknown
Psychiatric disorders	Hallucinations, nervousness, anxiety and paranoid reaction and depersonalisation	Frequent
	Euphoria, depression, hostility and acute toxic delirium, drug tolerance and dependence	Frequency Unknown
Nervous system disorders	Headache, confusion, dizziness,	Frequent

	abnormal coordination, abnormal thinking, abnormal gait, abnormal dreams, agitation, amnesia, central nervous system depression and stupor	
	Somnolence, aphasia, tremor, paraesthesia, syncope and vertigo	Frequency Unknown
Eye disorders	Amblyopia	Frequent
Cardiac disorders	Arrhythmia and bradycardia	Frequent
Vascular disorders	Hypotension and hypertension	Frequency Unknown
Respiratory, thoracic and mediastinal disorders	Hypoventilation, apnoea, haemoptysis, respiratory disorder and asthma	Frequent
	Dyspnoea, pharyngitis, hiccups and stertorous breathing	Frequency Unknown
Gastrointestinal disorders:	Nausea, vomiting, constipation, abdominal pain, diarrhoea, flatulence, indigestion and abdominal distension	Frequent
	Dry mouth and dyspepsia	Frequency Unknown
Skin and subcutaneous tissue disorders:	Sweating, erythema, itching and exfoliative dermatitis	Frequent
	Pruritus and rash	Frequency Unknown
Musculoskeletal and connective tissue disorders:	Asthenia, hypertonia and hypotonia	Frequency Unknown
Renal and urinary disorders:	Urinary retention, bladder pain and urinary frequency	Frequent
	Oliguria	Frequency Unknown
General disorders and administration site conditions:	Papules and chest pain	Frequent
	Oedema and pustules	Frequency Unknown

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPPRA website.

4.9 Overdose

Clinical effects of fentanyl overdose:

Cold, clammy skin; confusion; convulsions; severe dizziness; drowsiness; nervousness; restlessness; weakness; low blood pressure; pinpoint pupils; slow heartbeat; slow or troubled breathing and unconsciousness.

General measures would be to remove the **TENYL** transdermal system and monitor the patient, keeping in mind that fentanyl absorption continues, and plasma concentrations decline slowly after the system has been removed. Prolonged monitoring may be needed.

The manifestations of fentanyl overdose are an extension of its pharmacologic actions, the most serious effect of fentanyl overdosage is respiratory depression. Toxic leukoencephalopathy has also been observed with fentanyl overdose.

Specific treatment would be physical or verbal stimulation. The specific opioid antagonist, 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 should be at a rate titrated to the needs of the individual patient. Reversal of the narcotic effect may result in acute onset of pain and release of catecholamines. It may also precipitate withdrawal in opioid dependent patients.

If a clinical situation warrants, a patent 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, atropine can be used.
For hypotension, use of intravenous fluids and/or vasopressors and using other supportive measures as needed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A: 2.11. Other central nervous system depressants

ATC code: N02AB03

5.2 Pharmacokinetic properties

- **Absorption:**

  Fentanyl transdermal therapeutic system is designed to deliver fentanyl through intact skin in a controlled manner over a period of 72 hours.

- **Distribution:**

  Fentanyl is contained in two layers in the transdermal patch, an upper reservoir layer (containing 6 % fentanyl) and a lower donor layer in contact with the skin (containing 4 % fentanyl). The upper layer replenishes the donor layer so that the donor layer can maintain its fentanyl concentration and deliver a constant flux of fentanyl.

- **Biotransformation:**

  Fentanyl is highly lipid soluble and rapidly crosses the blood-brain barrier.

  The average quantity of fentanyl absorbed per hour into the systemic circulation of an individual patient is sufficiently consistent to permit dosage titration over extended periods of time.

  After the initial application of the transdermal system, the serum fentanyl concentrations increase gradually, generally levelling off between 12 and 24 hours. The serum fentanyl concentration is proportional to the fentanyl transdermal therapeutic system patch size.

- **Elimination:**

  After removal of a transdermal patch, the serum fentanyl concentration gradually declines by about 50 % in approximately 17 hours (range, 13 to 22 hours). Fentanyl undergoes hepatic metabolism and renal excretion.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acrylic polymer; lauryl alcohol; polyester/ethyl vinyl acetate laminated film; siliconized polyester film.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months (3 years)

6.4 Special precautions for storage

Store in a cool (at or below 25 °C) dry place.

Keep medication in sealed pouch until ready to apply.

6.5 Nature and contents of container

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 is available in four strengths:

TENYL 25 µg/h

TENYL 50 µg/h

TENYL 75 µg/h

TENYL 100 µg/h

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 thermosealed at its four sides.

6.6 Special precautions for disposal

Dispose of used or unneeded patches by folding in half with adhesive layer inside the fold, before appropriately discarding.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MC Pharma (Pty) Ltd.

62 Constantia Avenue

Mnandi

Centurion

0157

Telephone: 0126683019

Email: pharmacist@mcpharma.co.za

8. REGISTRATION NUMBERS:

TENYL 25 µg/h: 41/2.11/0255

TENYL 50 µg/h: 41/2.11/0256

TENYL 75 µg/h: 41/2.11/0257

TENYL 100 µg/h: 41/2.11/0258

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

05 August 2011

10. DATE OF REVISION OF THE TEXT

17 August 2026