# Fencino®

Transdermal Fentanyl Patch

# Because adhesion matters.

**Adults:** Fencino® Transdermal Fentanyl Patch is indicated for management of severe chronic pain that requires continuous long term opioid administration.[1]

**Children:** Fencino® Transdermal Fentanyl Patch is indicated for long term management of severe chronic pain in children from 2 years of age who are receiving opioid therapy.[1]

Prescribing information and adverse event reporting can be found at the end of this brochure.

UK-FEN-006a(1) February 2024

Luye Pharma

# Fencino® Transdermal Fentanyl patches (Fencino®) shows similarly good skin adherence to the originator brand*[1,2]

**92.5% of Fencino® patients report essentially no lift off from the skin compared to 89.2% of Durogesic® patients at all time points assessed during the clinical practice-based study*[1,2]**

Significance not reported

Skin adhesion is one of the most important functional properties for a transdermal patch.[3]

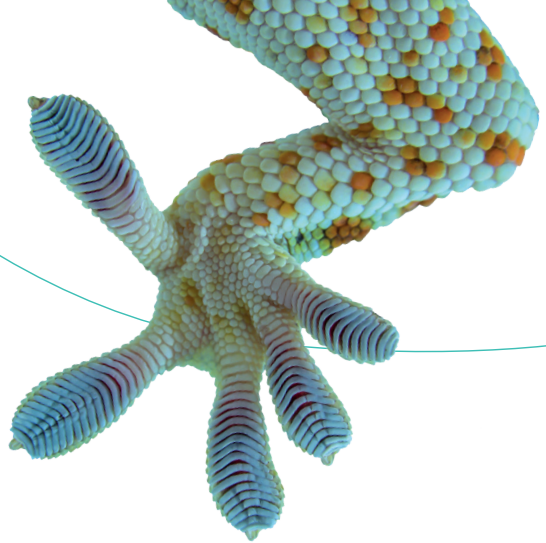
Poor adhesion results in improper dosing of patients and so transdermal patches rely on good adhesion over a period of time to ensure proper drug delivery.[3]

In a non-interventional study of Transdermal Fentanyl (Fentavera**) Matrix Patches in 426 patients with chronic pain, physicians reported:

**'very good'** or **'good'** adhesiveness of Fencino® in >87% of patients with chronic pain, at both the one and two month assessment intervals.***[4]

**German brand name for Fencino®
***Using a 5-point scale (very good, good, satisfactory, poor, very poor).

*A multiple dose 2-fold crossover phase I study to investigate the pharmacokinetics of a fentanyl transdermal system (Fentanyl NOVOSIS transdermal system, 8.5 cm2) in 40 healthy male volunteers compared with Durogesic® SMAT 25 µg/h.



## In an open label, 2-fold crossover trial in intervals up to 72 hours:

Significance not reported

- Fencino® scored 0 (≥90% adhered) at **92.7%** of patch assessments[2]
- Durogesic® SMAT (German brand name for Durogesic DTrans) scored 0 (≥90% adhered) at **88.7%** of patch assessments[2]

### Higher Adhesion %

### Lower Detachment %

| | Adhered (essentially no lift off from the skin) | Adhered (some edges lifting off from the skin) | Adhered (less than half lifting off from the skin) | Adhered but not detached (more than the half lifting off from the skin without falling off) | Patch detached (patch completely off the skin) |
|---|---|---|---|---|---|
| Fencino® | **92.7** | **5.6** | **1.4** | **0.2** | **0** |
| Durogesic DTrans | **88.7** | **8.8** | **2** | **0.5** | **0** |

**Frequency of patch adhesion scores(%)[2] (ITT analysis, n=44)**

**Patch adhesion estimated by use of an adhesion score as defined by US-FDA**

# Local tolerability assessments show Fencino® to be well tolerated in >90% of patients in the 2 months assessment trial*[4]

Physician-assessed local skin tolerability with Fencino® was 'very good' or 'good' in >90% of patients at the one and two months assessment intervals.**[4]

## Fencino patches contain aloe vera[5]

Aloe vera can be used to retain skin moisture and integrity.[5]

*A non-interventional study of transdermal fentanyl (Fentavera) matrix patches in chronic pain patients: analgesic and quality of life effects; 426 patients were observed at month 1 and month 2 of treatment for changes from baseline of patient (11-point scales) and physician (5-point scales) ratings (ratings of pain intensity, and impairment of walking, general activity, sleep quality, and QoL).

**Using a 5-point scale (very good, good, satisfactory, poor, very poor).

# Prescribe Fencino® by brand name for a cost-effective solution for your patients' pain[6,7,8]

Fencino® offers a 32% saving versus the originator patch (Durogesic® DTrans®)*[6,7,8]

## The Fencino® Primary Care Rebate Scheme offers further savings when prescribing Fencino® by brand name[8]

For further information, please contact Luye at infoUK@luye.com

Packed individually into a sealed child resistant sachet[1]

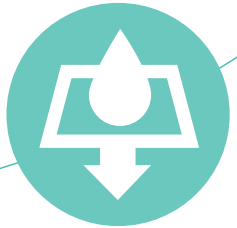
At least 32% saving**

*Durogesic® DTrans® list price £12.59 - Fencino® list price £8.46
**Based on list price when Fencino® is prescribed instead of Durogesic® DTrans®

# Prescribe Fencino® by brand name to ensure your patients receive the same product with each repeat prescription and reduce the risk of administration error[10]

Effective pain relief[4]

Good adhesion[2,4]



Bioequivalent to the originator patch (Durogesic® DTrans®)[9]

Contains aloe vera[5]

Child-resistant packaging[1]

Cost-effective prescribing [6,7,8]

# Important safety information from the MHRA – Drug Safety Updates

## Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression (March 2020)[12]

Benzodiazepines and opioids can both cause respiratory depression, which can be fatal if not recognised in time.[12] Only prescribe together if there is no alternative and closely monitor patients for signs of respiratory depression.

For more information, please refer to the full Drug Safety Update: https://www.gov.uk/drug-safety-update/benzodiazepines-and-opioids-reminder-of-risk-of-potentially-fatal-respiratory-depression.

## Opioids: risk of dependence and addiction (September 2020)[13]

New recommendations following a review of the risks of dependence and addiction associated with prolonged use of opioid medicines (opioids) for non-cancer pain. Before prescribing opioids, discuss with the patient the risks and features of tolerance, dependence, and addiction, and agree together a treatment strategy and plan for end of treatment.

For more information, please refer to the full Drug safety Update: https://www.gov.uk/drug-safety-update/opioids-risk-of-dependence-and-addiction.

## Adverse Reactions:[1]

The adverse reactions reported with the use of fentanyl patches from 11 clinical studies, and from post-marketing experiences are listed below.

The displayed frequency categories use the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available clinical data). The adverse reactions are presented by System Organ Class and in order of decreasing seriousness within each frequency category.

* the assigned frequency (uncommon) is based on analyses of incidence including only adult and paediatric clinical study subjects with non-cancer pain.

**Adverse reactions in adult and paediatric patients**

| System/organ class | Frequency category | | | | |
|---|---|---|---|---|---|
| | Very common | Common | Uncommon | Rare | Not known |
| Immune system disorders | | Hypersensitivity | | | Anaphylactic shock, Anaphylactic reaction, Anaphylactoid reaction |
| Metabolism and nutrition disorders | | Anorexia | | | |
| Endocrine disorder | | | | | Androgen deficiency |
| Psychiatric disorders | | Insomnia, Depression, Anxiety, Confusional state, Hallucination | Agitation, Disorientation, Euphoric mood | | Delirium |
| Nervous system disorders | Somnolence, Dizziness, Headache | Tremor, Paraesthesia | Hypoaesthesia, Convulsion (including clonic convulsions and grand mal convulsion), Amnesia, Depressed level of consciousness, Loss of consciousness | | |
| Eye disorders | | | Vision blurred | Miosis | |
| Ear and labyrinth disorders | | Vertigo | | | |
| Cardiac disorders | | Palpitations, Tachycardia | Bradycardia, Cyanosis | | |
| Vascular disorders | | Hypertension | Hypotension | | |
| Respiratory, thoracic and mediastinal disorders | | Dyspnoea | Respiratory depression, Respiratory distress | Apnoea, Hypoventilation | Bradypnoea |
| Gastrointestinal disorders | Nausea, Vomiting, Constipation | Diarrhoea, Dry mouth, Abdominal pain, Abdominal pain upper, Dyspepsia | Ileus | Subileus | |
| Skin and subcutaneous tissue disorders | | Hyperhidrosis, Pruritus, Rash, Erythema | Eczema, Dermatitis allergic, Skin disorder, Dermatitis, Dermatitis contact | | |
| Musculoskeletal and connective tissue disorders | | Muscle spasms | Muscle twitching | | |
| Renal and urinary disorders | | Urinary retention | | | |
| Reproductive system and breast disorders | | | Erectile dysfunction, Sexual dysfunction | | |
| General disorders and administration site conditions | | Fatigue, Oedema peripheral, Asthenia, Malaise, Feeling cold | Application site reaction, Influenza-like illness, Feeling of body temperature change, Application site hypersensitivity, Drug withdrawal syndrome, Pyrexia* | Application site dermatitis, Application site eczema | |

**References**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12. Gov.uk. Opioids: risk of dependence and addiction. Available at https://www.gov.uk/drug-safety-update/opioids-risk-of-dependence-and-addiction. Last accessed February 2024.

**Adverse events should be reported.**
**Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/**
**Adverse events should also be reported to Luye Pharma Ltd at safety@luyepharma.co.uk**

**Fencino (Fentanyl) Transdermal Patches Prescribing Information.**
**See Summary of Product Characteristics (SmPC) before prescribing.**

**Presentation:** Transdermal patches of varying sizes releasing 12, 25, 50, 75 or 100 micrograms (mcg) of fentanyl per hour. **Indication:** ***Adults:*** Severe chronic pain that requires continuous long-term opioid administration. ***Children over 2 years old:*** Long term management of severe chronic pain in children who are receiving opioid therapy. **Dosage and Administration:** Use the lowest effective dose and individualise the dose based upon the status of the patient and assess at regular intervals after application. ***Adults:*** See SmPC for guidance on converting opioid-tolerant patients from oral or parenteral opioids to Fencino. *Opioid-naïve patients:* Not recommended; consider alternative routes of administration (oral, parenteral). If Fencino is the only appropriate treatment option, only the lowest starting dose (12 mcg/h) should be considered and the patient must be closely monitored because of the potential for developing serious or life-threatening hypoventilation. *Dose titration and maintenance therapy:* Replace patch every 72 hours. Individually titrate the dose using increments of 12 or 25 mcg/hr until a balance between analgesic efficacy and tolerability is attained. It may take up to 6 days for the patient to reach equilibrium on the new dose level. Patients should wear the higher dose patch through two 72-hour applications before increasing the dose further. More than one Fencino patch may be used for doses greater than 100 mcg/h. Patients may require periodic supplemental doses of a short acting analgesic for "breakthrough" pain. Some patients may require additional or alternative methods of opioid administration when the Fencino dose exceeds 300 mcg/h. See SmPC for guidance when the patch falls off or if the analgesia is insufficient during the first application only. *Treatment duration and goals:* Before and during treatment with Fencino a treatment strategy and discontinuation plan should be agreed with patient in accord with patient management guidelines. In absence of adequate pain control, the possibility of hyperalgesia, tolerance, and progression of underlying disease should be considered (See under Precautions and Warnings). *Discontinuation:* Replacement with other opioids should be gradual, starting at a low dose and increasing slowly. It may take 20 hours or more for the fentanyl serum concentrations to decrease by 50%. In general, the discontinuation of opioid analgesia should be gradual in order to prevent withdrawal symptoms (see sections 4.4 and 4.8). There have been reports that rapid discontinuation of opioid analgesics in patients who are physically dependent on opioids has resulted in serious withdrawal symptoms and uncontrolled pain. Tapering should be based on the individual dose, treatment duration and response of the patient regarding pain and withdrawal symptoms. Patients on long-term treatment may need a more gradual tapering. For patients who had been treated for a short period, a faster reduction schedule may be considered. Some patients may experience opioid withdrawal syndrome after conversion or dose adjustment. *Special populations: Elderly or patients with renal or hepatic impairment:* Observe carefully and individualise dosing according to patient status. In opioid-naïve patients, treatment should only be considered if the benefits outweigh the risks. In these cases, only Fencino 12 mcg/h dosage should be considered for initial treatment. *Children 16 years and above:* Follow adult dosage. *Children 2 to 16 years old:* Only use in opioid-tolerant children already receiving at least 30 mg oral morphine equivalents per day. See SmPC for conversion guide and for dose titration and maintenance. *Children below 2 years:* Do not use due to lack of data. See SmPC. *Method of administration:* Apply the patch to non-irritated and non-irradiated, dry skin, on a flat surface of the torso or upper arms. In young children, apply the patch on the upper back. Change the patch application site and allow several days to elapse before applying to the same skin area. **Contra-indications:** Hypersensitivity to fentanyl, peanut, soya or to any of the excipients of the transdermal patch. Acute or post-operative pain. Severe respiratory depression. **Precautions and Warnings:** Patients who have experienced serious adverse events should be monitored for at least 24 hours after removal of the patch due to the long serum half-life of fentanyl (20 – 27 hours). Keep out of sight and reach of children both before and after use as fentanyl can be fatal to a child. Because of the risks, including fatal outcome, associated with accidental ingestion, misuse, and abuse, patients and their carers must be advised to keep Fencino in a safe and secure place, not accessible by others. *Opioid-naïve and not opioid-tolerant states:* In opioid-naïve patients, very rare cases of significant respiratory depression and/or fatality have been observed, especially in non-cancer pain. *Respiratory depression:* Some patients may experience significant respiratory depression with Fencino which persists beyond the removal of the patch and has a higher incidence as the dose is increased. Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose dependent manner. In patients with CSA, a reduction in total opioid dose should be considered. *Risk from concomitant use of central nervous system (CNS) depressants including sedative medicines such as benzodiazepines or related drugs, alcohol and CNS depressant narcotic drugs:* Concomitant use with sedative medicines such as benzodiazepines or related drugs, alcohol, or CNS depressant narcotic drugs may result in sedation, respiratory depression, coma or death. If concomitant use is necessary, the lowest effective dose should be used, and the duration of treatment should be as short as possible. Advise patients and caregivers to be aware of signs and symptoms of respiratory depression and sedation. *Chronic pulmonary disease:* Fencino may have more severe adverse effects in patients with chronic obstructive or other pulmonary disease. In such patients, opioids may decrease respiratory drive and increase airway resistance. *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 the patient should be reviewed frequently to evaluate the need for continued treatment, discontinuation and dosage adjustment. When it is decided that there is no benefit for continuation, gradual down titration should be applied to address withdrawal symptoms. Fencino should not be stopped abruptly in a patient who is physically dependent on opioids. Drug withdrawal syndrome may occur with abrupt discontinuation of therapy or dose reduction. There have been reports that rapid withdrawal of Fencino in patients physically dependent on opioids has resulted in severe withdrawal symptoms and uncontrolled pain. When a patient no longer requires therapy, it is advisable to taper the dose gradually to minimize withdrawal symptoms. Tapering off a high dose can take weeks to months. Opioid withdrawal syndrome is characterized by some or all of the following symptoms: Restlessness, lacrimation, rhinorrhoea, yawning, sweating, chills, myalgia, mydriasis and palpitations. Other symptoms may also occur including irritability, excitation, 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 Fencino may lead to Opioid use disorder (OUD), with the risk being increased with higher doses and longer duration. Abuse or intentional misuse of Fencino 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 and during treatment with Fencino, treatment goals and discontinuation plan should be agreed with the patient and patient also informed about OUD risks and signs. Patients treated with opioid medications 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 drugs (like benzodiazepines). For patients with signs and symptoms of OUD, consultation with an addiction specialist should be considered. If opioid discontinuation is to occur, see above. *Central nervous system conditions including increased intracranial pressure:* Use with caution in patients with brain tumours or those susceptible to the intracranial effects of CO2 retention (raised intracranial pressure, impaired consciousness, or coma). *Cardiac disease:* Use with caution in patients with bradyarrhythmias. *Hypotension:* Correct any underlying symptomatic hypotension and/or hypovolaemia before starting fentanyl. *Hepatic impairment:* Hepatic impairment increases the risk of toxicity, so consider a dose reduction. *Renal impairment:* Use cautiously in renal impairment because of a lack of PK data in this patient population. Treatment should only be considered if the benefits outweigh the risks. *Fever/external heat application:* A rise in skin temperature due to fever or other heat source (advise patients to avoid these) may result in overdose or death due to increased fentanyl concentration. *Serotonin syndrome:* Life-threatening serotonin syndrome may occur if used with Selective Serotonin Re-uptake Inhibitors (SSRIs), Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs), Monoamine Oxidase Inhibitor (MAOIs) and if suspected, Fencino should be discontinued. *Interactions with other medicinal products:* The concomitant use of Fencino with CYP3A4 inhibitors is not recommended because this may increase fentanyl concentrations that could lead to serious respiratory depression. **See SmPC for more information.** *Accidental exposure due to patch transfer:* Sharing beds etc. may result in accidental patch transfer and overdose in a non-patch wearer (e.g. child). *Use in elderly patients:* Observe elderly patients for signs of fentanyl toxicity as they may have reduced clearance. *Gastrointestinal tract:* Fentanyl has a constipating effect, and the use of a prophylactic laxative should be considered. Stop treatment if paralytic ileus is present or suspected. *Patients with myasthenia gravis:* Use with caution as non-epileptic (myo)clonic reactions can occur. *Concomitant use of mixed opioid agonists/antagonists:* The concomitant use of buprenorphine, nalbuphine or pentazocine is not recommended. *Paediatric population:* Fencino should not be administered to opioid-naïve paediatric patients. The potential for serious or life-threatening hypoventilation exists regardless of the dose of Fencino transdermal system administered. Fencino has not been studied in children under 2 years of age. Fencino should be administered only to opioid-tolerant children age 2 years or older. To guard against accidental ingestion by children, use caution when choosing the application site for Fencino and monitor the adhesion of the patch closely. *Opioid induced hyperalgesia:* Opioid induced hyperalgesia (OIH) is a paradoxical response to an opioid in which there is an increase in pain perception despite stable or increased opioid exposure. It differs from tolerance, in which higher opioid doses are required to achieve the same analgesic effect or treat recurring pain. OIH may manifest as increased levels of pain, more generalised pain (i.e., less focal), or pain from ordinary (i.e. non-painful) stimuli (allodynia) with no evidence of disease progression. When OIH is suspected, the dose of opioid should be reduced or tapered off, if possible. **Interactions: Refer to SmPC for full details.** *Centrally-acting medicinal products/CNS depressants, including alcohol and CNS depressant narcotics:* The concomitant use of Fencino with other CNS depressants, (including benzodiazepines and other sedatives/hypnotics, opioids, general anaesthetics, phenothiazines, tranquilizers, sedating antihistamines, alcohol and CNS depressant narcotic drugs), skeletal muscle relaxants and gabapentinoids (gabapentin and pregabalin) may result in respiratory depression hypoventilation, hypotension, profound sedation, coma or death. Concomitant prescribing of CNS depressants and Fencino should be reserved for patients for whom alternative treatment options are not possible. The use of any of these medicinal products concomitantly with Fencino requires close monitoring and observation. The dose and duration of concomitant use should be limited. *MAOIs:* Concomitant administration not recommended. Fencino should not be used within 14 days after discontinuation of treatment with MAOIs. *Serotonergic medicinal products:* Concomitant use with SSRIs, SNRIs and MAOIs increases the risk of life-threatening serotonin syndrome. Use concomitantly with caution. Carefully observe the patient, particularly during treatment initiation and dose adjustment. *Concomitant use of mixed opioid agonists/antagonists:* The concomitant use of buprenorphine, nalbuphine or pentazocine is not recommended. *Pharmacokinetic-related interactions: CYP3A4 Inhibitors:* Concomitant use is not recommended (risk of overdose/death), unless the patient is closely monitored. *CYP3A4 Inducers:* Concomitant use may reduce efficacy of fentanyl. Use with caution and careful monitoring. *Paediatric population:* Interaction studies have only been performed in adults. **Fertility, Pregnancy and Lactation:** *Fertility:* No clinical data. *Pregnancy:* Lack of data. Do not use unless necessary and be aware of the potential to cause respiratory depression in the newborn infant. *Lactation:* Fentanyl is excreted into human milk and may cause sedation/respiratory depression in a breastfed infant. Breastfeeding should be discontinued during treatment with Fencino and for at least 72 hours after removal of the patch. **Effects on ability to drive and use machines:** Fencino may impair the ability to drive or operate machinery. **Undesirable effects:** Based on data from 11 clinical studies with 1565 adult and 289 paediatric subjects and from post-marketing experience, the following adverse reactions were reported: *Very Common* (>1/10): somnolence, dizziness, headache, nausea, vomiting and constipation. *Common* (>1/100 to <1/10): hypersensitivity, anorexia, insomnia, depression, anxiety, confusional state, hallucination, tremor, paraesthesia, vertigo, palpitations, tachycardia, hypertension, dyspnoea, diarrhoea, dry mouth, abdominal pain, abdominal pain upper, dyspepsia, hyperhidrosis, pruritus, rash, erythema, muscle spasms, urinary retention, fatigue, peripheral oedema, asthenia, malaise, feeling cold. *Uncommon:* (≥1/1,000 to <1/100): respiratory depression – significant in some patients, patients must be observed for these effects. Fencino contains soya oil: In very rare cases soya oil may cause allergic reactions. *Paediatric population:* The safety of fentanyl transdermal patches was evaluated in 289 paediatric subjects (<18 years): see SmPC for full details. *Drug tolerance and dependence:* Risk can develop and vary on repeated use of Fencino. Cases of serotonin syndrome have been reported when fentanyl was administered concomitantly with highly serotonergic drugs (see above). Consult SmPC for full information regarding Undesirable Effects). **Overdose:** Respiratory depression is the most serious effect of fentanyl overdose. Toxic leukoencephalopathy also observed. Consult SmPC for management guidance including the use of an opioid antagonist such as naloxone.

Marketing Authorisation Number and Basic NHS Price:
Fencino 12 micrograms/hour PL 50827/0025 (5 patches: £8.46);
Fencino 25 micrograms/hour PL 50827/0026 (5 patches: £12.10);
Fencino 50 micrograms/hour PL 50827/0027 (5 patches: £22.62);
Fencino 75 micrograms/hour PL 50827/0028 (5 patches: £31.54);
Fencino 100 micrograms/hour PL50827/0029 (5 patches: £38.88).

Marketing Authorisation Holder: Luye Pharma Ltd. 40 Occam Road, Guildford, GU2 7YG, United Kingdom. Legal Category: POMCD.

Further information: Luye Pharma Ltd., 40 Occam Road, Guildford, GU2 7YG.
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Luye Pharma